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Editorial

Dear reader

Vigilance News continues to enjoy unbroken popularity. Like its predecessors, the May 2026 edition, which featured the new format introduced shortly beforehand, with summaries of each article in four languages, attracted lively interest.

This latest edition, number 37, once again offers readers a wide array of primarily medical, but also regulatory, topics and reports.

A case report from Universitätsspital Zürich (University Hospital Zurich) examines passive transfer of hepatitis B antibodies following intravenous immunoglobulin therapy and underscores the importance of careful interpretation of hepatitis B serological results. A further report from Geneva University Hospitals discusses two cases of persistent B-cell depletion following rituximab treatment. One challenge here is the fact that clinical manifestation can evolve over time and a consensus definition and harmonised guidelines for long-term monitoring are lacking. A report from Lausanne University Hospital uses the example of a patient with HIV and Hodgkin lymphoma to examine the potential of dexamethasone to act as a dose-dependent inducer of drug metabolising enzymes. These interactions may require a careful review of concomitant medications and proactive dose adjustment or treatment changes.

Three authors from Swissmedic's Safety of Medicines Division address a regulatory issue with practical relevance for healthcare professionals and patients: Since 1 November 2026, healthcare professionals and patients have been able to access officially mandated information (or "educational") material in electronic form from a central resource – an important contribution to drug and patient safety, and a valuable source of support for everyone involved, including family members.

Two annual reports for 2025 round off this current edition. The first is a summary of adverse events following immunization, the emphasis of which has switched back to non-COVID vaccines. The second is the pharmacovigilance report for veterinary medicinal products. In addition to a broad range of varying reports involving veterinary medicinal products and vaccines, this also covers procedures connected with safety signals and measures.

I hope you find this latest edition interesting and enjoyable reading.

Christoph Küng
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Safety of medicines and case reports

Passive transfer of hepatitis B antibodies following intravenous immunoglobulin therapy: a case report

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Summary

Intravenous immunoglobulins (IVIg) are widely used for immunoglobulin replacement therapy in patients with antibody deficiencies and for various immunomodulatory indications. As IVIg preparations are derived from pooled plasma from healthy donors, a broad spectrum of polyclonal IgG antibodies may be passively transferred to recipients.

We report on the case of a 54-year-old woman with plasma cell myeloma and hypogammaglobulinaemia who developed newly detectable hepatitis B surface (anti-HBs) and total hepatitis B core (anti-HBc) antibodies two days after the second IVIg administration. Serological testing prior to treatment had been negative for hepatitis B surface antigen (HBsAg), anti-HBs and anti-HBc antibodies. At the time of anti-HBs/anti-HBc positivity, HBsAg remained negative. Further evaluation with hepatitis B virus (HBV) DNA testing by polymerase chain reaction (PCR) showed no detectable viral load, and liver function tests remained within the normal range, arguing against an active infection.

Given the close temporal association, the biological plausibility and the absence of evidence of active infection, the newly detected antibodies were considered consistent with passive antibody transfer following IVIg administration. Passive transfer of viral antibodies following IVIg therapy may lead to misleading serological results and inappropriate clinical management. This case highlights the importance of awareness of this phenomenon and of careful interpretation of hepatitis B serology in patients receiving IVIg.

Introduction

Intravenous immunoglobulins (IVIg) are widely used therapeutic agents with favourable efficacy and safety profiles. IVIg products are highly purified human immunoglobulin preparations consisting predominantly of IgG derived from pooled plasma from healthy donors.

IVIg products contain a wide range of antibodies, including those directed against viral antigens. In the context of hepatitis B, donor screening primarily aims to exclude active infection, with testing for hepatitis B surface antigen (HBsAg) and hepatitis B virus (HBV) DNA to minimise the risk of HBV transmission.

In contrast, antibodies such as hepatitis B surface antibodies (anti-HBs) and hepatitis B core antibodies (anti-HBc) are not considered markers of infectivity and are therefore not specifically targeted during donor screening. As a result, these antibodies may be present in the final product and can be passively transferred to recipients. Understanding this mechanism is essential for the correct interpretation of hepatitis B serology in patients receiving IVIg. Here, we report a case of anti-HBs/anti-HBc positivity following IVIg administration.

Case report

We present the case of a 54-year-old woman with IgG kappa-type plasma cell myeloma diagnosed in December 2024, which had evolved from a monoclonal gammopathy of undetermined significance (MGUS) diagnosed in 2023. She received induction therapy with daratumumab, bortezomib, lenalidomide and dexamethasone (Dara-VRd regimen) starting in December 2024, followed by high-dose chemotherapy with melphalan and autologous stem cell transplantation in May 2025. Subsequently, consolidation therapy with daratumumab and lenalidomide was administered. Maintenance therapy with the bispecific antibody elranatamab was initiated on 1 December 2025 as part of a clinical trial.

The next day, the patient developed fever and elevated inflammatory markers, and a coronavirus disease 2019 (COVID-19) infection was diagnosed. Initial treatment with nirmatrelvir/ritonavir was administered. However, the clinical course was prolonged and complicated by the development of COVID-19 pneumonia, diagnosed on 31 December 2025, requiring hospitalisation. During hospitalisation, the patient was treated with remdesivir and dexamethasone in the context of immunosuppression and a pronounced inflammatory syndrome. In addition, antibiotic therapy was initiated due to suspected bacterial superinfection.

Given the prolonged infectious course, serum immunoglobulin levels were assessed and revealed severe hypogammaglobulinaemia (IgG 1.7 g/L; reference range 7–16 g/L). The patient subsequently received IVIg therapy, administered as two separate 20 g doses in January 2026, 12 days apart.

Two days after the second IVIg administration, laboratory testing revealed newly positive anti-HBs antibodies (309 IU/L; reference <10 IU/L) and total anti-HBc antibodies, while HBsAg remained negative. Serological testing approximately two months prior had been negative for HBsAg, as well as anti-HBs and total anti-HBc antibodies. Liver function tests remained within the normal range throughout hospitalisation and were not suggestive of active hepatitis.

To further exclude active hepatitis B infection, hepatitis B virus (HBV) DNA testing by polymerase chain reaction (PCR) was performed and yielded negative results. The newly detected anti-HBs and total anti-HBc antibodies were therefore considered likely to be related to IVIg administration.

Upon inquiry, the marketing authorisation holder reported that no further comparable cases involving the batches administered to the patient had been identified.

The patient was discharged in early February 2026 and has continued to receive regular IVIg therapy in the outpatient setting to maintain a target IgG level of >5 g/L.

The revaccination schedule following stem cell transplantation was initiated, with hepatitis B vaccination starting on 8 April 2026. No further hepatitis B serology testing was performed.

Discussion

The Swiss prescribing information for the IVIg preparation administered to the patient states that passive transfer of antibodies following IVIg infusion may lead to transiently positive serological test results and may result in misinterpretation of serological testing (1). However, specific reference to hepatitis B serology is limited.

Intravenous immunoglobulin preparations are derived from pooled plasma obtained from more than 1,000 healthy donors. Donor selection includes careful screening procedures, and both individual donations and plasma pools undergo extensive virological testing. All plasma donations are screened using serological assays for HBsAg and antibodies against hepatitis C virus (HCV) and human immunodeficiency virus (HIV)-1/2. In addition, nucleic acid testing (NAT) is performed for HBV, HCV, HIV-1 and parvovirus B19. Only plasma that has successfully passed all screening tests is used for manufacturing, with an accepted threshold for parvovirus B19 DNA of $\leq 10^4$ IU/mL in the plasma pool. To further reduce the risk of viral transmission, multiple validated

manufacturing steps are implemented, including octanoic acid fractionation, incubation at pH 4 for inactivation of enveloped viruses, depth filtration and nanofiltration based on size exclusion, which removes both enveloped and non-enveloped viruses down to approximately 20 nm. Despite these extensive safety measures, the risk of transmission of infectious agents cannot be completely excluded (1, 2). In response to the hepatitis C virus transmission events in the 1990s, changes to the IVIg manufacturing process, including additional pathogen removal and inactivation steps, were introduced. Currently available IVIg products are considered to be free of known pathogens and the risk of infection transmission is extremely low (3).

Importantly, routine screening does not include testing for anti-HBs or anti-HBc antibodies. As these antibodies are not indicative of active infection, they may be present in the plasma pool and can be passively transferred to recipients following IVIg administration.

Differentiation between passive antibody transfer and true hepatitis B infection is essential. In acute HBV infection, HBsAg and HBV DNA are typically detectable, followed by the appearance of anti-HBc IgM antibodies (Table 1) (4). In contrast, isolated anti-HBc and/or anti-HBs positivity after IVIg use in the absence of viral markers and without biochemical evidence of hepatic injury is suggestive of passive transfer.

Data from the World Health Organization (WHO) pharmacovigilance database indicate that cases of positive anti-HBc and anti-HBs serology, as well as misleading serological test results due to passive antibody transfer, have been reported in association with IVIg products (5). Passive transfer of anti-HBs and/or anti-HBc antibodies following IVIg therapy is well described in the literature but may be underappreciated in clinical practice, particularly when serological testing is performed shortly after IVIg administration (6–12).

In a retrospective study of cancer patients, 15% of patients who were anti-HBc-negative before IVIg subsequently tested positive for anti-HBc, with a modelled probability of anti-HBc positivity of 34% within the first week after IVIg administration (8). In a small cohort of patients with autoimmune skin diseases, all patients tested four weeks after IVIg had detectable anti-HBs antibodies, and 71% had detectable anti-HBc antibodies (9). The persistence of passively transferred antibodies appears to be variable and may extend for several months, with one study reporting detectable anti-HBc antibodies 44 to 321 days after the last IVIg infusion (7).

Failure to recognise passive antibody transfer may therefore lead to unnecessary diagnostic investigations and potentially inappropriate clinical management.

In the present case, newly positive anti-HBs and total anti-HBc antibodies were detected two days after the second IVIg administration, whereas serological testing approximately two months earlier had been negative. HBsAg was negative, HBV DNA was not detectable and liver function tests remained within the normal range throughout hospitalisation. Taken together, the close temporal relationship, the biological plausibility and the absence of evidence of active infection were considered consistent with passive antibody transfer following IVIg administration. Alternative explanations, such as newly acquired HBV infection, occult HBV infection, or HBV reactivation, were considered unlikely based on HBV testing.

Conclusion

Passive transfer of viral antibodies following intravenous immunoglobulin therapy is a recognised but potentially underappreciated phenomenon that may lead to misleading serological findings.

This case highlights the importance of carefully interpreting hepatitis B serological results following IVIg administration and considering passive antibody transfer to avoid misdiagnosis and unnecessary diagnostic procedures.

Table 1: Typical interpretation of test results for hepatitis B infection and vaccination. Adapted from (4).

Phase	HBsAg	Anti-HBc IgM	Total anti-HBc	Anti-HBs	HBV DNA
Acute infection	+	+	+	–	+
Chronic infection	+	–	+	–	+
Past infection	–	–	+	+	-
Vaccination	–	–	–	+	-

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Persistent B-cell depletion following rituximab: a case series

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Summary

B-cell-depleting therapies targeting CD20 are widely used in haematological malignancies and autoimmune conditions. They induce peripheral B-cell depletion, which is typically reversible within six to 12 months. However, rare cases of prolonged or irreversible B-cell depletion have been reported, with potentially serious consequences. This complication remains poorly characterised, and no monitoring or clinical decision-making framework has been formally established.

We report on two patients who developed persistent complete B-cell depletion for five years or more after rituximab exposure, identified in the context of active collaboration between the oncology department and the Geneva Regional Pharmacovigilance Centre. The first patient has remained completely B-cell depleted, with secondary hypogammaglobulinaemia, for over a decade. The second patient, a 61-year-old woman with a B2 thymoma, has since exhibited persistent B-cell depletion, complicated by recurrent severe infections including septic shock.

Proposed mechanisms include impaired central B-lymphopoiesis and BAFF receptor downregulation; however, the pathophysiology remains incompletely understood. Clinical expression can evolve over time, and the absence of a consensus definition and of harmonised long-term monitoring guidelines likely contributes to under-recognition and under-reporting of this adverse event.

These cases highlight the potential value of long-term B-cell and immunoglobulin monitoring after rituximab therapy, and support closer pharmacovigilance surveillance of this potentially severe and under-recognised adverse effect.

Introduction

B-cell-depleting therapies targeting CD20 have transformed the treatment of B-cell malignancies and, subsequently, that of a broad range of autoimmune diseases, including rheumatoid arthritis, anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis, systemic lupus erythematosus, and various autoimmune glomerular diseases. Anti-CD20 monoclonal antibodies – including the chimeric antibody rituximab and more recent humanised or fully human agents such as ocrelizumab, ofatumumab and obinutuzumab – deplete mature B cells and their precursors while sparing haematopoietic stem cells and plasma cells. This occurs through complement-dependent cytotoxicity, antibody-dependent cellular cytotoxicity, and direct apoptosis (1).

Under expected pharmacodynamic conditions, B-cell repopulation typically occurs within three to 12 months of the last infusion, following a natural ontogenic sequence: emergence of transitional B cells from bone

marrow precursors followed by reconstitution of the naive and then memory subset (2). This predictable reconstitution pattern underlies current therapeutic monitoring strategies and retreatment decisions in clinical practice.

However, B-cell repopulation following depletion therapy exhibits both high inter- and intra-individual variability, and a minority of patients deviate from the expected pattern, experiencing unusually prolonged B-cell depletion. Proposed mechanisms underlying this include impaired central B-lymphopoiesis and underexpression of the B-cell activating factor receptor (BAFF-R) on B cells (3). The precise pathophysiology remains incompletely understood, and no monitoring or clinical decision-making framework has been formally established.

From a pharmacovigilance perspective, persistent B-cell depletion following B-cell-depleting therapy constitutes a potentially serious and under-reported adverse drug reaction (ADR), with significant clinical consequences including secondary hypogammaglobulinaemia, recurrent and severe infections, late-onset neutropenia, and, in some series, increased mortality (2). The absence of a consensus definition, the lack of systematic long-term immunological follow-up, and the tendency to attribute persistent cytopenias to the underlying disease rather than to the drug, likely contribute to under-detection and under-reporting to pharmacovigilance centres.

We report here the cases of two patients who developed complete, persistent B-cell depletion for five years or more after rituximab exposure, identified in the context of active collaboration between the oncology department and the Geneva Regional Pharmacovigilance Centre.

Case reports

Case 1

A patient diagnosed in 1994 with relapsing-remitting multiple sclerosis underwent treatment with interferon beta, beginning in 1996. This was discontinued in 2006 following a cutaneous hypersensitivity reaction, and replaced by natalizumab until 2008, followed by two cycles of intravenous rituximab in 2008 and 2010. Since then, the patient has remained completely B-cell depleted, with secondary hypogammaglobulinaemia documented since at least 2013.

A thoraco-abdominal CT scan performed in 2020 showed bronchiectasis with no other abnormalities – in particular no lymphadenopathy, hepatosplenomegaly or imaging suggestive of a thymoma (Good syndrome). Intravenous immunoglobulin replacement therapy was initiated in 2020 and discontinued in 2022. The patient also experienced two infectious episodes that resolved following appropriate treatment.

Table 1: Peripheral B-cell counts and immunoglobulin levels following rituximab treatment.

Date	CD19+ B cells (/µL) (N: 90–660)	IgG (g/L) (N: 7.0–16.0)	IgA (g/L) (N: 0.7–4.0)	IgM (g/L) (N: 0.4–2.3)
17.01.2007	62	–	–	–
02.10.2008	62	–	–	–
11.02.2010	24	–	–	–
25.01.2012	4	7.85	0.61	0.08
31.01.2013	6	5.04	0.53	<0.04
13.05.2015	0	4.76	0.45	<0.04
12.10.2020	0	8.54*	0.23	<0.04
16.08.2023	0	4.37	0.18	<0.04

*IgG value obtained while the patient was receiving intravenous immunoglobulin replacement (initiated in 2020, discontinued in 2022), which likely accounts for the transient normalisation.

Case 2

A 61-year-old woman with a B2 thymoma that was diagnosed while investigating myasthenia gravis, underwent surgical resection followed by adjuvant radiotherapy for focally positive margins in October 2013. She developed lymphopenia in 2013 (CD19+ B cells: 8/µL; CD3+ T cells: 211/µL), which was probably related to prednisone treatment and slowly resolved after the medication was withdrawn. Prednisone was reintroduced in August 2018 due to a worsening of her myasthenia gravis symptoms and was progressively discontinued in 2019.

Since 2017, the patient's oncological condition has progressed, requiring chemotherapy, surgery and rituximab treatment between September 2018 and October 2019.

The patient has exhibited immunosuppression characterised by persistent B-cell depletion since December 2018, following rituximab treatment. Concomitant B-cell lymphopenia and thymoma raised suspicion of Good syndrome, although no confirmatory investigation was performed.

Since November 2024, the patient has experienced several severe infectious episodes. Secondary hypogammaglobulinaemia, for which immunoglobulin replacement therapy was subsequently initiated, was also documented in December 2024.

Table 2: Peripheral B and T lymphocyte counts and immunoglobulin levels following rituximab treatment.

Date	CD19+ B cells (/µL) (N: 90–660)	CD3+ T cells (/µL) (N: 690–2540)	IgG (g/L) (N: 7.0–16.0)	IgA (g/L) (N: 0.7–4.0)	IgM (g/L) (N: 0.4–2.3)
20.09.2018	242	1,376	10.30	2.0	1.0
12.12.2018	2	454	–	–	–
22.01.2019	0	635	–	–	–
30.03.2022	0	914	7.24	1.06	0.22
06.12.2024	–	–	1.23*	0.22	<0.05
04.03.2025	–	–	5.16	0.42	0.06
17.07.2026	0	1,506	7.31	0.48	0.08

*IgG value marking the onset of documented secondary hypogammaglobulinaemia, leading to initiation of immunoglobulin replacement therapy; subsequent values reflect partial biological correction under substitution.

Discussion

B-cell depletion is a well-recognised and very common adverse reaction to rituximab, affecting 70% to 80% of treated patients according to the current product information (1). Under normal circumstances, B-cell repopulation begins within six months of treatment completion, and levels normalise within 12 months. Both patients described here, however, exhibited a markedly different course, with complete B-cell depletion persisting for more than a decade in Case 1 and for more than 6 years in Case 2.

The largest available case series of 1,519 patients treated with rituximab for autoimmune and glomerular diseases reported that 2% (n=30) of rituximab-treated patients developed persistent B-cell depletion (defined as fewer than five CD19+CD20+ cells/µL for more than two years), resulting in clinically significant consequences, including hypogammaglobulinaemia in nearly all affected patients, severe infections in more than half, and death in almost a third, predominantly related to complications of the underlying chronic disease (2).

A case report further illustrates the potential clinical consequences of unrecognised, longstanding humoral immunodeficiency following rituximab treatment: a 38-year-old patient with a history of Burkitt lymphoma developed chronic enterovirus meningoencephalitis four years after treatment, in the context of persistent B-cell depletion and hypogammaglobulinaemia (IgG 5.41 g/L, IgA 0.66 g/L, IgM <0.1 g/L). Treatment with intravenous immunoglobulins led to marked clinical improvement (4).

Our two patients experienced several severe infectious episodes in addition to isolated hypogammaglobulinaemia, which illustrates the two major clinical consequences described in the literature, such as infection and humoral immunodeficiency.

The mechanisms underlying persistent B-cell depletion remain incompletely understood. A recent study in patients with ANCA-associated vasculitis identified defects in central B-lymphopoiesis – including a reduced transitional B-cell count and under-expression of BAFF-R on B cells – as contributing factors to prolonged B-cell depletion (3). A potentiating effect of concomitant or prior cytotoxic treatment has also been suggested, as in Case 2, who received chemotherapy for recurrent thymoma; however, this hypothesis has not been formally established and remains speculative (2).

Persistent B-cell depletion may also unmask or overlap with a pre-existing primary immunodeficiency. Secondary, rituximab-associated hypogammaglobulinaemia and primary antibody deficiencies can be difficult to distinguish, particularly when pre-treatment immunological work-up is lacking, as impaired reconstitution of memory B cells can be observed in both settings (5). Additionally, quantifying the potential risk of infections following rituximab treatment can be challenging due to concomitant use of immunosuppressive or chemotherapeutic agents. Notably, in Case 2, hypogammaglobulinaemia was first detected shortly after an episode of septic shock in November 2024. This raises the question of whether the severe infectious event contributed to a further decline in humoral immunity or whether it unmasked an underlying progressive immunodeficiency that was already present alongside the persistent B-cell depletion.

The infectious burden is consistent with the broader literature on anti-CD20 therapies beyond rituximab alone. In a large retrospective cohort study of patients with demyelinating diseases who were treated with anti-CD20 antibodies (rituximab, ocrelizumab, ofatumumab), the risk of severe infection was independently associated with comorbidities, treatment duration and disability score. However, although serum IgG and IgM levels decreased with treatment duration, they were not found to be independent predictors of severe infection. In contrast, zoster reactivation was associated with lymphopenia (6). A more recent real-world cohort study found that around a third of anti-CD20-treated patients had hypogammaglobulinaemia, with a positive correlation between lower IgG levels and serious infections. Longer treatment exposure was associated with both a higher risk of IgG deficiency and of serious infection (7). Along with our cases, these data suggest that the risk of clinically significant infection is not confined to the period of active B-cell depletion, but can persist, or even manifest with a delay, for years after treatment.

Although there are some recommendations for continued B-cell monitoring after rituximab for B-lymphocytic non-Hodgkin's lymphoma, no consensus guideline currently defines how patients with autoimmune diseases and kidney transplant recipients should be monitored, particularly beyond the treatment period (8). In a large multicentre study across four non-lymphoma indications (kidney transplantation, membranous nephropathy, pemphigus and neuromyelitis optica), the timing and rate of B-cell regeneration after rituximab varied markedly by indication, with kidney transplant and pemphigus patients showing regeneration as early as four weeks, while patients with membranous nephropathy or neuromyelitis optica typically remained depleted until at least eight weeks (8). A recent real-world study also noted the absence of consensus recommendations for monitoring serum immunoglobulin levels or managing hypogammaglobulinaemia risk in this setting (dose reduction or extended dosing intervals) due to

insufficient robust evidence (7). Existing recommendations generally advise periodic reassessment of immunoglobulin levels, typically every six months, and clinical reassessment of disease-modifying therapy based on infectious risk factors, with no defined threshold (7).

At a single-centre level, structured pre-treatment screening and prophylaxis protocols tailored to anti-CD20/CD52 agents have been shown to meaningfully reduce infective adverse events from 37.5% to 24.6% of treated patients (9); however, implementation of such protocols remains local rather than forming part of a harmonised international standard. Notably, available evidence on infection risk and B-cell kinetics after anti-CD20 therapy has focused predominantly on the period of ongoing or recently discontinued treatment (6–8). Our cases suggest that clinically significant infectious complications can also emerge many years after treatment discontinuation, a scenario not addressed by current monitoring recommendations for either B-cell repopulation or immunoglobulin surveillance.

Our two cases illustrate the potential severity of this complication and its unpredictable course over time. The lack of a standardised definition, systematic long-term immunological monitoring and harmonised recommendations for surveillance likely contributes to the under-recognition and under-reporting of this adverse event.

Out of a total of 187,669 reported cases for rituximab in the WHO pharmacovigilance database, there are 662 cases of lymphopenia, seven cases of prolonged lymphopenia and 15 cases of B-cell aplasia. However, these are spontaneous reports of adverse reactions, with no established causal link to the suspected medicine (10).

Conclusion

These two cases illustrate that complete and persistent B-cell depletion can develop following rituximab exposure, sometimes persisting for over a decade, and can manifest through distinct but related clinical pathways. In Case 1, the complication remained largely confined to asymptomatic secondary hypogammaglobulinaemia, accompanied by recurrent but manageable infections and a period of immunoglobulin replacement therapy. In Case 2, persistent B-cell depletion was followed more than six years later by recurrent severe infections and, subsequently, by overt secondary hypogammaglobulinaemia requiring ongoing immunoglobulin replacement therapy. This illustrates that the clinical manifestation of this adverse drug reaction can evolve and worsen over time, rather than remaining static. Based on the chronology and available literature, the causal role of rituximab in both cases is considered possible; in Case 2, a mixed aetiology cannot be excluded given the underlying suspicion of Good syndrome.

Long-term monitoring of B-cell counts, and immunoglobulin levels should be considered after rituximab therapy, particularly in patients with recurrent or unusual infections. This monitoring should not be limited to the first months following treatment discontinuation. However, as highlighted by the recent literature, there is currently no consensus on the optimal frequency, duration or biological thresholds for such monitoring, whether for immunoglobulin surveillance or for B-cell repopulation itself, and available recommendations remain fragmented across disease indications. Standardising these approaches across specialities would help ensure earlier recognition of this potentially serious and currently under-reported complication. Healthcare professionals are encouraged to report suspected cases of persistent B-cell depletion to the pharmacovigilance authorities as the accumulation of real-world pharmacovigilance data is essential for strengthening safety signals, deepening our understanding of its clinical course and in turn optimising patient safety.

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Dexamethasone acts as a dose-dependent inducer of drug metabolising enzymes

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Summary

Dexamethasone is widely used across a broad range of clinical conditions, with doses varying from less than 1 mg to more than 40 mg daily and treatment given as short-term, long term or intermittent therapy. Dexamethasone is both a substrate and a dose-dependent inducer of CYP3A4 and other drug metabolising enzymes, and can therefore cause clinically significant drug-drug interactions. We report on a patient with HIV and Hodgkin lymphoma receiving bictegravir-based antiretroviral therapy and dexamethasone 40 mg daily as part of a chemotherapy regimen for Hodgkin lymphoma. After four days of dexamethasone treatment, bictegravir trough concentrations were reduced by 70%, requiring a switch to an alternative antiretroviral regimen. Available evidence suggests that dexamethasone causes weak induction at daily doses below 16 mg, moderate induction at 16–24 mg, and strong induction at higher doses. Clinically significant induction may occur even during short treatment courses, and dosing recommendations used for continuous dexamethasone administration may generally also be applied to intermittent regimens. Careful review of concomitant medications and proactive dose adjustment or treatment changes may therefore be required with dexamethasone treatment.

Introduction

Dexamethasone is a glucocorticosteroid with potent anti-inflammatory activity which is widely used to treat a broad range of inflammatory, allergic, endocrine, hematologic, neoplastic and other conditions (1). Because dexamethasone has numerous clinical indications, the initial dosage varies considerably, ranging from 0.5 to 40 mg daily, depending on the condition being treated (1). Low doses, such as 0.5–2 mg every six hours for two days, are commonly used to test for Cushing's syndrome. Higher doses, such as 30 mg daily, may be used to treat acute exacerbations of multiple sclerosis. In patients with cancer, dexamethasone is frequently administered at doses ranging from 1 to 40 mg daily as an anti-inflammatory, antiemetic, or antineoplastic agent (2).

High doses have also been used to manage severe immune-mediated complications, such as immune effector cell-associated neurotoxicity syndrome (ICANS), which can occur as an adverse effect of chimeric antigen receptor (CAR) T-cell therapy (3). Dexamethasone treatment may be short-term, long-term, or intermittent (1). Dexamethasone is both a substrate and a dose-dependent inducer of cytochrome P450 (CYP) 3A4 (2), making evaluation of potential drug-drug interactions particularly challenging for the following reasons:

- Wide dosage range: different dexamethasone doses may produce varying degrees of enzyme induction.
- Bidirectional interactions: dexamethasone may act as both a victim and a perpetrator of drug-drug interactions, resulting in complex bidirectional interaction potential.

- Variable treatment duration: treatment courses may be short, such as 48 hours for diagnostic testing; intermediate, such as three to seven days for acute conditions; or prolonged, lasting weeks to months for chronic conditions. Treatment duration may affect the time required to reach maximal enzyme induction and subsequent de-induction.

We report the drug-drug interaction between a bictegravir-containing antiretroviral regimen and intermittent courses of dexamethasone administered at a dose of 40 mg daily as part of a chemotherapy regimen for Hodgkin lymphoma in a patient living with HIV. We discuss the available evidence regarding the drug-drug interaction potential of dexamethasone across different doses and treatment durations, including intermittent dosing regimens.

Case report

A 41-year-old man was diagnosed with stage IVB Epstein-Barr virus-positive classical Hodgkin lymphoma of the nodular sclerosis subtype, with bone involvement. Immediately following the diagnosis, the patient received the first cycle (C1) of BrECADD, with subsequent cycles planned every 21 days. The BrECADD protocol consists of brentuximab vedotin (1.8 mg/kg intravenously on day [D] 1), etoposide (150 mg/m² intravenously on D2, D3, and D4), cyclophosphamide (1,250 mg/m² intravenously on D2), doxorubicin (40 mg/m² intravenously on D2), dacarbazine (250 mg/m² intravenously on D3 and D4) and dexamethasone (40 mg orally on D2, D3, D4, and D5). This first cycle was well tolerated.

The patient was also known to have HIV-1 infection, which had been diagnosed five years earlier. His antiretroviral therapy consisted of a fixed-dose combination of bictegravir (50 mg), emtricitabine (200 mg), and tenofovir alafenamide (25 mg), administered once daily. Despite this treatment, low-level viremia had been documented for at least the 12 months preceding the diagnosis of lymphoma, with HIV-1 RNA levels ranging from 100 to 170 copies/mL during this period.

Given the theoretically expected drug–drug interaction between dexamethasone and bictegravir, plasma bictegravir concentrations were measured before and after exposure to dexamethasone. The baseline concentration, measured immediately before initiation of BrECADD and 11 hours after the last administered dose of bictegravir, was 2025 ng/mL. Based on the half-life of bictegravir (approximately 16 hours), the corresponding expected trough concentration was estimated at 1,150 ng/mL. At C1D5, after four doses of dexamethasone 40 mg, the bictegravir trough concentration was 345 ng/mL. This value was substantially lower than the baseline estimated trough concentration and below the minimum concentration threshold recommended for efficacy (760 ng/mL).

In this context, bictegravir was replaced with dolutegravir at a dose of 50 mg twice daily to compensate for the interaction with dexamethasone. The dolutegravir trough concentration, measured immediately before C3 of BrECADD and 17 days after the last dose of dexamethasone, was 4,398 ng/mL. Notably, this concentration was higher than the median trough concentrations typically observed with dolutegravir 50 mg twice daily, even in the absence of enzyme-inducing co-medications (4). Dolutegravir was well tolerated. Three weeks after switching to dolutegravir, HIV RNA was suppressed to <20 copies/mL for the first time.

Discussion

Dexamethasone, administered at a dose of 40 mg daily on days one to four, reduced the trough concentration of bictegravir by 70%, resulting in a level below the minimum efficacy threshold (Figure 1), which may potentially lead to treatment failure. Thus, it was decided to replace bictegravir by dolutegravir dosed at 50 mg twice daily to compensate for the strong inducing effect of high-dose dexamethasone (4, 5).

Bictegravir is an integrase strand transfer inhibitor approved for the treatment of HIV as part of a three-drug, fixed-dose, single-tablet combination that also contains the two nucleoside reserve transcriptase inhibitors

emtricitabine and tenofovir alafenamide. While emtricitabine and tenofovir are primarily eliminated renally, bictegravir is metabolised equally by CYP3A4 and uridine diphosphate glucuronosyltransferase (UGT) 1A1 and is also a substrate of P-glycoprotein, making it susceptible to drug-drug interactions, notably with inducers (6). For example, the strong inducer rifampicin was shown to reduce bictegravir area under the curve (AUC) by 75%. In comparison, the moderate inducer rifabutin reduced bictegravir AUC and trough concentration by 38% and 56%, respectively (5, 6).

Dexamethasone is both a substrate of CYP3A4 and an inducer of drug metabolising enzymes. In HuH-7 hepatoma cells, dexamethasone was shown to increase the expression and activity of CYP3A4, UGT1A1 and UGT2B7, while having minimal effects on CYP1A2, CYP2B6, or CYP2C9 (7). In vitro studies using primary human hepatocytes further demonstrated that dexamethasone induces CYP3A4 in a concentration-dependent manner (8). CYP3A4 activity increased 1.7, 1.9, 3.9, 6.9, and 6.6-fold following exposure to dexamethasone at concentrations of 2, 10, 50, 100, and 250 µmol/L respectively (8).

The effect of dexamethasone on CYP3A4 has also been demonstrated in a small number of clinical drug-drug interaction studies. For example, dexamethasone administered at 1.5 mg once daily for four days reduced triazolam AUC by 19%, an effect that is not considered clinically relevant (9). CYP3A4 activity increased by 26% following the administration of dexamethasone at 8 mg daily for five days (8) and by 55% following administration at doses of 16–24 mg daily for two to nine days (10). Although limited, these clinical data are consistent with *in vitro* findings indicating that dexamethasone induces CYP3A4 in a dose-dependent manner. Altogether, these data suggest that daily dexamethasone doses up to 16 mg are expected to produce only weak enzyme induction. Daily doses of 16–24 mg are likely to result in moderate induction, whereas higher doses may cause strong induction, as observed in our case. Therefore, the magnitude of dexamethasone-mediated enzyme induction is expected to vary with the dose administered and, consequently, with the underlying condition being treated. It is also important to consider that dexamethasone is a substrate of CYP3A4. Consequently, its systemic exposure – and therefore its enzyme-inducing potential – may be influenced by the concomitant administration of CYP3A4 inhibitors or inducers. For example, co-administration of a single 4.5 mg oral dose of dexamethasone with 200 mg of the strong CYP3A4 inhibitor itraconazole increased dexamethasone exposure by three to four-fold in healthy volunteers (11). Conversely, dexamethasone bioavailability was reduced by 60% in patients receiving 4 mg dexamethasone concomitantly with the strong CYP3A4 inducer phenytoin (12).

The duration of dexamethasone treatment is also an important consideration, given that enzyme induction requires several days to reach its full effect because it involves *de novo* enzyme synthesis. In a modelling study, the onset and offset of induction were shown to be more rapid for UGT1A1 than for CYP3A4 (13). This finding is supported by a clinical drug interaction study of dolutegravir, which is metabolised predominantly by UGT1A1, and to a lesser extent by CYP3A4, and rifapentine, a strong inducer of both enzymes. Dolutegravir trough concentrations decreased by 23%, 64% and 56% on days one, two, and six after rifapentine administration, respectively (14). By contrast, more than 10 days were required to achieve maximal hepatic CYP3A4 induction with rifampicin (15). Based on these data, maximal enzyme induction may occur even during a short course of dexamethasone – less than one week at a daily dose exceeding 16 mg. This was observed in our case, in which the bictegravir trough concentration had already decreased by 70% four days after dexamethasone initiation.

The effect of intermittent inducer administration has been evaluated using once-weekly rifapentine for the treatment of latent tuberculosis infection (16). Enzyme induction was shown to be time-dependent, with the greatest effect observed between two and six days after rifapentine initiation. For bictegravir, once-weekly rifapentine produced a rapid, time-dependent induction,

resulting in a reduction in bictegravir trough concentrations of up to 83% by day four after rifapentine initiation. Importantly, bictegravir trough concentrations did not return to pre-rifapentine steady-state concentrations before the subsequent weekly dose. Therefore, coadministration of bictegravir with once-weekly rifapentine is not recommended because of the potential for reduced therapeutic efficacy and the development of resistance (5, 16). In our case, bictegravir was replaced with dolutegravir, as the effect of strong enzyme induction can be compensated for by doubling the dolutegravir dose to 50 mg twice daily (4), whereas doubling the bictegravir dose does not fully overcome the strong enzyme induction (6). This observation can be explained by the fact that bictegravir undergoes more CYP3A4 metabolism compared to dolutegravir (6). Although dexamethasone was administered every 21 days, dolutegravir was maintained at 50 mg twice daily because de-induction takes approximately 14 days (13) and to minimise the risk of dosing error, particularly given the good tolerability of dolutegravir. Based on these data, the dosing recommendations established for continuous dexamethasone administration may also be applied to intermittent dosing regimens, provided that the coadministered drug does not have a narrow therapeutic index. For drugs with a narrow therapeutic index, a return to the standard dose may be necessary approximately two weeks after dexamethasone administration and before the start of the next dexamethasone treatment cycle. The management of drug-drug interactions between antiretrovirals and dexamethasone at daily low doses or doses >16 mg has been summarised in a previously published paper (17).

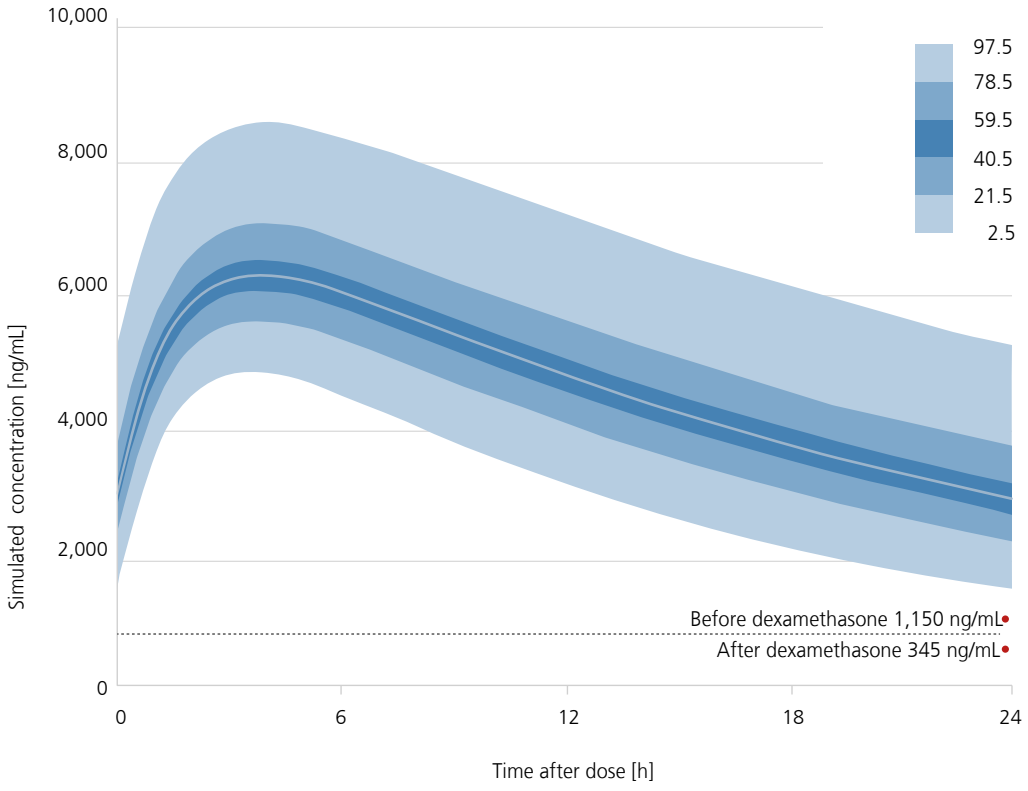


Figure 1: Bictegravir plasma concentration in the patient.

Conclusion

Dexamethasone induces drug metabolising enzymes in a dose-dependent manner, with weak induction expected at daily doses below 16 mg, moderate induction at doses of 16–24 mg, and strong induction at higher doses. Clinically significant induction may occur even during short courses of dexamethasone treatment. The dosing recommendations established for continuous dexamethasone administration may generally also be applied to intermittent dosing regimens.

The red dots represent the patient's bictegravir trough concentrations during treatment with bictegravir 50 mg once daily, before dexamethasone and on day 5 of cycle 1, following 4 days of dexamethasone (40 mg once daily from day 2 to day 5). The graph shows the simulated bictegravir concentration percentiles obtained from a population pharmacokinetic analysis (18). The solid line represents the median (50th percentile), and the dotted line indicates the minimum concentration threshold recommended for efficacy (760 ng/mL).

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Regulatory

Officially mandated information material now easily accessible in one central location at www.swissmedicinfo-pro.ch

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Summary

Since 1 November 2026, healthcare professionals and patients have been able to access officially mandated information material in electronic form from a central resource: www.swissmedicinfo-pro.ch for healthcare professionals and www.swissmedicinfo.ch for patients. It is possible to search for materials by medicinal product or active substance and download them directly. Furthermore, the platforms also provide contact addresses for the marketing authorisation holders, from whom physical versions of the materials can be ordered.

For some medicinal products, information material may be needed in addition to the medicinal product information (Information for healthcare professionals and Patient information) to give healthcare professionals and/or patients detailed instructions on the safe use of the medicinal product. This information is officially mandated and a precondition for placing the medicinal product in question on the market. Various materials are used, including guidelines and checklists for healthcare professionals, or information brochures and patient cards for patients.

Since 1 November 2026, healthcare professionals and patients have been able to access officially mandated information material in electronic form from a central resource: www.swissmedicinfo-pro.ch for healthcare professionals and www.swissmedicinfo.ch for patients. It is possible to search for materials by medicinal product or active substance and download them directly. Furthermore, the platforms also provide contact addresses for the marketing authorisation holders, from whom physical versions of the materials can be ordered. In cases where therapies involve special safety requirements, information materials can make an important contribution in routine clinical practice. Making this important information available in a central electronic resource will guarantee fast and straightforward access at any time. This measure is intended to provide support for the implementation of risk-minimising measures in everyday practice and strengthen drug safety.

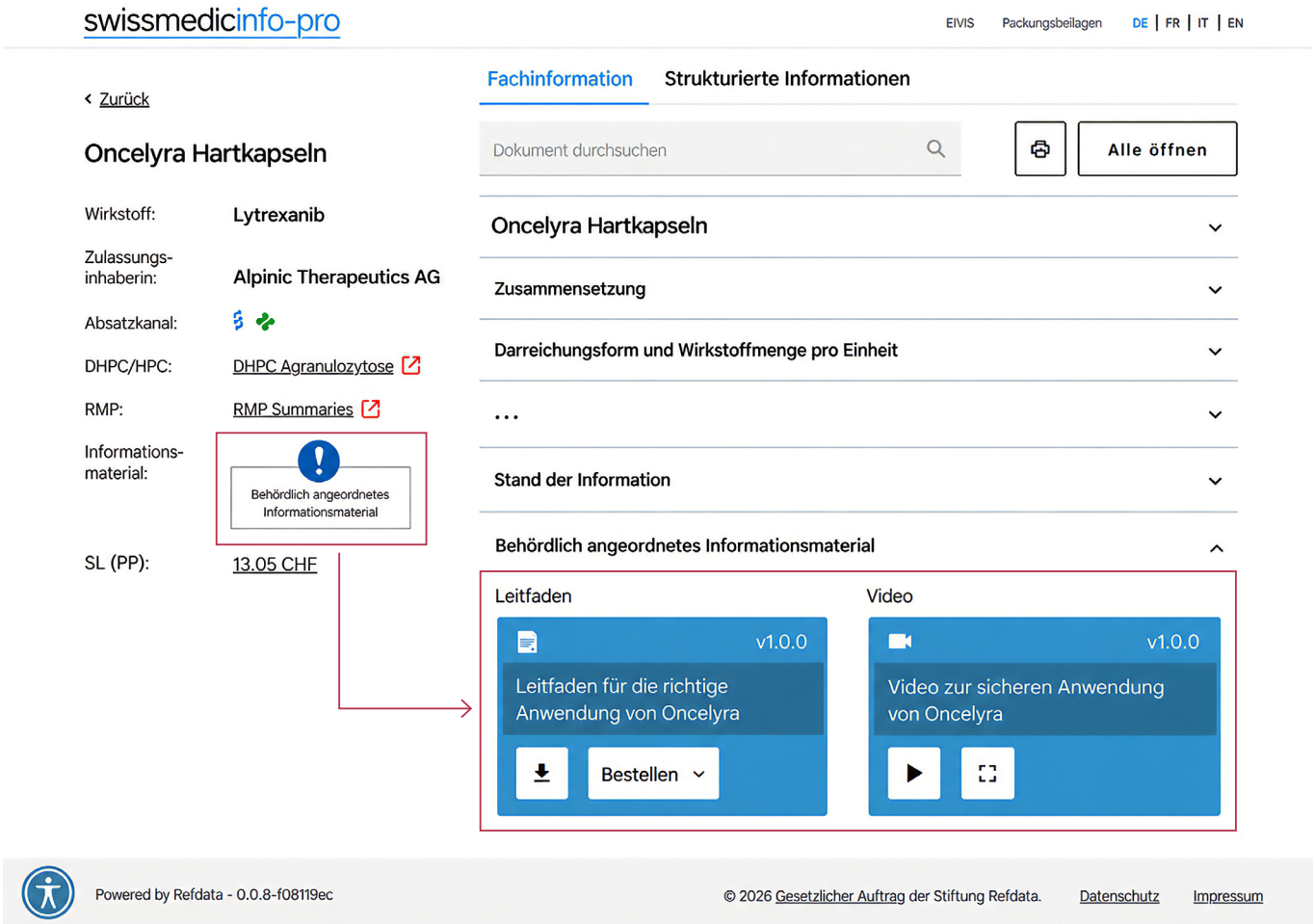


Figure: Direct access to information material via www.swissmedicinfo-pro.ch.
(fictional example created with the assistance of artificial intelligence)

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Statistical review 2025

Summary of adverse events following immunization reported in Switzerland during 2025

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Summary

During 2025, Swissmedic received a total of 356 reports of "adverse events following immunization (AEFIs)" from Switzerland. The decrease in total AEFI reports compared to 2024 (n=504) was caused mainly by a lower number of reports in relation to COVID-19 vaccinations (n=100 case reports in 2025 compared to 244 cases in 2024). In addition, 256 AEFI reports were submitted for non-COVID vaccines during 2025, which is a slightly lower number compared with 2024 (260 reports) and with 2023 (264 reports, see Fig. 1). Of the 256 cases, 134 (52.3%) were submitted directly to Swissmedic by reporters, whereas 122 (47.7%) case reports were received from marketing authorisation holders of the vaccines. The focus of this report is on non-COVID vaccines. Nevertheless, a brief summary of COVID-19 AEFI reports received during 2025 is presented in the final section.

AEFI reports were recorded, assessed and analysed in the Swiss pharmacovigilance database. Swissmedic is encouraging reporting of AEFIs in high quality, which enables early detection of new safety signals. Important safety issues are evaluated in international collaboration with other regulatory agencies and/or with the participation of the Human Medicines Expert Committee (HMEC) of Swissmedic, if necessary. An increased AEFI reporting rate, followed by an assessment of relevant cases, can lead to risk minimisation measures in order to ensure vaccine safety.

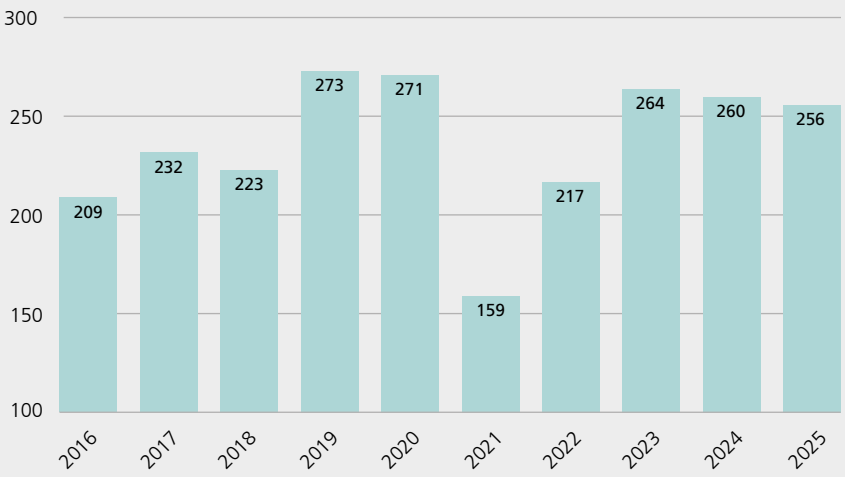


Figure 1: Number of non-Covid AEFI reports received between 2016 and 2025

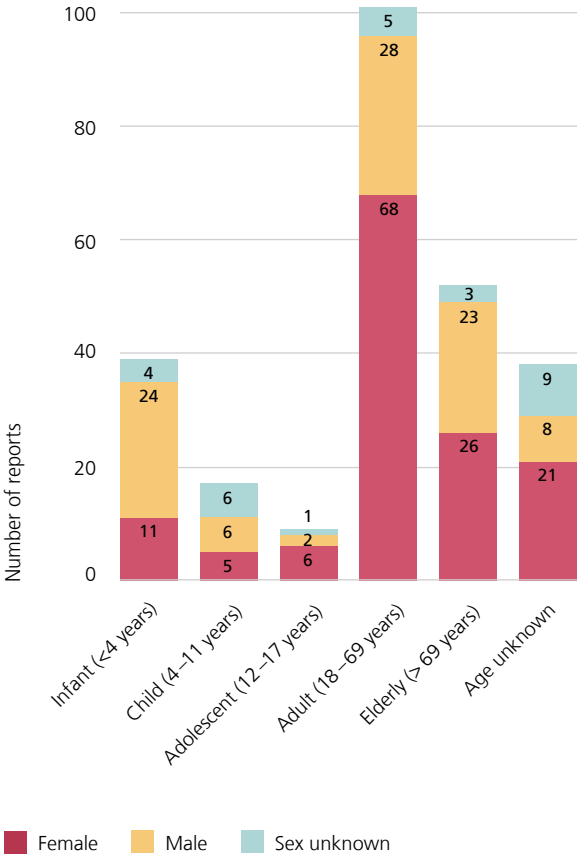


Figure 2: Number of AEFI reports by age group and sex, 2025

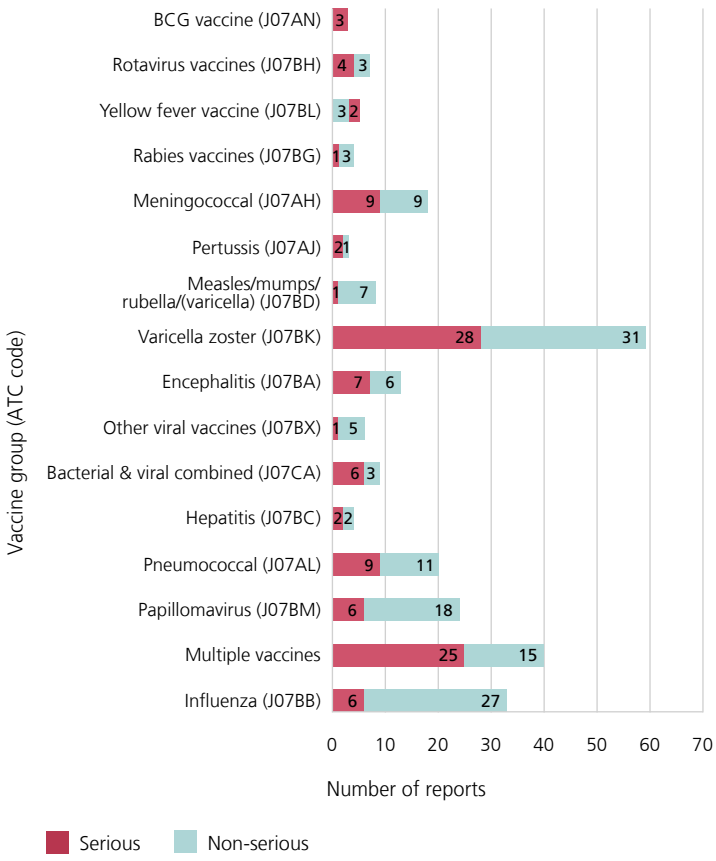


Figure 3: Number of reports by vaccine group (ATC code) and seriousness, 2025

Figure 2 compares the number of reports by age group and sex. The largest number of AEFI reports involved adults (101 reports), followed by the elderly (52 reports), infants (39 reports), children (17 reports) and adolescents (9 reports). Overall, in 2025 the number of reports concerning females (137 reports; 53.5%) exceeded those concerning males (91 reports; 35.6%). In 28 AEFI reports (10.9%), the sex of the persons remained unknown. In 38 case reports (14.8%), the age group of the patients was not recorded.

Figure 3 shows the number of spontaneous AEFI reports by vaccine group (ATC code) and seriousness. Generally, a safety report is assessed as "serious" if it involves an adverse event leading to death, to hospitalisation or to prolongation of an existing hospitalisation, if it is life-threatening or results in a significant or persistent disability or a congenital anomaly. Furthermore, a report is assessed as "medically important" (and therefore, also as "serious") even if it does not fulfil the aforementioned criteria for "seriousness", but involves an event considered to be significant by medical judgement. All other reports are assessed as "non-serious" (e.g. self-limiting adverse events with good recovery). Of the 256 spontaneous reports received in 2025, 143 (55.8%) were "non-serious", 88 (34.4%) included only medically important events and 25 (9.8%) of the reports involved AEFIs with serious consequences.

Generally, considering all vaccines in 2025, the relative frequency (percentage) of "serious", including "medically important", cases taken together (113 reports; 44.1%) was slightly higher than 2024 (37.7%) and 2023 (36%). Cases where several (n >1) vaccines were reported as suspected in relation to AEFIs are shown in Figure 3 as "Multiple vaccines". Many of these cases concerned multiple immunizations in children.

As in 2023 and 2024, during 2025 a higher number of cases relating to the herpes zoster vaccination were submitted, and these are included in Figure 3 as ATC code "Varicella zoster (J07BK)". The majority of these case reports were assessed as "non-serious" (31 of 59 cases; 52.5%), which was a similar percentage to 2023 (54.8%) and 2024 (55.4%).

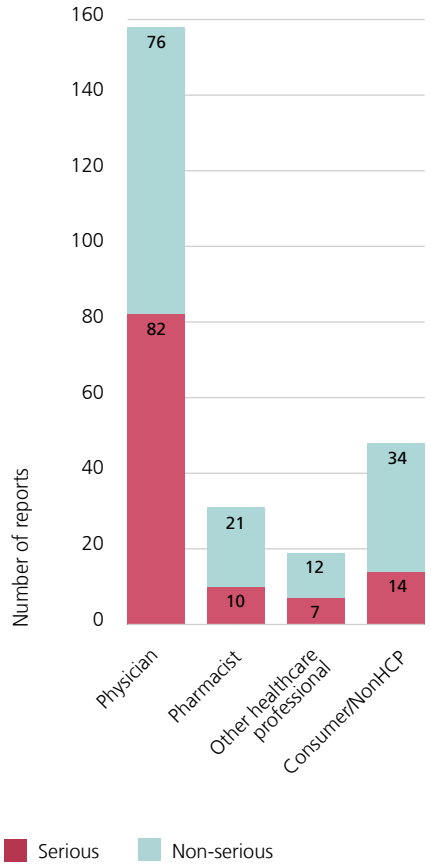


Figure 4: Number of AEFI reports by reporter qualification and seriousness, 2025

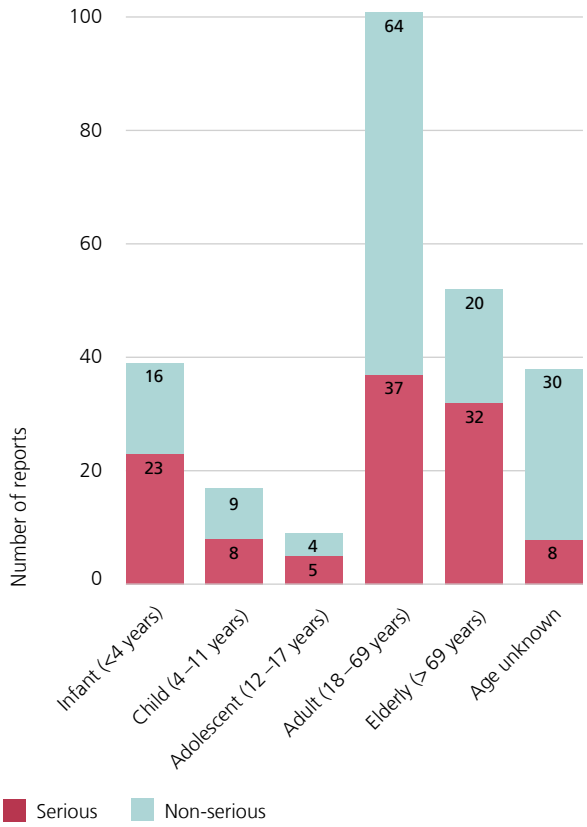


Figure 5: Number of AEFI reports by age group and seriousness, 2025

Figure 4 shows the number of Swiss AEFI reports in 2025 grouped by primary reporter and seriousness. Healthcare professionals – providing medically confirmed data and good quality individual AEFI reports – were primary reporters in the vast majority of cases. Physicians submitted the largest number of AEFI reports (158 of 256), including a higher number of reports assessed as "serious" or "medically important" (82 of 158 reports). Consumers/patients submitted the second-highest number (48 AEFI reports), followed by pharmacists (31 reports).

Figure 5 shows the number of spontaneous AEFI reports by age group and seriousness. It is evident that the highest number of "serious" or "medically important" cases (37 of 101 AEFI reports in total) were recorded in the adult age group, followed by the elderly (32 of 52 reports), infants (23 of 39 reports), children (8 of 17 reports) and adolescents (5 of 9 reports).

AEFI reports received by Swissmedic in 2025 following COVID-19 vaccinations

In Switzerland, the COVID-19 vaccinations continued during 2025 with updated vaccines; Swissmedic received far fewer reports of suspected adverse reactions in this year (100 cases) compared to the previous years (2024: 244 reports; 2023: 727 reports; 2022: >5,000 reports). Of these 100 cases, 80 were submitted directly to Swissmedic and 20 were received from marketing authorisation holders of COVID-19 vaccines.

No case report with fatal outcome was reported in 2025 for COVID-19 vaccines.

Swissmedic evaluates COVID-19 vaccine reports thoroughly, continually reviews the latest drug safety findings, follows the scientific literature and works in close contact with international regulatory authorities.

Overall, the reports of suspected adverse reactions received and analysed did not alter the positive benefit-risk profile of the COVID-19 vaccines used in Switzerland, largely confirming their known safety profile. Known side effects of COVID-19 vaccines are listed in the continually updated, published Swiss product information texts (1).

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Pharmacovigilance for veterinary medicinal products in 2025

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Complete report:

Vigilance for veterinary medicinal products – Annual report 2025

Summary

In 2025, a total of 722 reports were submitted, marking a 9.7% increase compared with 2024. The most commonly affected species were dogs (424) and cats (161), followed by cattle or calves (65) and horses (25). The most frequently involved medicinal product types were antiparasitics, vaccines and nervous system modulators.

A significant number of the reports (175) involved suspected lack of efficacy, particularly for antiparasitics and a hormonal implant used to induce temporary infertility in male dogs. In these latter cases, efficacy was assessed by measuring testosterone levels, which were shown to be too high in 26 cases.

Reports on vaccines mainly involved local and systemic reactions to frequently used products, mainly in dogs and horses. Nervous system modulators were primarily represented by anti-NGF monoclonal antibodies in dogs and cats. Publications and media reports led to increased awareness and, consequently, to a high number of reports. Most of the reported adverse events remained in line with the authorised product information.

Tox Info Suisse forwarded 225 cases, 70 animal exposures, mostly accidental ingestion of flavoured tablets, and 155 human exposures, often due to confusion with human medicines or accidental contact.

30 safety signals were opened, 12 closed with an official decision, resulting in updates to product information to improve safety.

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Information on the Swissmedic website

Pharmacovigilance in the spotlight

Learning from adverse reaction reports – cases from pharmacovigilance

02.11.2026
Eye disorders during amiodarone treatment

06.01.2026
Phosphonorm® administered instead of Phoscap capsules

12.10.2026
Neuroleptic malignant syndrome associated with antipsychotic treatment

24.10.2025
Risk of intraoperative floppy iris syndrome in patients treated with tamsulosin

24.04.2026
Hepatic and pulmonary side effects after the long-term administration of low-dose methotrexate

12.09.2025
Drug-induced aseptic meningitis

06.02.2026
Jarisch-Herxheimer reaction during antibiotic treatment of spirochaetal infections

07.08.2025
Drug-induced taste disorders



Reporting of ADRs by healthcare professionals

Explainer video

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Safety Update – product information updates

Now available in English!

Since November 2025, Swissmedic provides a monthly overview of product information updates in the **Safety of Medicines** newsletter. This monthly overview provides information about selected active substances or active substance groups whose Information for healthcare professionals has been or will be updated with new safety-related information.

The new safety-related information is available in German, French, and Italian, and now also in English!

Subscribe to the **Safety of Medicines newsletter** to receive the overview Safety Update – product information updates monthly

Safety Update November 2026

Active substance(s)	New safety information	Updates section(s)	(D)HPC
Galantamine	Nightmares	Undesirable effects	–
Velmanase alfa	Infusion-related reactions: apathy, hypotonia, pallor	Undesirable effects	–
GLP-1 receptor agonists	Necrotising pancreatitis	Warnings and precautions; Undesirable effects	–
SGLT2 inhibitors	Fournier's gangrene	Warnings and precautions	–
Dabrafenib	Potentiation of radiation damage	Warnings and precautions; Undesirable effects	–
Trametinib	Potentiation of radiation damage	Warnings and precautions; Undesirable effects	–
Non-steroidal antiandrogens	Leukopenia, neutropenia	Undesirable effects	–
Alectinib	Severe hypertriglyceridemia with resulting acute pancreatitis: blood triglyceride monitoring; discontinue treatment if occurs.	Dosage/use; Warnings and precautions; Undesirable effects	DHPC – Alecensa® (Alectinib)
Olmesartan	Sprue-like enteropathy: In addition to the small intestine, other sections of the gastrointestinal tract can be affected by changes, for example in the form of colitis (including microscopic colitis).	Warnings and precautions	–
Peanut allergens (Arachis hypogaea)	Oral inflammation or lesions: Increased risk of severe systemic allergic reactions in patients with acute severe oral or oesophageal inflammation or oral lesions; delay start of treatment or temporarily interrupt ongoing treatment until healed.	Warnings and precautions	–
Peanut allergens (Arachis hypogaea)	Chronic urticaria can falsify the safety assessment of the treatment.	Warnings and precautions	–
Peanut allergens (Arachis hypogaea)	Hypersensitivity	Undesirable effects	–

Active substance(s)	New safety information	Updates section(s)	(D)HPC
Aflibercept	Reactions due to intravitreal injections (e.g. retinal tear, traumatic cataract, retinal vasculitis with/without occlusion), immunogenicity: Patients should be informed of the symptoms of ocular complications and encouraged to report them immediately.	Warnings and precautions; Undesirable effects	–
Aflibercept	Increased intraocular pressure: The injection must not be performed while the intraocular pressure is ≥ 30 mmHg.	Warnings and precautions	–
Aflibercept	Bilateral treatment: The risk of systemic adverse events may be increased.	Warnings and precautions	–
Aflibercept	Concomitant use of other anti-VEGF agents: Limited experience with concomitant systemic or ocular treatment with other anti-VEGF agents	Warnings and precautions	–
Aflibercept	Suspend treatment in the event of significant loss of visual acuity or ocular complications.	Warnings and precautions	–
Aflibercept	Retinal pigment epithelium tear: Increased risk with extensive and/or severe detachments of the retinal pigment epithelium. Caution is advised in these patients.	Warnings and precautions	–

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Healthcare Professional Communications

Some links are available in German only

26.09.2026
DHPC – Clozapin
Überarbeitete Empfehlungen für die routinemässige Kontrolle des Blutbildes im Hinblick auf das Risiko einer Agranulozytose

25.09.2026
DHPC – Remsima® (Infliximab)
Die neue intravenöse Formulierung (100 mg und 350 mg, Konzentrat zur Herstellung einer Infusionslösung) enthält Sorbitol und ist daher bei Patientinnen und Patienten mit hereditärer Fruktoseintoleranz (HFI) kontraindiziert

21.09.2026
DHPC – Apremilast Leman (apremilastum)
Fehler beim Verfallsdatum

10.09.2026
DHPC – Tavneos® (Avacopan)
Negatives Nutzen-Risiko-Verhältnis – Widerruf der Zulassung

28.08.2026
DHPC – Gabapentin Viatris (gabapentinum)
Falsche Kapselbeschriftung

25.08.2026
DHPC – Alecensa® (Alectinib)
Empfehlungen zur Vorgehensweise bei schwerer Hypertriglyzeridämie

14.08.2026
DHPC – Rhophylac (immunoglobulinum humanum anti-D)
Wichtige Mitteilung – Partikel

12.08.2026
DHPC – Bonviva 150 mg (acidum ibandronicum)
Veraltete Patienteninformation (Packungsbeilage, PIL)

06.08.2026
DHPC – Tavneos® (Avacopan)
Medikamentös bedingte Leberschädigung (Drug-Induced Liver Injury - DILI) und Gallengang-verlustsyndrom (Vanishing-Bile-Duct-Syndrom - VBDS) – verschärfte Überwachung der Leberfunktion

06.08.2026
DHPC – Aranesp (darbepoetinum alfa)
Potenzielle sichtbare Partikel

27.07.2026
DHPC – Mounjaro KwikPen (tirzepatidum)
Notwendigkeit sachgemässe Verwendung

22.07.2026
DHPC – Caspofungin Labatec®, Caspofungin Leman®, Caspofungin Mepha®, Caspofungin Viatris, Caspofungin Sandoz® eco (Caspofungin)
Caspofungin: Vermeiden Sie die Verwendung von Polyacrylnitril-(PAN)-Membranen während der kontinuierlichen Nierenersatztherapie (TRR)

20.07.2026
DHPC – Paxlovid® (Nirmatrelvir/Ritonavir)
Wichtiger Hinweis zur Vermeidung von Medikations-fehlern bei pädiatrischen Patienten ab 6 Jahren mit einem Körpergewicht von mindestens 20 kg und weniger als 40 kg

15.07.2026
DHPC – Primovist 0.25 mmol/ml (dinatrii gadoxetas)
Zusätzliche visuelle Kontrolle

14.07.2026
DHPC – Fungizone, Injektionspräparat (i.v.) (amphotericinum B)
Verzögerte Implementierung der zuletzt genehmigten Packungsbeilage (Stand Februar 2025) mit neuem Warnhinweis zu Hyperkaliämie

10.07.2026
DHPC – Domperidon axapharm lingual®, Domperidon lingual Spirig HC®, Domperidon-Mepha® oro, Motilium®, Motilium lingual®, Motilium lingual Gastrosan® (Domperidon)
Domperidonhaltige Arzneimittel: Neue Kontraindikation Phäochromozytom

09.07.2026
DHPC – Ontozry (Cenobamat)
Risiko für schweren Leberschaden und neue Empfehlungen zur Überwachung der Leberfunktion

09.07.2026
DHPC – Konakion MM paediatric / Konakion MM (phytomenadionum)
Glasartige Partikel nach dem Öffnen von Konakion MM-Ampullen

25.06.2026
DHPC – Miostat (carbacholum)
Abweichung in den Packungsmaterialien (Faltschachtel, Blister; Etikette, Packungsbeilage)

22.06.2026
DHPC – MisoOne (misoprostolum)
Wichtige Sicherheitsinformation

15.06.2026
DHPC – Menopur Multidose (menotropinum)
Wichtige Mitteilung zur Arzneimittelsicherheit

09.06.2026
DHPC – Tigecyclin Leman (tigecyclinum)
Abweichung zwischen dem im 2D-Barcode auf der Umverpackung kodierten Verfallsdatum und dem lesbaren Verfallsdatum

08.06.2026
DHPC – Dafalgan® (paracetamolum)
Packungsbeilage mit fehlendem Sicherheitshinweis

08.06.2026
DHPC – Vyvgart® (efgartigimod alfa)
Wichtige Mitteilung zur Arzneimittelsicherheit

08.06.2026
DHPC – Dafalgan® DOLO (paracetamolum)
Packungsbeilage mit fehlendem Sicherheitshinweis

28.05.2026
DHPC – Evrysdi® (Risdiplamum)
Important drug safety notification

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Announcements

02.11.2026
Update of publications on parenteral products without a medical purpose
Swissmedic has updated the position paper "Parenterals without an intended medical purpose – Enforcement at product level " and the "Information sheet for the cosmetic sector – Parenterals without an intended medical Purpose". The updates concern clarifications in the wording and do not affect the current enforcement practice. The updated versions are now available for download

01.11.2026
Modification of the "Form DMF"
Encrypted e-mail delivery to DMF holder via IncaMail

01.11.2026
Update to the forms New authorisation of human medicinal products and Variations and extensions HAM
Due to changes to the medicinal products categories and the central publication of officially mandated information material by conformation, an update to the forms New authorisation of human medicinal products and Variations and extensions HAM is necessary

26.10.2026
Neue Informationen zur Einführung von eCTD v4.0
Swissmedic veröffentlicht das Paket des Schweizer Implementation Guide in der Version 2.0

20.10.2026
Neuer strategischer Ansatz zur Minimierung von Tierversuchen bei der Entwicklung von Arzneimitteln
Swissmedic unterstützt internationale 3R-Strategie konsequent

16.10.2026
Die neue Pharmacopoea Helvetica 13
Die neue Pharmacopoea Helvetica ist publiziert. Der Institutsrat hat beschlossen, die 13. Ausgabe der Schweizerischen Pharmakopöe auf den 1. April 2027 in Kraft zu setzen.

14.10.2026
Swissmedic Journal
Aktuelle Ausgabe
Swissmedic Journal September 2026

13.10.2026
Haemovigilance Annual report 2025
Evaluation of haemovigilance reports in 2025

12.10.2026
Neuroleptic malignant syndrome associated with antipsychotic treatment
Learning from adverse reaction reports – cases from pharmacovigilance

09.10.2026
GMP compliance by foreign manufacturers
Simplifications for industry and clarification of unresolved issues

01.10.2026
Changes to the Guidance document "Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)"
Swissmedic has updated the Guidance document on parallel imports. In particular, the changes concern clarifications on country of export, additions to the requirements for packaging, storage instructions and information on handling in the medicinal product information for parallel imported medicinal products

01.10.2026

Revision of the Guidance document Authorisation Biosimilar

Following finalisation of the EMA Reflection paper on a tailored clinical approach in biosimilar development, the Guidance document Authorisation Biosimilar has been adapted accordingly

01.10.2026

Adaptations required for issuing establishment licences and GMP certificates for manufacturers of active substances

As of 15 November 2026, the prior registration of active substances in the EMA SMS database (Substances Management Services) will become a mandatory requirement for their inclusion in establishment licences and GMP certificates

29.09.2026

HPC - Librela ad us. vet., Injektionslösung für Hunde (Bedinvetmabum)

Neue Vorsichtsmassnahmen für die Anwendung bei Tieren und neue Nebenwirkungen

24.09.2026

Swissmedic Portal Release Notes – 23.09.2026

In the release on September 23rd, we enable the viewing of specialist data for complementary medicines in the notification procedure (Chapter 7 KPTPO; basic company dossier, master dossier and medicines (single notifications)) for marketing authorisation holders. Furthermore, the submission of major changes in accordance with Article 41(2) of the AMBV has been introduced for establishment licence holders.

24.09.2026

Swissmedic Portal Release – New Features Available from 23 September 2026

Submission of major changes (establishment licences) and viewing of specialist data for complementary medicines in the notification procedure

24.09.2026

Information on the Swissmedic Portal release – 23 September 2026

Specialist data for complementary medicines in the notification procedure (Chapter 7 KPTPO) in the Swissmedic Portal for marketing authorisation holders

23.09.2026

I-SMI.TI.22e Notifications according to Article 41, MPLO

Swissmedic has published a new version of the document

17.09.2026

Advance notice regarding the Swissmedic Portal release of 23 September 2026

Specialist data for complementary medicines in the notification procedure (Chapter 7 KPTPO) in the Swissmedic Portal for marketing authorisation holders

15.09.2026

Summary report on authorisation – Abrysvo®

Extension of therapeutic indication (01)

15.09.2026

Summary report on authorisation – Tranylcypromine Rivopharm®

First authorisation

15.09.2026

Summary report on authorisation – Ogsiveo®

First authorisation

10.09.2026

New guideline «Schweizerische Gute Praxis der Materiovigilance in der In-vitro-Diagnostik» (GPMV-IVD)

Swissmedic publishes the new «Schweizerische Gute Praxis der Materiovigilance in der In-vitro-Diagnostik» (GPMV-IVD). This guideline is intended to support professionals using in vitro diagnostic medical devices (IVDs) for medical purposes, as well as persons responsible for the implementation of medical device vigilance in the field of in vitro diagnostics

09.09.2026
Swissmedic Journal
Latest edition
Swissmedic Journal August 2026

04.09.2026
Summary report on authorisation – Opdualag®
Extension of therapeutic indication (01)

04.09.2026
ElViS 2.0
The Electronic Vigilance System (ElViS) is being replaced by an updated reporting tool in E2B(R3) format

03.09.2026
swissdamed Webinar 10 November 2026
How to register and manage medical device data in swissdamed

03.09.2026
swissdamed Webinar 10 November 2026
How to register and manage medical device data in swissdamed

02.09.2026
Summary report on authorisation – Serum autolog Insel, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Serum autolog USZ, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Sérum autologue HOJG, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Sérum autologue ICH, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Serum autolog Blutspende Zürich, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Serum autolog LUKS, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Serum autolog KSGR, eye drops®
First authorisation

02.09.2026
Summary report on authorisation – Serum autolog Universitätsspital Basel, eye drops®
First authorisation

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