swissmedic

Vigilance-News

Edition 12 – June 2014

New Swissmedic telephone numbers in use!

With immediate effect Swissmedic can also be contacted via 058 numbers.

→ Details see last page

Report of a suspected adverse drug reaction (ADR)

The ADR reporting form can be filled in electronically:

Meldung einer vermuteten unerwünschten Arzneimittelwirkung (UAW) (German)

Annonce d'effets indésirables suspectés d'un médicament (EI) (French)

Contacts

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Editorial

Dear Reader,

The question of the role played by patients and their relatives in the reporting of adverse drug reactions (ADR) is one that arises more and more often. Influenced by the media, and also being far more self-confident regarding the ways to manage their own health or their illnesses as compared to previous generations, patients today also wish to be involved in decisions regarding their therapy. Questions regarding potential side effects or interactions with other medicinal products/foods, or about precautionary measures, may of course constitute an expression of this new state of awareness.

Patients are becoming more and more aware of what is to be done in the case of an ADR. Should this happen, they may contact a regional pharmacovigilance centre (RPVC) directly and/or their treating physician. In Switzerland, it is mandatory for healthcare professionals to report ADR, with the corresponding information, to Swissmedic (via the RPVC). In order to simplify the reporting process and also the communication between healthcare professionals, Swissmedic and marketing authorisation holders, Swissmedic provides various tools, e.g. ElViS, MedDRA, etc. (see also the articles under the «Regulatory» section).

Swissmedic provides direct, rapid information on safety risks related to particular medicinal products and active pharmaceutical ingredients on its website. The «Communications regarding the safety of medicines» are now even more easily found on the newly designed website. In addition, periodic updates (Isotretinoin) and reports on signals (Domperidone and Methylphenidate) are included in the Vigilance News.

Since the use of medical devices (in combination with active pharmaceutical ingredients or not) and the resulting adverse events are gaining importance in daily medicine, this topic is also highlighted in the Vigilance News.

We would be pleased to receive any feedback or questions on this edition of the Vigilance News at vigilance@swissmedic.ch and hope you will find it interesting reading.

The Editors

Editorial team

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We want to thank all colleagues for their contribution to the realisation of this edition of Vigilance-News.

Flash: Signals relating to the safety of medicines

Domperidone – QT-interval prolongation and associated arrhythmia

To summarise the precautionary measures:

- Weigh up the indication with extreme care
- Lowest effective dose, short treatment duration
- No combination with potent CYP3A4 inhibitors or with substances that prolong QT (for example, azole antimyotics, erythromycin and others have both effects!)
- Avoid in the case of congenital and acquired predisposing heart conditions (long QT, bradycardia, severe cardiac insufficiency, etc.)
- Monitor for electrolyte imbalance (hypokalaemia, etc.)
- Contraindicated in the case of moderate or severe liver insufficiency.

Background

Oral forms of domperidone have been authorised in Switzerland since 1979. The indications are broad, and encompass «dyspeptic disorders» caused by gastro-oesophageal reflux or delay in gastric emptying, and also nausea and vomiting of various aetiologies. The indication for the product Motilium® lingual Gastrosan®, which can be obtained in pharmacies only, is restricted to dyspeptic disorders. Motilium® film-coated and orodispersible tablets, suspension and suppositories are also authorised for nausea and vomiting. Domperidone is a dopamine antagonist and chemically related to butyrophenones; its mechanism of action is the result of the peripheral gastrokinetic characteristics and the influence on the central chemoreceptor trigger zone. These lie beyond the blood-brain barrier: since the substance only penetrates the barrier to a very small extent, it is assumed that there are no marked extrapyramidal effects or other such effects on the psyche.

QT-interval prolongation

The fact that like other dopamine antagonists, the substance does however present the risk of QT-interval prolongation and the related, potentially life-threatening arrhythmia was recognised soon after the introduction of the parenteral form, which was withdrawn from the market worldwide in 1985. It took longer until various spontaneous reports, including from Canada, led to the conclusion that the oral forms also had the (considerably lesser) potential to provoke such adverse effects.

Important elements (that in many cases also apply to other active pharmaceutical ingredients with this risk) are:

- The **metabolism via CYP enzymes**: CYP3A4: N-desalkylation, CYP1A2, 2E1 and 3A4: aromatic hydroxylation and the considerable **first pass effect** – the oral bioavailability is 15%. If the first-pass-metabolism is blocked – for example by ketoconazole – the AUC increases by factor 3.5, whereby QTc increases by less than 10 ms → **pharmacokinetic interactions**
- **Pharmacodynamic interactions with concomitant QT-prolonging drugs**
- Congenital and acquired predisposing heart conditions
- **Electrolyte imbalance**

Regulatory measures

Swissmedic was among the first authorities to require the corresponding warning, so the medicinal product information has already indicated the problem since 2005. The results of epidemiological studies later indicated a very small but significantly increased risk of cardiac death under domperidone. In 2011, the warnings were tightened in various countries including those of the EU, Canada, and also Switzerland: the substance is not authorised in the USA. In February 2014, an article was published in the French journal «*La revue Prescrire*» (Prescribing) which among other aspects criticised the (too) broad use of the substance in France and the frequent prescription with potentially interacting concomitant drugs and also – last but not least – it estimated the number of additional deaths caused by domperidone based on an extrapolation. On 7 March 2014, the EU *Pharmacovigilance Risk Assessment Committee* (PRAC) recommended more stringent restrictions, particularly of the indications (to symptoms of nausea and vomiting only), and regarding the maximum dose for children and adults, the dosage strengths, the duration of treatment, and the inclusion of new contraindications (which were previously included, for the most part, among the warnings). After the competent *EU Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)* did not approve these recommendations unanimously, a decision by the Commission is awaited this summer. Swissmedic will take this into consideration with regard to enhanced measures in Switzerland.

Reports from Switzerland: status March 2014

Since the beginning of the database in 1989, a total of only 4 reports of QT prolongation, ventricular arrhythmia and possible manifestations such as sudden death have been received regarding oral forms of domperidone. Emphasis was nevertheless consistently placed on other factors such as underlying diseases, risk factors and other medication (e.g. amiodarone). A larger number of reports exist in which domperidone is included as a non-suspect concomitant drug, e.g. in the case of «*Torsades de pointes*» under overdosed methadone or of cardiotoxic zytostatics and the administration of domperidone. Overall, the concurrence of several predisposing factors appears to be decisive for the occurrence of severe complications.

Spontaneous reports of adverse drug reactions (ADR) regarding oral Isotretinoin* – update on the case numbers as reported in Switzerland

Swissmedic is issuing an updated overview on oral isotretinoin with regard to the ADR reports that have been recorded in the national pharmacovigilance database during the period from 1 October 2012 to 28 February 2014. The focus is on psychiatric disorders, serious skin and liver reactions, as well as exposures during pregnancy (see also Vigilance-News December 2010, December 2011 and December 2012).

It is very important to carefully observe signs and/or symptoms of a possible depression in order to identify them as early as possible and be able to start with the appropriate treatment.

Given the high teratogenic potential of isotretinoin, the precautions regarding use in women of child-bearing age are to be strictly followed.

For women of childbearing age, prescriptions for oral isotretinoin preparations must be limited to 30 days. Continuation of treatment requires a new prescription.

The preparations are all classified in dispensing category A: dispensing based on a non-repeatable prescription.

Oral isotretinoin preparations are authorised in Switzerland for the treatment of severe forms of acne (such as acne nodularis, acne conglobata or acne with the risk of permanent scarring) which have proved resistant to appropriate

standard treatment regimens with systemic antibiotics and topical therapies.

Pregnancy or the possibility of pregnancy constitute an absolute contraindication for treatment with isotretinoin, given the high risk of extremely serious and severe foetal malformations.

The good level of efficacy is also associated with a potential for serious adverse effects. For that reason, all the other precautions regarding use as mentioned in the product information must also be strictly adhered to.

Pharmacovigilance of isotretinoin focuses particularly on serious skin and liver reactions, psychiatric disorders and exposure during pregnancy.

The case reports received in Switzerland reveal no relevant changes to the overall safety profile of the product, or in the distribution of the ADR reported for isotretinoin over the various organ categories since the last edition of the Vigilance-News in December 2012. Between 1 October 2012 and 28 February 2014, a total of 24 ADR reports were submitted in Switzerland, which is consistent with the known usual reporting frequency.

Psychiatric disorders

During the period concerned, a total of 6 reports were received for this organ class, including one of attempted suicide but no cases of completed suicide were reported. This constitutes a cumulated total of 12 attempted suicides since the last publication of the Vigilance-News in December 2012 on oral isotretinoin and an unchanged level of 21 completed suicides.

One report concerned an acute depressive episode in a female patient with pre-existing, well-managed depression. In that case, there was a close temporal relationship with isotretinoin administration. These symptoms improved once the drug was withdrawn.

A male patient suffered from a depression six months after renewed treatment with isotretinoin, resulting in hospitalisation and withdrawal of isotretinoin. Subsequently, the patient recovered completely.

Finally, a complex clinical case report described the onset of depression, attempted suicide, schizophrenic reactions and obsessive-compulsive disorder, which, however, only took place six months after stopping treatment with isotretinoin.

For physicians, it is particularly important to monitor patients carefully for any signs of depression and/or similar symptoms in order to identify them at an early stage, particularly in patients whose medical history already includes psychiatric disorders.

It still remains important that patients and their relatives are made aware of the possible onset of mood changes or even of depression, and to report them immediately to the health professional treating the patient (see section «Reporting adverse reactions»).

Rare serious skin reactions

During the above-mentioned time period, two reports concerning this organ class were reported (hyperhidrosis). «Increased sweating» is mentioned in the product information as a very rare adverse reaction. Otherwise, no further cases were reported in this organ class. The cumulative total therefore remains at 3 reports of serious skin reactions.

Serious liver reactions

No new reports were received in this connection during the period concerned.

Exposure during pregnancy

Since isotretinoin is a teratogenic drug and it is therefore contraindicated for woman of childbearing age, the measures described in the framework of the pregnancy prevention programme must be strictly followed (see product information for oral isotretinoin containing me-

dicinal products). Although isotretinoin should only be administered for 30 days, the proof of at least 2 negative pregnancy tests is required and a reliable method of contraception is mandatory, cases of exposure during pregnancy are still being reported. A total of 13 **new** cases of exposure during pregnancy were reported.

In one badly-documented case, a patient gave birth to a child without malformations.

Another case concerned a peri-conceptional exposure to isotretinoin. The child was diagnosed with persistent pulmonary hypertension, patent ductus arteriosus and patent foramen ovale. The causal association was assessed as «unlikely», since no increased risk of these particular deformities and their resulting complications is currently documented in literature.

A further case described a woman who gave birth to a child who suffers from epidermolysis bullosa. Here, the relatedness of drug to reaction was also classified as «unlikely», since epidermolysis bullosa is a genetic disease.

In 5 of the cases, the pregnancy was interrupted, and a spontaneous abortion occurred in one case. For the other 4 cases, the outcome is unknown.

Foetal malformations related to exposure to isotretinoin include deformities of the central nervous system (hydrocephalus, malformations/deformities of the cerebellum, microcephalus), facial dysmorphia, cleft palate, deformities of the external auditory canal (anotia, narrow or missing external auditory canal), deformities of the eyes (microphthalmia), cardiovascular deformities (conotruncal malformations such as tetralogy of Fallot, transposition of the great vessels, septum defects), and deformities of the thymus and of parathyroid glands. In addition, the miscarriage rate is increased.

To date, the cumulative total number of cases of newborns with retinoid-typical deformities remains at 4: they concern the heart, ears and face.

No further reports of children with congenital malformation were received.

Update on alitretinoin, another oral retinoid with a different indication

The active substance alitretinoin, with the trade name Toctino®, is used for the «Treatment of adults with refractory, severe chronic eczema of the hands who have received extensive local treatment for at least 4 weeks and have not responded to it. Pre-treatment measures include avoiding contact with triggers, skin protection and potent topical corticosteroids.»

The contraindications, warnings and precautionary measures which are to be followed strictly concern the same main points, and particularly the risk of birth malformations when taken during pregnancy. All safety sections in the product information are to a large extent identical with those for isotretinoin.

Of a total of 22 ADR reports received to date, one concerned depression, one concerned an aggravated depression and one concerned suicidal thoughts. However, no cases have been reported in the particularly important area of drug exposures during pregnancy.

Conclusions

Oral isotretinoin preparations may only be prescribed by physicians familiar with the use of systemic retinoids for the treatment of severe acne and who have extensive knowledge of the risks of isotretinoin treatment and of the necessary precautionary measures.

It is very important to carefully observe signs and/or symptoms of a possible depression in order to identify them as early as possible and be able to start with the appropriate treatment.

Given the high teratogenic potential of isotretinoin, the precautions of use in women of childbearing age are to be strictly followed.

For women of childbearing age, prescriptions for oral isotretinoin preparations must be limited to 30 days. Continuation of treatment requires a new prescription.

The preparations are all classified in dispensing category A: dispensing based on a non-repeatable prescription.

Oral isotretinoin products will continue to be under intensive surveillance. The reports received will be continuously evaluated and the corresponding analysis will be published.

Reporting of adverse reactions

Please submit reports on adverse reactions to the appropriate regional Pharmacovigilance Centre, using the reporting form. The form can be found on the Swissmedic website (www.swissmedic.ch → Information for Healthcare professionals → Reporting undesirable side-effects) or can be ordered from Swissmedic (Tel. 058 462 02 23).

Comprehensive information on warnings, precautionary measures and adverse reactions can be found in the information for healthcare professionals concerning oral isotretinoin products: http://www.swissmedicinfo.ch.

*In Switzerland, the following oral isotretinoin products are currently authorised (last update 28 February 2014): Roaccutan®, Curakne®, Tretinac® and Isotretinoin Mepha®.

Priapism and Methylphenidate

The indications for methylphenidate must be carefully weighed against the risks and adverse drug reactions (ADR). The following presents an overview of the precautionary measures and prerequisites for the use of the preparations and detailed explanations of a rare but serious risk, priapism, which was recently the object of a notification by the US FDA. This disorder can have severe sequelae if it is not diagnosed soon enough, the cause identified, and suitable treatment initiated. Not only the treating physicians but also the patients must be able to recognise this condition.

In June 2012, the Swiss Agency for Therapeutic Products concluded the review procedure for all preparations containing methylphenidate in Switzerland[1]. At the same time, the prerequisites for use were reiterated in the form of «Questions and Answers»[2].

Currently there are various preparations on the market (Ritalin®, Ritalin®-SR/-LA, Concerta®, Equasym® XR, Medikinet®, Medikinet® MR, Methylphenidate® Sandoz and Focalin® XR) that differ with regard to indications (children 6 years of age and older, adolescents, adults) and release kinetics.

Ritalin®, the oldest preparation, has been on the market since 1954. Later on, other preparations with expanded indications were authorised, however, important precautionary measures are to be observed for all of these due to the risk of manifold ADR. The most frequent are neuropsychiatric, cardiovascular and cerebrovascular ADR, as well as growth delay in younger children. The risks of misuse and dependency also require close monitoring.

The US FDA recently made reference to the risk of priapism in males (1–2) that was not listed in the information for healthcare professionals for all preparations containing methylphenidate. In this rare disorder, an erection that lasts for more than 4 hours occurs without any kind of sexual stimulation (3) due to a reduced outflow of the venous blood from the cavernous body of the penis. If this venous congestion persists longer, it can lead to thrombosis, ischemia and ultimately fibrosis of the cavernous body with the risk of secondary loss of erection (6–7).

In childhood, the most frequent cause of priapism is sickle cell anaemia, while in adults pharmacologic substances are responsible in the majority of cases (4). Regardless of age, this disorder usually does not occur at the start of treatment but only after a certain delay, often

1 https://www.swissmedic.ch/marktueberwachung/00135/00157/00373/index.html?lang=de

2 https://www.swissmedic.ch/marktueberwachung/00135/00752/01840/index.html?lang=de

after an increase in dose or interruption in treatment (2–5). There is the danger that boys who have not yet reached puberty will not properly recognise the problem or dare to report it. Therefore, it is important that the treating physicians as well as the patients are informed about this risk and recognise the symptoms. Patients presenting a painful and persisting (more than 2 hours) erection are advised to seek medical help as quickly as possible in such a case in order to prevent irreversible damage.

Priapism is a urological emergency. During the initial hours, **simple measures** (cooling of the skin) are generally sufficient. Then, **alpha receptor agonists** (e.g. pseudoephedrine) are administered orally or by injection into the cavernous body and depending on the case, **puncture of the cavernous body** is additionally performed. If these measures fail, a **surgical intervention** is performed as a last resort (with implantation of a spongiocavernous shunt) (3).

In December 2013, the US FDA published its data from the time period 1997–2012: 15 cases of priapism were reported whereby the average age of the patients was 12.5 years (8 to 33 years of age). In four cases, priapism occurred after an interruption or definitive discontinuation of methylphenidate. Two cases required local intervention (puncture, shunt).

Only two cases were reported to Swissmedic since 1990 to date. These involved children between the ages of 7 to 11 years. In one case, the patient recovered; the outcome of the other case is not known.

In conclusion, it can be stated that priapism is a rare unexpected event in association with methylphenidate treatment that can, however, entail severe sequelae. Swissmedic considers that the information for healthcare professionals and patient information, which previously contained no corresponding warning, should be adapted.

References

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7. Hosam S. Al-Qudah, E.D. Kim et al. Priapism. Medscape 25 November 2013. http://emedicine.medscape.com/article/437237-overview

Regulatory

MedDRA as a coding system for adverse drug reactions at Swissmedic

In January 2014, Swissmedic changed the coding system in the national adverse drug reaction database Vigiflow from the WHO Adverse Drug Reaction Terminology (WHO-ART) to the MedDRA coding system (Medical Dictionary for Regulatory Activities).

MedDRA, as medically validated terminology, is of particular importance for the standardised classification of adverse drug reactions (side effects) in pharmacovigilance and for the electronic recording and processing of case reports on an international basis. Moreover, MedDRA considerably facilitates systematic searches in the database. The product-related sections, contained in the Swiss medicinal product information for healthcare professionals and for patients, are also based on MedDRA terminology.

More details on MedDRA can be found at: http://www.meddra.org/.

Electronic Vigilance Reporting Portal ElViS

At the moment when a medicinal product is granted authorisation, the knowledge regarding adverse drug reactions (ADR) is limited to the results of clinical trials. However, these are conducted with a limited number of participants only (patients or healthy subjects). The study participants are moreover selected using specific criteria for the clinical trial, and are thus not representative of the population affected by a disease.

To broaden this limited status of knowledge once a drug is authorised, it is particularly important for healthcare professionals to report suspected ADR that take place afterwards, and particularly if they are medically important or serious. These spontaneous reports make it possible to detect and evaluate safety signals early in order to initiate measures to protect patients if necessary.

The spontaneous reporting system can, however, only work as a successful tool for preventing risks if physicians, pharmacists and other healthcare professionals make intensive use of it, since new findings on the safety of medicinal products are particularly based on a detailed analysis of well-documented individual cases.

Swissmedic is currently developing ElViS (Electronic Vigilance System), an electronic online vigilance system that permits suspected ADR to be reported directly via the Internet. Healthcare professionals who have reported such suspected cases to the regional pharmacovigilance centres (RPVC) by means of the reporting form can use this online system in the future. Pharmaceutical companies without a direct transmission option (Gateway) to the Swissmedic database (mostly small and medium-sized companies) may also transmit their reports to Swissmedic electronically in the future. ElViS also permits the transmission of case-related documents such as laboratory reports or hospital letters. Once a report has been successfully submitted, users can save the acknowledgment of receipt to local disk for their own records. The data protection and security aspects comply with the most stringent requirements.

By developing this new, user-friendly possibility to report adverse drug reactions, Swissmedic aims to further contribute towards improving the safety of medicinal products. Persons in charge are hoping for increased awareness of reporting duties by healthcare professionals, and an improvement of the quality of the reports.

It is planned to launch ElViS throughout Switzerland at the beginning of October 2014, following a test and pilot phase lasting several months.

Clinical Studies with Medical Devices – How PV works if SAE occur?

Why is a contribution on medical devices included here? In fact, they have common features with medicinal products: for example the possible occurrence of adverse reactions, trials involving patients that are authorised and monitored by the authorities, the increasing number of reports, and the transparency required on the part of the public. What many people are not aware of is the fact that medical devices combined with drugs exist. Examples are drug-eluting coronary stents (also known as medication-coated or medicated stents), intra-uterine systems, bone graft material with growth factors, inhalers to treat asthma, and others.

During the second half of 2013, a series of advertisements on a renal denervation system to treat hypertension were included in one of the most famous medical journals, the «New England Journal of Medicine» (Vol. 369). This is an excellent example of how medical devices now rival interventions using medicinal products or surgery. Physicians encounter medical devices thanks to advertising. Knowledge, experience and adjustments influence the way in which possible side effects are handled.

Only **serious adverse events** (SAE) reported from pre-marketing clinical trials with medical devices and in which Swiss trial centres take part are highlighted in this contribution. This means it refers to national studies only or multinational studies of which some even include centres on other continents.

The reports, compiled as an overall list, address all events during the study, and are categorised as *«a» = added, new reportable event; «m» = modified, new information for this already reported event; «u» = unchanged, no new information for this time.*

During the pre-marketing studies, SAE reports are received almost exclusively from the manufacturers or their mandated clinical research organisations (CRO).

The most important points of the SAE report, the so-called «notification», are not related to patient, product and dose as is the case for a medicinal product, but are related to the medical device, the therapeutic procedure and the site (hospital).

So what is usually reported with regard to an SAE related to a medical device?

- *Description of event / Device deficiency / Organ system / Preferred Term MedDRA*
- *Action / Treatment / Patient outcome*
- *Treatment Arm: Investigational Device – Control Group – Blinded – N.A.*
- *Event Status: Resolved – Resolved with sequelae – Ongoing – Death*
- *Unanticipated SADE (Serious Adverse Device Event): Yes – No*
- *Date of resolution*
- *Country, Study Center*
- *Date of procedure / First use*
- *Date of event onset*
- *Investigator assessment of **relationship to procedure**: Yes – No – Possibly*
- *Investigator assessment of **relationship to investigational device**: Yes – No – Possibly*
- *CEC (Clinical Evaluation Committee) assessment of relationship to procedure: Yes – No – Possibly*
- *CEC assessment of relationship to investigational device: Yes – No – Possibly*
- *CEC assessment of seriousness: AE – SAE – SADE – Bundled*
- *CEC assessment of unanticipated SADE: Yes – No*

It can be seen that the worst case «death» is also included. In reports from clinical studies where a fatal outcome is possible, **a double assessment** is always carried out:

- Of the person who has introduced the medical device into the patient's body (the investigator) and of the manufacturer/sponsor, which must – like the authorities – have a full overview;
- An assessment of the possible causal link with the medical device, with the measure/ procedure or with both.

At present, the relevant Swissmedic division is supervising around 90 clinical trials with around 600 status reports (case listings) sent per year: a number that is on the increase.

Information on the Swissmedic website

(Most of the links are available in German/French only)

Communications regarding the safety of medicines

- 13.06.2014
  HPC Priapismus und Methylphenidat
- 11.06.2014
  DHPC - Granocyte® (Lenograstim)
  Wichtige Information über das Risiko eines Kapillarlecksyndroms in Verbindung mit Granocyte® (Lenograstim) bei Krebspatienten und gesunden Spendern
- 23.05.2014
  DHPC - Temodal® (Temozolomid)
  Schwere Lebertoxizität in Verbindung mit Temozolomid
- 13.05.2014
  DHPC – PERIOLIMEL/OLIMEL (Infusionslösungen zur totalen parenteralen Ernährung mit & ohne Elektrolyte)
  Überarbeitung in der Packungsbeilage für pädiatrische Patienten.
- 09.05.2014
  HPC - Revlimid® (Lenalidomid)
  Leberschäden bei Patienten mit multiplem Myelom: Anpassung der Arzneimittelinformation
- 17.04.2014
  Rückruf der Mepha-App HCP für Fachpersonen
- 18.03.2014
  DHPC - Erbitux® (Cetuximab)
  Wichtige sicherheitsrelevante Information hinsichtlich der Bedeutung des Nachweises des RAS-Wildtyp-Status (Exons 2, 3 und 4 von K-RAS und N-RAS) vor der Behandlung mit Erbitux® bei Patienten mit metastasiertem Kolorektalkarzinom
- 05.03.2014
  Botulinumtoxin vom Typ A
  Zugelassene Arzneimittel und Indikationen, korrekte Anwendung, Risiken und Vorsichtsmassnahmen
- 05.02.2014
  DHPC – Benlysta® (Belimumab)
  Progressive multifokale Leukoenzephalopathie (PML) bei Patienten mit systemischem Lupus erythematodes (SLE)
- 29.01.2014
  DHPC – Lariam® (Mefloquin) (betrifft auch Generika Mepahaquin® und Mefloquin-Acino 250®)
  Erhöhtes Risiko von Augenerkrankungen und Erinnerung an das bekannte Risiko neuropsychiatrischer unerwünschter Wirkungen
- 19.12.2013
  DHPC - Wichtige Sicherheitsrelevante Information: Akute Überempfindlichkeitsreaktionen unter intravenösen Eisenpräparaten
  Aktualisierung der Schweizer Arzneimittelinformation: Ferinject® (Eisencarboxymaltose) und Venofer® (Ferrum ut Ferri oxidum saccharatum)
- 18.12.2013
  DHPC – Xeloda® und Generika (Capecitabin)
  Die Zulassungsinhaberin Roche Pharma (Schweiz) AG informiert.

- 17.12.2013
  HPC – EXJADE® (Deferasirox)
  Einzelfälle von metabolischer Azidose unter Behandlung mit EXJADE® : Anpassung der Arzneimittelinformation
- 16.12.2013
  DHPC - Wichtige Information zu Gynipral® (Hexoprenalin)
  Widerruf der Zulassung für Gynipral®, Tabletten (Hexoprenalin)

Archive HPC

Liste der von Swissmedic veröffentlichten Health Professional Communication "Dear Doctor Letters"
(18.12.2012, 292 KB, XLS) (only in German)

Guidance document DHPC

MU301_10_001e_MB DHPC content, recipients publication template
(28.08.2013, 139 KB, PDF)

New on this website

- 13.06.2014
  Batch recall / Soliris 300 mg Konzentrat zur Herstellung einer Infusionslösung
- 10.06.2014
  Anwendung von hochenergetischen Lichtquellen (Laser und Nichtlaser Lichtquellen) in Medizin und Kosmetik
  Diese Information ersetzt das Merkblatt „Anwendung von hochenergetischen Lasern in Medizin und Kosmetik“ von Dezember 2004.
- 05.06.2014
  Active pharmaceutical ingredients from the Ranbaxy production site in Toansa, India
  Swissmedic currently sees no risks for patients in Switzerland
- 27.05.2014
  2013 Annual Report Swissmedic
- 22.05.2014
  Illegal drug imports: More narcotic-containing medicines confiscated
- 21.05.2014
  Batch recall / Ecodipin retard 20mg, 100 Filmtabletten
  Die Firma Sandoz Pharmaceuticals AG zieht die obenerwähnten Chargen von Ecodipin retard 20mg, 100 Filmtabletten vorsorglich bis auf Stufe Grossist vom Markt zurück.
- 20.05.2014
  Batch recall / Sidroga® Beruhigungstee, geschnittene Droge
  Die Firma Sidroga AG zieht die obenerwähnte Charge von Sidroga® Beruhigungstee, geschnittene Droge vorsorglich bis auf Stufe Detailhandel vom Markt zurück.

- 08.05.2014
  New Swissmedic telephone numbers in use

- 07.05.2014
  Rezeptformulare für Betäubungsmittel - Liste gesperrte Rezepte
  Update

- 17.04.2014
  Alert of falsified Herceptin vials across the EU – Switzerland not affected
  This text is only available in German, French or Italian.

- 15.04.2014
  Medicinal product to treat influenza A and B
  Swissmedic's reaction to current reports on the efficacy of the influenza medicines Tamiflu and Relenza.

- 11.04.2014
  Kombinierte hormonale Verhütungsmittel – Harmonisierung der Arzneimittelinformationen
  Swissmedic unternimmt einen weiteren Schritt, damit die Anwenderinnen kombinierter hormonaler Verhütungsmittel (CHC) und die Fachleute zuverlässig über die Risiken dieser Arzneimittel orientiert werden.

- 03.04.2014
  Batch recall / Midazolam Actavis 5 mg/5 ml, Injektionslösung
  Die Firma Actavis Switzerland AG zieht die obenerwähnte Charge von
  Midazolam Actavis 5 mg / 5 ml Injektionslösung vorsorglich vom Markt zurück.

- 27.03.2014
  Batch recall / Gonal®-f Pen 900 IU Injektionslösung
  Die Firma Merck (Schweiz) AG zieht die obenerwähnte Charge von Gonal®-f Pen 900 IU, Injektionslösung vorsorglich vom Markt zurück.

- 25.03.2014
  Batch recall / Antistax, Kapseln
  Die Firma Boehringer Ingelheim (Schweiz) GmbH zieht alle Chargen von Antistax, Kapseln vom Markt zurück, weil im Rahmen von Stabilitätsprüfungen geringfügig nicht konforme Resultate bzgl. des Gehaltes an Flavonoiden auftraten.

- 21.03.2014
  Batch recall / Dafalgan, 500mg Tabletten
  Die Firma Bristol-Myers Squibb SA zieht die obenerwähnten Chargen von Dafalgan, 500mg Tabletten vorsorglich vom Markt zurück, weil im italienischen Teil der Packungsbeilage ein Fehler bezüglich der Altersbeschränkung für Kinder festgestellt wurde.

- 21.03.2014
  Batch recall / Trinitrine simple Laleuf, Dragées
  Die Firma Sanofi SA zieht die obenerwähnten Chargen von Trinitrine simple Laleuf, Dragées vorsorglich vom Markt zurück.

- 19.03.2014
  Falsch tief gemessene Blutzuckermesswerte der FreeStyle Mini und FreeStyle Blutzuckermesssysteme in Kombination mit FreeStyle Blutzucker-Teststreifen der Firma Abbott Diabetes Care
  Recall

- 14.03.2014
  Batch recall / Thymoglobuline, Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
  Die Firma Sanofi-Aventis (Schweiz) AG zieht die oben erwähnten Chargen von Thymoglobuline, Pulver für ein Konzentrat zur Herstellung einer Infusionslösung vom Markt zurück.

- 21.02.2014
  Chargenrückruf / Clear-Flex NaCl 0,9% - 13K1550
  Die Firma Baxter AG zieht die obenerwähnte Charge von Clear-Flex NaCl 0,9%, Isotone Infusionslösung vom Markt zurück.

- 18.02.2014
  Batch recall / Betacorton S, solution - lot N011
  Die Firma Spirig Pharma AG zieht die obenerwähnte Charge von Betacorton S, Lösung vorsorglich bis auf Stufe Grossist vom Markt zurück.

- 03.02.2014
  Spontanmeldungen aus der Schweiz zu hormonalen Kontrazeptiva und venösen Thromboembolien
  aktualisierte Zahlen mit Stand 31.12.2013

- 20.12.2013
  Swissmedic Internetauftritt überarbeitet

Please find the complete list at the following web address: www.swissmedic.ch/updates.

New Swissmedic telephone numbers in use

From 1 March 2014, the Federal Administration's telephone numbers will be changed in a measure associated with the introduction of the Confederation's new fixed-line telephone facilities. The old telephone numbers will remain valid at least until spring 2015, the Federal Administration can be contacted via both the old and new numbers until spring 2015.

Therefore Swissmedic can be contacted via 058 telephone numbers.

To ensure a gradual changeover, the old telephone numbers will remain valid at least until spring 2015. Existing mobile telephone numbers will not be affected by this renumbering for the time being.

The new telephone numbers of the Federal Administration can be looked up individually on the website of the Federal IT Steering Unit (FITSU).

Federal Administration's new telephone numbers

Online inquiry of the numbers old - new

With few exceptions the new Swissmedic phone numbers including the area code 058 start with 46 (058 46x xx xx).