swissmedic

Date: 6 November 2026
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report
Extension of therapeutic indication

Verdye

International non-proprietary name:	indocyanine green
Pharmaceutical form:	powder for solution for injection
Dosage strength(s):	25 mg
Route(s) of administration:	intravenous, intradermal, subcutaneous or peritumoral
Marketing authorisation holder:	Mediconsult AG
Marketing authorisation no.:	68489
Decision and decision date:	extension of therapeutic indication approved on 01.10.2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

Table of contents

1 Terms, Definitions, Abbreviations 3
2 Background information on the procedure 4
2.1 Applicant's request(s) and information regarding procedure 4
2.2 Indication and dosage 4
2.2.1 Requested indication 4
2.2.2 Approved indication 4
2.2.3 Requested dosage 4
2.2.4 Approved dosage 4
2.3 Regulatory history (milestones) 4
3 Clinical aspects 6
4 Risk management plan summary 7
5 Appendix 8

1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

Extension(s) of the therapeutic indication(s)
The applicant requested the addition of a new therapeutic indication or modification of an approved one in accordance with Article 23 TPO.

Authorisation in accordance with Article 14 paragraph 1 a^{bis} TPA
The applicant requested a simplified authorisation procedure in accordance with Article 14 paragraph 1 a^{bis} TPA.

2.2 Indication and dosage

2.2.1 Requested indication

Intraoperative identification of sentinel lymph nodes and visualisation of lymphatic pathways in breast cancer.

2.2.2 Approved indication

Intraoperative identification of sentinel lymph nodes and visualisation of lymphatic pathways in breast cancer.

2.2.3 Requested dosage

Identification of sentinel lymph nodes and visualisation of lymphatic pathways regardless of body weight:
5 to 10 mg per injection (intradermal, subcutaneous or peritumoral). This corresponds to 1 to 2 ml of the reconstituted 5 mg/mL solution. The volume per injection should not exceed 2 mL. If higher dilutions (<5 mg/mL) are used, larger volumes per injection can also be administered (e.g. to obtain an indocyanine green concentration of 2.5 mg/mL, the reconstituted solution can be further diluted with 5 mL or 10 mL water for injections depending on the vial size).

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	7 January 2026
Formal control completed	3 February 2026
Preliminary decision	29 May 2026
Response to preliminary decision	7 July 2026
Final decision	1 October 2026
Decision	approval

Based on Art. 14 para. 1 letter a^{bis} TPA, the authorisation of Verdye is based primarily on the medicinal product of the same name, which contains the same active substance and has been authorised in Austria for more than 10 years. This SwissPAR refers to the authorisation of the foreign medicinal product Verdye.

3 Clinical aspects

For the application for extension of the therapeutic indication of the medicinal product Verdye, Swissmedic has conducted only a summary review of efficacy and safety. The authorisation of Verdye is based primarily on the medicinal product of the same name, which contains the same active substance and has been authorised in Austria for more than 10 years. This SwissPAR refers to the authorisation of the foreign comparator medicinal product Verdye.

4 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

5 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Verdye was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo-pro.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

Verdye, powder for solution for injection

The efficacy and safety of Verdye have only been reviewed in summarised form by Swissmedic. The marketing authorisation of Verdye is based on the Verdye 5 mg/ml preparation for injection, information as of October 2022, which contains the same active substance and is authorised in Austria.

Composition

Active substances

Indocyanine green

Excipients

Verdye contains no excipients.

The medicinal product may contain small amounts of iodide from the manufacturing process.

Pharmaceutical form and active substance quantity per unit

Powder for solution for injection (5 mg/ml after reconstitution) for intravenous, intradermal, subcutaneous or peritumoral administration.
Each vial contains 25 mg indocyanine green (to be reconstituted with 5 ml of water for injections).
1 ml of the reconstituted solution for injection contains 5 mg indocyanine green.

Indications/Uses

This medicinal product is for diagnostic use only.

Diagnostic indications

Cardiac, circulatory and micro-circulatory diagnostics

- measurement of cardiac output and stroke volume
- measurement of circulating blood volumes
- measurement of cerebral perfusion

Liver function diagnostics

- measurement of liver blood flow
- measurement of excretory function of the liver

Ophthalmic angiography diagnostics

- measurement of perfusion of the choroid

Intraoperative identification of sentinel lymph nodes and visualisation of lymphatic pathways in adult patients with breast cancer.

Dosage/Administration

Verdye should only be administered by healthcare professionals under the supervision of a doctor.

Usual dosage

Single dose per measurement in adults, adolescents and children

Cardiac, circulatory, micro-circulatory and tissue perfusion diagnostics as well as cerebral blood flow: 0.1 to 0.3 mg/kg body weight as intravenous bolus injection

Liver function diagnostics: 0.25 to 0.5 mg/kg body weight as intravenous bolus injection

Ophthalmic angiography: 0.1 to 0.3 mg/kg body weight as intravenous bolus injection

Identification of sentinel lymph nodes and visualization of lymphatic pathways regardless of body weight:
5 to 10 mg per injection (intradermal, subcutaneous or peritumoral). This corresponds to 1 to 2 ml of the reconstituted 5 mg/ml solution. The volume per injection should not exceed 2 ml. If higher dilutions (<5 mg/ml) are used, larger volumes per injection can also be administered (e.g. to obtain an indocyanine green concentration of 2.5 mg/ml, the reconstituted solution can be further diluted with 5 ml or 10 ml water for injections depending on the vial size).

Total daily dose for adults, adolescents and children when administered intravenously

Adults, adolescents 12-18 years:
The total daily dose of Verdye should be kept below 5 mg/kg body weight.

Children 2-11 years:
The total daily dose of Verdye should be kept below 2.5 mg/kg body weight.

Children 0-23 months:
The total daily dose of Verdye should be kept below 1.25 mg/kg body weight.

Total daily dose for adults when administered intradermal, subcutaneous or peritumoral

Identification of sentinel lymph nodes and visualization of lymphatic pathways
For the identification of sentinel lymph nodes and visualization of lymphatic pathways, the total daily dose of Verdye should not exceed 10 mg. The use in children and adolescents is not recommended due to insufficient data on safety and efficacy.

Special dosage instructions

Patients with renal impairment

Verdye has not been formally studied in patients with renal impairment. No specific dose recommendations for this patient population are available. Patients with severe renal impairment should be carefully monitored for adverse reactions (see "Undesirable effects" section).

Patients with hepatic impairment

Verdye has not been formally studied in patients with hepatic impairment. No specific dose recommendations for this patient population are available. In patients with severe hepatic impairment (e.g. alcoholic or biliary cirrhosis), plasma clearance of indocyanine green may be reduced.

Elderly patients

No adjustment to the dose is required based on age.

Mode of administration

Before administration, the powder must be reconstituted with water for injections. The reconstituted solution is clear and free from visible particles.

Verdye is administered by intravenous, intradermal, subcutaneous or peritumoral injection.

Methods of measurement

The absorption and emission maximum of indocyanine green are both in the near infrared range, the absorption maximum at 800 nm and the emission maximum for fluorescence measurement at 830 nm.
In *in vitro* tests, indocyanine green remains stable in human serum for several days. In contrast, when dissolved in water, it shows no detectable degradation for only a few hours.

Diagnostic procedures with Verdye should be performed under the supervision of a physician.

Measurement of cardiac, circulatory, and cerebral blood flow as well as liver function diagnostics and ophthalmologic angiography

For cardiac, circulatory, microcirculatory and liver function diagnostics, as well as for ophthalmologic angiography, Verdye is intended for intravenous injection via an injection needle, a central or peripheral catheter or cardiac catheter.

The administration and site of Verdye are of critical importance for the quality of the measurements. In principle, for obtaining optimal quality first pass indicator dilution curves, the injection should be as close as possible to the vascular bed, organ or tissue of interest.
On peripheral intravenous injection, venipuncture should be done after application of a tourniquet. After release of the tourniquet, Verdye should be injected immediately and the arm should be raised. This ensures rapid transport of the dye from the site of injection and peripheral injection is then practically equivalent to central venous injection.

Areas under the first pass curve, transit time, half-life, plasma disappearance rate and retention rate of Verdye can be determined

a. non-invasively by pulse dye densitometry or near infrared spectroscopy
b. invasively by fibre optic probes/catheters in suitable vessels
c. conventionally by determination of the concentration either by continuous withdrawal of heparinised blood through a cuvette densitometer or by collection of blood samples and measurement of the plasma concentration in a photometer

Evaluation of fundus perfusion in ophthalmic angiography:

The perfusion of the fundus of the eye can be determined and quantified by ophthalmic fluorescence angiography.

Measurement of tissue perfusion

Tissue perfusion of the superficial tissue layers can be made visible and quantified by near infrared fluorescence video angiography.

Identification of sentinel lymph nodes and visualization of lymphatic pathways

Because of the protein binding rate of Verdye in the lymph fluid, the sentinel lymph nodes can be imaged by means of fluorescence angiography.

For the identification of sentinel lymph nodes and visualization of lymphatic pathways in breast cancer, Verdye is injected into a region that is upstream of the particular lymph nodes that are of interest and that is drained by these. The injection can be intradermal, subcutaneous (interstitial) or peritumoral. It is possible to accelerate the transport of indocyanine green into the sentinel lymph nodes through a breast massage. Imaging may be started within 15 minutes after injection. Transcutaneous detection of sentinel lymph nodes is performed using a near-infrared fluorescence imaging system that visualizes the ICG fluorescence. The suitability of the near-infrared fluorescence imaging system for the detection of sentinel lymph nodes must have been tested in advance.

Contraindications

Verdye is contraindicated for safety reasons

- in patients with hypersensitivity to indocyanine green or to sodium iodide unless special precautions are taken,
- in patients with hypersensitivity to iodine,
- in patients with hyperthyroidism, patients with autonomic thyroid adenomas,
- as *in vitro* experiments have shown that indocyanine green displaces bilirubin from its protein binding, Verdye should not be used in premature infants or neonates in whom an exchange transfusion is indicated due to hyperbilirubinaemia,
- if injection of Verdye was poorly tolerated in the past, it must not be used again, since severe anaphylactic reactions might occur.

Warnings and precautions

Since severe anaphylactic reactions might occur after application of Verdye (see "Undesirable effects" section), it must only be applied under the supervision of a doctor. Readiness for resuscitation must be given. Patients should be monitored for at least an hour after administration of indocyanine green for the occurrence of hypersensitivity reactions.

Verdye should be used with caution in patients on beta-blocker therapy. Beta-blocker therapy may increase the symptoms of anaphylactic shock. Competitive inhibition of neurally-released noradrenaline at beta-adrenoreceptors results in an insufficient release of noradrenaline in the event of anaphylactic shock.

Since side effects under indocyanine green have occurred in patients with advanced renal insufficiency, there must be a particularly compelling indication for the use of Verdye in these patients.

Heparin preparations containing sodium bisulphite reduce the absorption peak of indocyanine green in plasma and blood and, therefore, should not be used as an anticoagulant for the collection of samples for analysis.

Indocyanine green is stable in plasma and whole blood so that samples obtained in discontinuous sampling techniques may be read hours later. Sterile techniques have to be used in handling the dye solution.

The iodine content of Verdye can interfere with thyroid tests performed before or after administration of the dye. Therefore, radio-active iodine uptake studies should not be performed for at least a week following the use of Verdye.

When Verdye is applied intradermally or subcutaneously, patients should be advised to avoid direct sun or UV radiation for at least 1 week or until any greenish discoloration at the injection site has disappeared.

The identification of sentinel lymph nodes and visualization of lymphatic pathways may be impaired if they are located in deeper tissue layers or are covered by fatty tissue. Similarly, in patients with pronounced obesity (BMI >40), the mapping of sentinel lymph nodes and visualization of lymphatic pathways may be impaired.

Verdye should be used immediately after reconstitution of the solution. Any remains are to be discarded.
Verdye should only be administered by doctors who are experienced in fluorescence diagnostic, liver function diagnostics or in cardiovascular and microcirculatory diagnostics.

Before commencing the intravenous injection of Verdye, it should be ensured that the needle has been correctly inserted into the vein. The injection must be stopped immediately if the preparation infiltrates into the surrounding tissue. It is recommended to leave the needle at the injection site for at least 5 minutes in order to have a venous route of administration in the event of an emergency. This applies in particular if there have been incidents beyond nausea and/or vomiting during previous ICG administration, or if the patient suffers from food or drug allergies, eczema, asthma or hay fever. An emergency kit, containing epinephrine 0.1 %, antihistamines, corticosteroids, aminophylline and oxygen, for example, should be on hand.

A prior Verdye tolerability test that has been carried out without any problems must not be regarded as a definitive guarantee that the medicinal product may be used.

Scheduled eye examinations, such as visual acuity testing, should be performed prior to the administration of Verdye.

As a precautionary measure, it may be useful to administer an agent to prevent nausea and vomiting in susceptible patients and to allow the injection to be administered slowly.

In the case of peripheral vein bolus injection, particular care must be taken to ensure that the solution for injection does not infiltrate into the tissue, as this may cause severe local tissue damage. Should the solution infiltrate into the tissue, severe pain in and around the injection site may persist for hours. In the event of tissue infiltration, the injection must be stopped, the damaged tissue treated and pain relief administered.

Interactions

The clearance of indocyanine green may be altered by medicinal products that interfere with liver function.

Probenecid and some of its metabolites may be secreted into the bile and may depress the biliary secretion of indocyanine green, which may result in an impaired indocyanine green liver function test.

Concomitant use of certain medicinal products and injectables can alter the absorption. Particular attention should be paid to the reduction in optical absorption caused by the use of injectables containing sodium bisulphite (especially in combination with heparin).

Medicinal products and substances that can reduce absorption:

Anticonvulsants
Bisulphite compounds
Haloperidol
Heroin
Metamizole
Methadone
Morphine
Nitrofurantoin
Opium alkaloids
Pethidine
Phenobarbital
Phenylbutazone

Medicinal products and substances that can increase absorption:

Cyclopropane
Probenecid
Rifamycin

Pregnancy, lactation

Pregnancy

Data on a limited number (242) of exposed pregnancies indicate no adverse effects of indocyanine green on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available. No animal studies on reproductive toxicity, teratogenicity or carcinogenicity are available. The potential risk for humans is unknown.

Caution should be exercised when administering the medicinal product during pregnancy. Repeated administration on any one day should be avoided.

Lactation

It is not known whether indocyanine green is excreted in human milk. Because many medicinal products are excreted in human milk, caution should be exercised when indocyanine green is administered to a nursing woman.

Fertility

There are no data regarding the effect of indocyanine green on fertility.

Effects on ability to drive and use machines

No corresponding studies have been performed.

Undesirable effects

The following frequencies are used as a basis for the evaluation of adverse reactions:

Very common (≥ 1/10)
Common (≥ 1/100, < 1/10)
Uncommon (≥ 1/1,000, < 1/100)
Rare (≥ 1/10,000, < 1/1,000)
Very rare (< 1/10,000)
Not known (frequency cannot be estimated form the available data)

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides.

Coronary artery spasm has been reported in very rare cases (< 1/10,000).
Furthermore, greenish reversible skin discoloration at the injection site following paravasal (intradermal, subcutaneous) application of indocyanine green has been reported.
Urticarial reactions of the skin occurred very rarely (<1/10 000).

Specific populations

It is known that injection of indocyanine green preparations can, in very rare cases, cause nausea and anaphylactoid or anaphylactic reactions (<1/10,000). The incidence of anaphylactic reactions appears to be increased in patients with end-stage renal failure. The following symptoms may occur: unrest, feeling of warmth, nausea, pruritus, urticaria, facial oedema, tachycardia, flushing, drop in blood pressure, dyspnoea, bronchospasm, laryngospasm, cardiovascular arrest. Hypereosinophilia may occur in conjunction with anaphylactic reactions (see "Warnings and precautions" section).

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected new or serious adverse reactions online via the ElViS portal (Electronic Vigilance System). Information on this can be found at www.swissmedic.ch.

Overdose

No cases of overdose have been reported.

Properties/Effects

ATC code

V04CX01

Mechanism of action

Indocyanine green exhibits no pharmacological effects when administered intravenously, intradermal, subcutaneous and peritumoral.

Pharmacodynamics

The active substance in Verdye is indocyanine green.

The molecular formula is $C_{43}H_{47}N_2NaO_6S_2$. The molecular weight is 774.96 daltons.

Indocyanine green has a sharply defined spectral peak absorption of near-infrared light at 800 nm in blood, plasma and lymph fluid. This is the same wavelength at which the optical density of oxygenated haemoglobin in blood approximately equals that of reduced haemoglobin. Therefore, this coincidental light absorption makes it possible to measure indocyanine green concentrations in blood, plasma, serum and lymph fluid in terms of its optical density at 800 nm, independent of variations in oxygen saturation level.

Indocyanine green permits recording of the indicator-dilution curves for both diagnostic and research purposes.

For the use of indocyanine green to identify sentinel lymph nodes in breast cancer, bibliographic data from 21 studies were analysed. In total, 2168 patients underwent indocyanine green imaging procedures. The mean detection rate of sentinel lymph nodes was 97.4% and the mean number of sentinel lymph nodes detected per patient generally ranged between 2.0 and 3.0. The clinical safety data from this patient population did not indicate any emerging safety concerns in this clinical setting.

Clinical efficacy

No details.

Pharmacokinetics

Absorption

Verdye is intended solely for intravenous, intradermal, subcutaneous and peritumoral administration. Indocyanine green is not absorbed following oral or topical administration. After intradermal,

subcutaneous and peritumoral injection, indocyanine green enters the lymph nodes via the lymphatic vessels and is then drained into the bloodstream. No pharmacokinetic data are available for humans, but animal data indicate very low plasma concentrations of indocyanine green.

Distribution

After injection indocyanine green undergoes no significant extrahepatic or enterohepatic circulation; simultaneous arterial and venous blood estimations have shown negligible renal, peripheral or lung uptake of the dye. In healthy volunteers, indocyanine green cannot be detected in either urine or cerebrospinal fluid. Indocyanine green does not cross the placental barrier. The volume of distribution corresponds to the blood volume. After oral or rectal administration, indocyanine green is not absorbed from the gut.
Following intravenous injection, indocyanine green is rapidly bound to plasma proteins, of which beta-apolipoprotein B is the principle carrier (95 %). In the lymph fluid and in the interstitium, indocyanine green preferentially binds to albumin.

Metabolism

Indocyanine green is not metabolised.

Elimination

Elimination of the dye from the blood is biphasic, showing an initial elimination half-life $t_{1/2}$ of 3-4 min and a secondary phase with a dose-dependent $t_{1/2}$ of approximately 60-80 min. After intradermal, subcutaneous and peritumoral application, $t_{1/2}$ can be prolonged.

Indocyanine green is taken up from the plasma almost exclusively by the hepatic parenchymal cells with a maximum rate of uptake (transport maximum: T_m of about 0.1 mg/minute/kg) and is secreted unmetabolized and unconjugated entirely into the bile. The concentration maximum in bile is reached after about ½–2 hours depending on the amount injected.

After biliary obstruction, indocyanine green appears in the hepatic lymph, independently of the bile, suggesting that the biliary mucosa is sufficiently intact to prevent diffusion of the dye, though allowing diffusion of bilirubin.

As indocyanine green is not reabsorbed in the intestine, there is no enterohepatic circulation.

Preclinical data

Acute toxicity

The LD_{50} after single IV dose was 87 mg/kg in rats, 60 mg/kg in mice, and between 50 mg/kg and 80 mg/kg in rabbits. After dissolution in water for injections and administration by intraperitoneal injection in mice, the LD_{50} was found to be 650 mg/kg body weight. No macroscopic or histopathological changes were observed.

Genotoxicity

Indocyanine green was not found to be mutagenic in the tests performed - Ames test, *in vitro* gene mutation assay (thymidine kinase locus/$TK^{+/-}$) in mouse lymphoma L5178Y cells (mouse lymphoma TK test) and *in vitro* chromosome aberration test in Chinese hamster V79 cells).
No investigations on reproduction, teratogenicity or carcinogenicity in animals are available.

Other information

Incompatibilities

This medicinal product must not be diluted with solutions containing salts (saline, Ringer's solution etc.), as this can lead to precipitation of the dye.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Effects on diagnostic methods

The iodide content of Verdye may interfere with thyroid function tests (see "Warnings and precautions" section).

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the pack.

Shelf life after opening

The reconstituted solution for injection should be protected from light.
It contains no preservative and must be used immediately for microbiological reasons.

Special precautions for storage

Do not store above 30°C.
Keep the vials in the outer carton in order to protect the contents from light.
Keep out of the reach of children.

Instructions for handling

Verdye should be reconstituted immediately prior to use.
This medicinal product is reconstituted by addition of 5 ml water for injections to a vial containing 25 mg of active substance, giving a dark-green solution for injection with a concentration of 5 mg/ml (0.5 % w/v).

If an incompatibility is noted in the form of an unclear solution, the reconstituted solution should be discarded.
The reconstituted solution should be visually inspected. Only use clear solutions free from visible particles.

This medicinal product is for single use only.

Authorisation number

68489 (Swissmedic)

Packs

Pack of 5 vials containing powder for solution for injection [A].

Marketing authorisation holder

Mediconsult AG, 9325 Roggwil TG

Date of revision of the text

Foreign comparator medicinal product: July 2025
Without safety-related supplements from Swissmedic: December 2022