swissmedic

Date: 26 May 2023
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Verdye

International non-proprietary name: indocyanine green
Pharmaceutical form: powder for solution for injection
Dosage strength(s): 25 mg
Route(s) of administration: intravenous
Marketing authorisation holder: Mediconsult AG
Marketing authorisation no.: 68489
Decision and decision date: approved on 24 April 2023

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.

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1 Terms, Definitions, Abbreviations

INN	International non-proprietary name
LoQ	List of Questions
MAH	Marketing authorisation holder
RMP	Risk management plan
SwissPAR	Swiss Public Assessment Report
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)

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2 Background Information on the Procedure

2.1 Applicant's Request(s)

New active substance status
The applicant requested new active substance status for indocyanine green in the above-mentioned medicinal product.

Authorisation in accordance with Article 14 para. 1 a^{bis} TPA
The applicant requested a simplified authorisation procedure in accordance with Article 14 para. 1 a^{bis} TPA.
For the application for the authorisation of the medicinal product Verdye, Swissmedic has reviewed the quality exclusively on the basis of primary data. The authorisation of Verdye is based primarily on a medicinal product of the same name, which contains the same active substance and has been authorised in Austria for more than 10 years. Apart from the quality-related aspects for which Swissmedic has conducted an independent scientific review, this SwissPAR refers to the authorisation of the Austrian medicinal product Verdye.

2.2 Indication and dosage

2.2.1 Requested indication

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

2.2.2 Approved indication

This medicinal product is for diagnostic use only.

Diagnostic indications

Cardiac, circulatory, and micro-circulatory diagnostics
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2.2.3 Requested dosage

Summary of the requested standard dosage:
Single dose per measurement in adults, the elderly, 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 a bolus injection
Liver function diagnostics: 0.25 – 0.5 mg/kg body weight as a bolus injection
Ophthalmic angiography: 0.1 to 0.3 mg/kg body weight as a bolus injection

Total daily dose:
Adults, the elderly, adolescents 11-18 years: The total daily dose of Verdye should be kept below 5 mg/kg body weight.
Children 2 – 11 years: The total daily dose should be kept below 2.5 mg/kg body weight.
Children 0 – 23 months: The total daily dose should be kept below 1.25 mg/kg body weight.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	28 April 2021
Formal objection	12 May 2021
Response to formal objection	6 July 2021
Formal control completed	3 August 2021
List of Questions (LoQ)	21 December 2021
Response to LoQ	8 May 2022
Preliminary decision	5 August 2022
Response to preliminary decision	28 September 2022
Labelling corrections	20 December 2022
Response to labelling corrections	12 February 2023
Second round labelling corrections	7 March 2023
Response to second round labelling corrections	4 April 2023
Final decision	24 April 2023
Decision	approval

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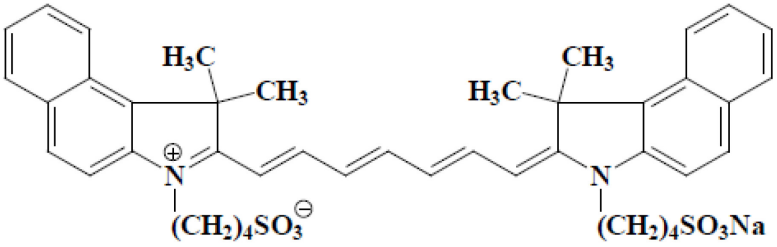
3 Quality aspects

3.1 Drug substance

INN:	Indocyanine green
Chemical name:	2-{7-[1,1-Dimethyl-3-(4-sulfobutyl)benz[e]indolin-2-ylidene]-1,3,5-heptatrienyl}-1,1-dimethyl-3-(4-sulfobutyl)-1H-benz[e]indolium hydroxide, inner salt, sodium salt
Molecular formula:	$C_{43}H_{47}N_2NaO_6S_2$
Molecular mass:	774.96 $g.mol^{-1}$
Molecular structure:	



Indocyanine green is an odourless, green crystalline powder.

Indocyanine green is manufactured in one step by one manufacturer using well-defined starting materials with acceptable specifications.
The crude active substance is purified by recrystallisation and washing to yield pure indocyanine green.

Appropriate proof-of-structure data have been supplied for the active substance.
All potential and actual impurities were well discussed with regards to their origin and have been characterised and monitored appropriately.

An appropriate specification is provided for the active substance. Analytical methods have been correctly validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification.

Appropriate stability data have been provided supporting a suitable retest period when stored in the proposed packaging.

3.2 Drug product

This product is a sterile, lyophilized dark green cake or loose powder in a single-use vial for intravenous use.
The composition is adequately described, qualitatively and quantitatively.

Suitable pharmaceutical development data have been provided for the finished product formulation and manufacturing process.

A satisfactory batch formula has been provided for the manufacture of the product, together with an appropriate account of the manufacturing process, which is described with a sufficient level of detail. The manufacturing process has been validated on three commercial-scale batches. The results are satisfactory. The in-process controls are adequate for this type of manufacturing process and pharmaceutical form.

The finished product specification is satisfactory. The test methods have been described and validated adequately. Batch data have been provided that comply with the release specifications.

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The primary packaging is a single-use, 25 ml, type I amber glass vial with a rubber stopper and an aluminium overseal with a flip-off polypropylene cap.

Finished product stability studies have been conducted in accordance with current guidelines and in the packaging proposed for marketing.
Samples were tested according to the shelf-life specifications (identical to the release specifications except that impurities content, where shelf-life limits differ from release limits, and the uniformity of dosage test, which is only performed at release).
Based on the results, a shelf-life of 5 years for the unopened vial is set, with the storage recommendation “Do not store above 30°C”. This is satisfactory.

3.3 Quality conclusions

Satisfactory and consistent quality of the drug substance and drug product has been demonstrated.

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4 Nonclinical aspects

In accordance with Art. 14 para. 1 a^{bis} TPA, Swissmedic has only reviewed the nonclinical overview for the authorisation of Verdye. The approval of Verdye is based on a medicinal product of the same name, which contains the same active substance and has been authorised in Austria for more than 10 years.

5 Clinical and clinical pharmacology aspects

In accordance with Art. 14 para. 1 a^{bis} TPA, Swissmedic has conducted only a summary review of efficacy and safety for the authorisation of Verdye. The approval of Verdye is based 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.

6 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.

7 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.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.

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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 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

Dosage/Administration

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

Usual dosage

Single dose per measurement in adults, elderly 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 bolus injection

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

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

Total daily dose:

Adults, elderly, 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.

Children and adolescents

Single doses to be used in paediatrics are the same as for adults but the total daily dose should be kept below 2.5 mg/kg body weight in children 2 to 11 years and below 1.25 mg/kg body weight in children 0 to 2 years.

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.

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.

Measurement of cardiac, circulatory, and cerebral blood flow and liver function

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.

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 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.
In the case of peripheral 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.

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.

  Immediate measures to be taken in the event of anaphylactic reactions:

  Stage 1: *Skin reactions (flushing, erythema, urticaria, oedema), general reactions (restlessness, headache)*
  Stop further administration of Verdye, leave injection catheter or cannula in the vein, administer antihistamines if necessary, give oxygen if necessary

  Stage 2: *Tachycardia, arterial hypertension*
  Antihistamines, glucocorticoids (e.g. 100 mg prednisolone IV), give oxygen if necessary

  Stage 3: *Shock, bronchospasm*
  Adrenaline (fractionated 0.1 mg IV), glucocorticoids (e.g. 500-1000 mg prednisolone IV), volume replacement, beta-2 sympathomimetics and theophylline if bronchospasm is predominant; intubate and ventilate with 100% oxygen if necessary

  Stage 4: *Respiratory and circulatory arrest*
  Cardiopulmonary resuscitation

  Simultaneous use of beta-blockers

  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.

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 either fluorescence angiography or liver function diagnostics or in cardiovascular and microcirculatory diagnostics.

Before commencing the 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).

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, death. 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 EIViS 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.

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 or blood. 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 and serum 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.

Clinical efficacy

No details.

Pharmacokinetics

Absorption

Verdye is intended solely for intravenous administration. Indocyanine green is not absorbed following oral or topical administration.

Distribution

After intravenous 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 %).

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.

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 unmetabolised 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/$TK^{+/-}$), 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: October 2022
Without safety-related supplements from Swissmedic: December 2022