swissmedic

Public Summary SwissPAR dated 29 June 2023

Verdye® (active substance: indocyanine green)

First authorisation in Switzerland: 24 April 2023

Medicinal product (powder for solution for injection) for diagnostic purposes

Information on authorisation

The medicinal product Verdye contains the active substance indocyanine green.

Verdye is used exclusively for diagnostic purposes in the following 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
- Ocular perfusion diagnostics (ophthalmic angiography)
  - Measurement of perfusion of the choroid

Verdye was authorised under Art. 14 para. 1 let. a^{bis} of the Therapeutic Products Act (TPA). The TPA enables certain categories of medicines to be authorised according to a simplified procedure, provided this is compatible with the quality, safety and efficacy requirements and there is no conflict with Swiss interests or international obligations.

The authorisation of Verdye is based on the medicinal product of the same name, which contains the same active substance and has been authorised for a comparable indication, dosage and use in Austria for more than 10 years.

Swissmedic assessed the quality data on the active substance and finished medicinal product but did not conduct its own comprehensive scientific review for other aspects. Efficacy and safety were only reviewed in summarised form.

The requirements for issuing a comprehensive SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR have therefore not been met. Swissmedic refers to the authorisation of the foreign comparator medicinal product:

Further information on simplified authorisation according to Art. 14 TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Verdye, the Information for healthcare professionals was not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch.

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.