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Summary report on authorisation dated 02.09.2026

Serum autolog Insel, eye drops® (active substance: autologous human serum)

Authorisation in Switzerland: 23.02.2026

Medicinal product for the treatment of dry eye in adults who do not experience adequate symptom relief with other authorised treatments

About the medicinal product

The medicinal product "Serum autolog Insel, eye drops" contains the active substance autologous human serum (blood serum), which is prepared from the patient's own blood. It is used to treat dry eye (keratoconjunctivitis sicca) in adults who do not experience adequate symptom relief with other authorised treatments. Dry eye is a common condition in which the natural tears are no longer able to adequately perform their protective function for the ocular surface. This can lead to symptoms and damage to the ocular surface and adversely affect quality of life.

Mode of action

The active substance in this medicinal product consists of autologous blood serum prepared from the patient's blood. Among other things, the blood serum contains proteins, growth factors, vitamins and other components found in natural tear film. It is used to moisten the surface of the eye and promote healing of the ocular surface.

Administration

"Serum autolog Insel, eye drops" is a prescription-only medicine that is only prescribed by a doctor specialising in ophthalmology. These eye drops contain either 100% or 20% autologous serum.

The dosage is based on the severity of the condition and is determined by the treating ophthalmologist. The duration of treatment is also determined on a case-by-case basis and reviewed at regular intervals.

Efficacy

The efficacy of "Serum autolog Insel, eye drops" was investigated by means of several

systematic literature reviews, meta-analyses and a Cochrane review[1], all of which involved the use of similar products. The most important basis was provided by five clinical trials involving a total of 92 patients with dry eye. The trials suggest that autologous serum eye drops can relieve symptoms in the first two weeks of treatment compared to artificial tears. However, the available trial data are still limited and disparate due to the variety of manufacturing processes used for the serum eye drops, dosages and the investigated patient groups. Moreover, no clear benefit has been demonstrated for a longer-term treatment.

Precautions, undesirable effects, & risks

"Serum autolog Insel, eye drops" may only be used by the person from whose own blood the medicinal product was prepared. It may not be used, for example, if the patient has certain eye infections or is hypersensitive to the active substance. In order to minimise the risk of microbial contamination and a consequent eye infection, the eye drops must be used carefully and in accordance with the storage directions and instructions for use. Eye irritation or burning, a feeling of the eyelids sticking together and blurred vision can often occur temporarily after administration.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

There is a medical need for additional treatment options for patients with dry eye whose symptoms cannot be adequately relieved by the currently available authorised treatments. In such cases, autologous serum eye drops can serve as an alternative treatment option. Although the scientific evidence is limited and the long-term benefit has not been clearly demonstrated, the risk is manageable overall and can be controlled by suitable manufacturing, storage and administration measures, and many years of experience have been accumulated with this treatment.

Based on all the available data, the benefit outweighs the risks. Based on these findings, Swissmedic has authorised the medicinal product "Serum autolog Insel, eye drops", which contains the active substance autologous human serum, in Switzerland for the treatment of dry eye (keratoconjunctivitis sicca) in adults whose symptoms cannot be adequately relieved by other authorised treatments.

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for "Serum autolog Insel, eye drops", the Information for healthcare professionals and the Patient information were not yet available. As soon as the medicinal product becomes available in Switzerland, the product information will be made available on the following website: www.swissmedicinfo.ch
Healthcare professionals can answer any further questions.

[1] Cochrane review: scientific summary and assessment of the available studies on a medical issue

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 Summary report on authorisation.

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.