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Public Summary SwissPAR vom 21.12.2020

Triogen® (active substance: trientine dihydrochloride)

First authorisation in Switzerland: 28.05.2020

Medicine (capsules) for the treatment of copper storage disease (Wilson's disease) in patients intolerant of D-penicillamine therapy.

Information on authorisation

Triogen is a medicinal product with the active substance trientine dihydrochloride that is used to treat a condition known as copper storage disease (Wilson's disease). This is a rare, inherited metabolic disorder in which a genetic defect impairs the elimination of copper from the body, resulting in the accumulation and deposition of copper in various organs – not just the liver, but also the heart, kidneys and bones. It can cause the affected organs to stop functioning properly.

With its active substance trientine dihydrochloride, Triogen is a "chelating agent" which binds excess copper and promotes its elimination from the body.

Triogen is used in patients who are unable to tolerate the active substance D-penicillamine.

Since this is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Triogen 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.

At the time the application was submitted, trientine dihydrochloride – the active substance in the medicine Triogen – had demonstrably been used in a medicinal product which had been authorised for at least 10 years in at least one EU or EFTA country and which is comparable in terms of indications, dosage and method of administration. The preconditions for simplified authorisation were therefore met.

Consequently, Swissmedic is not conducting its own comprehensive scientific review, and the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR do not apply. Swissmedic refers to the authorisation of the foreign comparator medicinal product:

The authorisation of Triogen capsules is based on the medicinal product Trientine dihydrochloride capsules 300 mg, which contains the same active substance and has been

authorised in the United Kingdom for more than 10 years.

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

Information for healthcare professionals: Information for healthcare professionals Triogen®

Information for patients (package leaflet): Information for patients Triogen®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated in 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.