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Public Summary SwissPAR dated 19 February 2021

Pheburane® (active substance: sodium phenylbutyrate)

First authorisation in Switzerland: 29 January 2020

Medicinal product (granules) for the treatment of patients of all ages with certain urea cycle disorders. It is used as add-on treatment in combination with a primary therapy.

Information on authorisation

Since these particular urea cycle disorders are rare, the medicinal product sodium phenylbutyrate is authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific conditions. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Pheburane 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, sodium phenylbutyrate – the active substance in the medicine Pheburane – 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: www.ema.europa.eu

The authorisation of Pheburane is based on the medicinal product Ammonaps granules, 940 mg/g, which contains the same active substance and has been authorised in the EU 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

At the time of publication of the Public Summary SwissPAR for Pheburane, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

This information is correct as at the date above. 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.