swissmedic

Public Summary SwissPAR dated 29 June 2023

milgamma® (active substance: benfotiamine)

First authorisation in Switzerland: 6 April 2023

Medicinal product (tablet) for adults with conditions that can be treated with vitamin B1.

Information on authorisation

The medicinal product milgamma contains the active substance benfotiamine.

milgamma is used in adults with conditions that can be treated with vitamin B1 such as:

- treatment and prophylaxis of a vitamin B1 deficiency that cannot be corrected by dietary means
- treatment of neurological disorders, such as alcoholic or diabetic polyneuropathy
- treatment of cardiovascular disease associated with vitamin B1 deficiency in patients with diabetes mellitus

milgamma 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 milgamma is based on the medicinal product milgamma mono 300, which contains the same active substance and has been authorised for a comparable indication, dosage and use in Germany 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 milgamma, 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 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.