swissmedic

Public Summary SwissPAR dated 06 June 2022

Sunosi® (active substance: solriamfetol)

First authorisation in Switzerland: 22 March 2022

Medicinal product (film-coated tablet) to improve wakefulness and reduce excessive daytime sleepiness in adults with narcolepsy or obstructive sleep apnoea.

About the medicinal product

Sunosi has been authorised to improve wakefulness and reduce excessive daytime sleepiness in adults with narcolepsy or obstructive sleep apnoea.

Narcolepsy is a chronic sleep disorder, which affects the ability to regulate the normal sleep-wake cycle.

In obstructive sleep apnoea, the affected person experiences repeated interruption of breathing during sleep due to airways becoming blocked. Sunosi is used for the treatment of obstructive sleep apnoea when previous treatments have not satisfactorily improved excessive daytime sleepiness. Sunosi is not used to treat the cause of the underlying blockage of the airways.

In deciding whether to authorise the medicinal product Sunosi, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator products.

www.ema.europa.eu
www.fda.gov

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Sunosi, 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.