LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tapentadol Depot Liconsa (tapentadol tartrate)

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Tapentadol Depot Liconsa
tapentadol tartrate

Prolonged-release tablet, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg

This is a summary of the public assessment report (PAR) for Tapentadol Depot Liconsa. It explains how Tapentadol Depot Liconsa was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Tapentadol Depot Liconsa.

For practical information about using Tapentadol Depot Liconsa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tapentadol Depot Liconsa and what is it used for?

Tapentadol Depot Liconsa is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Palexia® retard.
Tapentadol Depot Liconsa is used in the treatment of severe long-term pain in adults that can only be adequately managed with an opioid painkiller.

How does Tapentadol Depot Liconsa work?

Tapentadol, the active substance in Tapentadol Depot Liconsa, is a strong painkiller which belongs to the class of opioids.

How is Tapentadol Depot Liconsa used?

The pharmaceutical form of Tapentadol Depot Liconsa is prolonged-release tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Tapentadol Depot Liconsa have been shown in studies?

No additional studies were needed as Tapentadol Depot Liconsa is a generic medicine considered to be bioequivalent to the reference medicine, Palexia® retard.
Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Tapentadol Depot Liconsa?

Because Tapentadol Depot Liconsa is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of side effects, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is Tapentadol Depot Liconsa approved?

It was concluded that, in accordance with EU requirements, Tapentadol Depot Liconsa has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine

Palexia® retard. Therefore, the Swedish Medical Products Agency decided that, as for Palexia® retard, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Tapentadol Depot Liconsa?

A risk management plan has been developed to ensure that Tapentadol Depot Liconsa is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tapentadol Depot Liconsa, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Tapentadol Depot Liconsa

The full PAR for Tapentadol Depot Liconsa can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Tapentadol Depot Liconsa, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in July 2022.