LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Delipam
(oxazepam)

SE/H/2272/01-03/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Delipam
oxazepam

Tablet, 5 mg, 10 mg, 15 mg

This is a summary of the public assessment report (PAR) for Delipam. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Delipam and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Sobril.

The product is used for agitation, anxiety, restlessness and sleeping difficulties in connection with nervous conditions. The product may be used together with antidepressants for depression with episodes of anxiety.

The product may also be used for the treatment of withdrawal symptoms related to alcohol abuse such as confusion, anxiety, excitation, and agitation.

How does Delipam work?

The product contains the active substance oxazepam and belongs to a group of medicines called benzodiazepines. These work by enhancing the effect of an inhibiting substance (GABA) in the brain. Thus, the product has anxiety relieving, muscle-relaxing and calming effects.

How is Delipam used?

The pharmaceutical form is 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 Delipam have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Sobril. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Delipam?

Because the product 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 Delipam approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Sobril, 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 Delipam?

A risk management plan has been developed to ensure that the product 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, 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 Delipam

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

This summary was last updated in 2023-06.