

Summary Public Assessment Report

Orlistat Accord (orlistat)

SE/H/2256/01/DC

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orlistat

Capsule, hard, 120 mg

This is a summary of the public assessment report (PAR) for Orlistat Accord. 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 Orlistat Accord and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Xenical.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

Orlistat Accord is indicated in the treatment of obesity in conjunction with a low calorie intake diet.

How does Orlistat Accord work?

Orlistat Accord is a medicine used to treat obesity. It works in the digestive system to block about one-third of the fat in the food from being digested.

Orlistat Accord attaches to the enzymes in the digestive system (lipases) and blocks them from breaking down some of the fat in a meal. The undigested fat cannot be absorbed and is eliminated by the body.

How is Orlistat Accord used?

The pharmaceutical form is hard capsules 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 Orlistat Accord have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Xenical, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Orlistat Accord?

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 Orlistat Accord approved?

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

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 Orlistat Accord

The full PAR for Orlistat Accord can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Orlistat Accord , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-08.