LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Apremilast Anabiosis (apremilast)

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Summary Public Assessment Report

Apremilast Anabiosis
apremilast

Film-coated tablet, 10 mg + 20 mg + 30 mg, 30 mg, 10 mg, 20 mg, 30 mg

This is a summary of the public assessment report (PAR) for Apremilast Anabiosis. 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 Apremilast Anabiosis 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 Otezla.

The product is used in the treatment of:

- **Active psoriatic arthritis** – if you cannot use another type of medicines called 'Disease-Modifying Antirheumatic Drugs' (DMARDs) or when you have tried one of these medicines and it did not work.
- **Moderate to severe chronic plaque psoriasis** – if you cannot use one of the following treatments or when you have tried one of these treatments and it did not work:
  - phototherapy – a treatment where certain areas of the skin are exposed to ultraviolet light
  - systemic therapy – a treatment that affects the entire body rather than just one local area, such as 'ciclosporin', 'methotrexate' or 'psoralen'.
- **Behçet's disease (BD)** – to treat the mouth ulcers which is a common problem for people with this illness.

How does Apremilast Anabiosis work?
This product contains the active substance 'apremilast'. This belongs to a group of medicines called phosphodiesterase 4 inhibitors, which help to reduce inflammation.

How is Apremilast Anabiosis used?

The pharmaceutical form is film-coated 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 Apremilast Anabiosis 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, Otezla. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Apremilast Anabiosis?

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 Apremilast Anabiosis 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 Otezla, 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 Apremilast Anabiosis?

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 Apremilast Anabiosis

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

This summary was last updated in 2024-08.