LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Adapalene/Benzoyl peroxide Orifarm (adapalene, benzoyl peroxide, hydrous)

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Gel, 1 mg/g + 25 mg/g

This is a summary of the public assessment report (PAR) for Adapalene/Benzoyl peroxide Orifarm. 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 Adapalene/Benzoyl peroxide Orifarm 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 Epiduo® 0.1/2.5%, gel.

The product is used in the treatment of acne.

How does Adapalene/Benzoyl peroxide Orifarm work?

This gel combines two active ingredients, adapalene and benzoyl peroxide which work together but in different ways:

Adapalene belongs to a group of products known as retinoids and acts specifically on the skin processes that cause acne.

The other active ingredient, benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

How is Adapalene/Benzoyl peroxide Orifarm used?

The pharmaceutical form is gel for Cutaneous 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 Adapalene/Benzoyl peroxide Orifarm have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Epiduo® 0.1/2.5%, gel, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Adapalene/Benzoyl peroxide Orifarm?

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 Adapalene/Benzoyl peroxide Orifarm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Epiduo® 0.1/2.5%, gel, 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 Adapalene/Benzoyl peroxide Orifarm?

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 Adapalene/Benzoyl peroxide Orifarm

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

This summary was last updated in 2023-05.