LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Epiduo
(adapalene, benzoyl peroxide)
0.3% / 2.5% Gel

SE/H/664/02/DC

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Summary Public Assessment Report

Epiduo

(adapalene, benzoyl peroxide)

Gel, 0.3 %/2.5 %

This is a summary of the public assessment report (PAR) for *Epiduo* (0.3%/2.5%). It explains how *Epiduo* 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 *Epiduo.*

For practical information about using *Epiduo* (0.3%/2.5%), patients should read the package leaflet or contact their doctor or pharmacist.

What is *Epiduo* (0.3%/2.5%) and what is it used for?

Epiduo belongs to a group of medicines called “anti-acne preparation for topical use” i.e. it is used for the treatment of acne vulgaris, when comedones (blackheads, whiteheads), numerous papules and pustules (inflammatory pimples) are present. *Epiduo* (0.3%/2.5%) should only be used in adults and adolescents aged 12 years and over.

How does *Epiduo* work?

Epiduo 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.

- Benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

How is *Epiduo* used?

The pharmaceutical form of *Epiduo* is gel, used on the skin.

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.

What benefits of *Epiduo* have been shown in studies?

The company´s own data on efficacy and safety studies previously approved for the lower strength, *Epiduo* 0.1%/2.5%, is applicable for *Epiduo* 0.3%/2.5%. The company has also provided its own data on efficacy and safety studies for the higher strength. The studies have shown that *Epiduo* 0.3%/2.5% is effective in treating acne vulgaris, when comedones (blackheads, whiteheads), numerous papules and pustules (inflammatory pimples) are present.

What are the possible side effects of *Epiduo*?

For the full list of all side effects reported with *Epiduo*, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is *Epiduo* approved?

It was noted that the effect of *Epiduo* 0.3%/2.5% in the treatment of acne vulgaris, when comedones (blackheads, whiteheads), numerous papules and pustules (inflammatory pimples) are present, was significantly better than treatment with placebo. In comparison with the already authorised lower strength, no new or unexpected safety concerns arose from this application. Therefore, the Medical Products Agency in Sweden decided that *Epiduo*'s benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of *Epiduo*?

A risk management plan has been developed to ensure that *Epiduo* 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 *Epiduo*, 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 *Epiduo*

The marketing authorisation for *Epiduo* (0.3%/2.5%) was granted on 2016-11-11 in Sweden.

The full PAR for *Epiduo* (0.3%/2.5%) can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with *Epiduo* (0.3%/2.5%), please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-11-11.