

Summary Public Assessment Report

Epiduo **(adapalene, benzoyl peroxide)** **0.1% / 2.5% Gel**

SE/H/664/01/E02

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Epiduo

(adapalene, benzoyl peroxide)

Gel, 0.1%/2.5%

This is a summary of the public assessment report (PAR) for *Epiduo* (0.1%/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* (0.1%/2.5%), patients should read the package leaflet or contact their doctor or pharmacist.

What is *Epiduo* (0.1%/2.5%) and what is it used for?

Epiduo is used for the treatment of acne.

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 provided its own data on efficacy and safety studies. These studies have shown that *Epiduo* 0.1%/2.5% is effective in treating acne.

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* (0.1%/2.5%) in the treatment of acne was significantly better than treatment with placebo and the two monads. 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* (0.1%/2.5%) was granted on 2008-01-11 in Sweden.

The full PAR for *Epiduo* (0.1%/2.5%) can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with *Epiduo* (0.1%/2.5%), please read the [\[package leaflet\]](#) or contact your doctor or pharmacist.

This summary was last updated in 2017-04.