

**APPROVED PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:****S3****PROPRIETARY NAME AND PHARMACEUTICAL FORM:****Epiduo® 0,1 % / 2,5 % (gel)****Read all of this leaflet carefully before you start using Epiduo 0,1 % / 2,5 %.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Epiduo 0,1 % / 2,5 % has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**1. WHAT EPIDUO 0,1 % / 2,5 % CONTAINS**

The active substances are adapalene and benzoyl peroxide.

The other ingredients are: docusate sodium, disodium edetate, glycerine, poloxamer, propylene glycol (E1520), simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate) and purified water.

**2. WHAT EPIDUO 0,1 % / 2,5 % IS USED FOR**

Epiduo 0,1 % / 2,5 % is used for the treatment of acne.

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.

### **3. BEFORE YOU USE EPIDUO 0,1 % / 2,5 %**

#### **Do not use Epiduo 0,1 % / 2,5 %:**

- If you are allergic (hypersensitive) to any of the ingredients in Epiduo 0,1 % / 2,5 %.

#### **Take special care with Epiduo 0,1 % / 2,5 %:**

- You should not use Epiduo 0,1 % / 2,5 % on areas where you have cuts, scrapes or eczema.
- Make sure Epiduo 0,1 % / 2,5 % does not get into your eyes, mouth or nostrils, and other very sensitive areas of the body. Should this occur wash these areas immediately with plenty of warm water.
- Avoid excessive exposure to sunlight and UV lamps.
- Avoid getting Epiduo 0,1 % / 2,5 % on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used Epiduo 0,1 % / 2,5 %.
- Do not use other acne products (containing benzoyl peroxide and/or retinoids) at the same time as Epiduo 0,1 % / 2,5 %.
- Avoid using Epiduo 0,1 % / 2,5 % at the same time as cosmetics that are irritant, drying or exfoliate the skin.
- Epiduo 0,1 % / 2,5 % is FOR EXTERNAL USE ONLY.

#### **Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

#### **Pregnancy**

Epiduo 0,1 % / 2,5 % should not be used during pregnancy.

If you fall pregnant while using Epiduo 0,1 % / 2,5 %, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

### Breastfeeding

Epiduo 0,1 % / 2,5 % should not be used during breastfeeding.

To avoid contact exposure of the infant, application of Epiduo 0,1 % / 2,5 % to the chest should be avoided.

If you are pregnant or breastfeeding your baby while using Epiduo 0,1 % / 2,5 % please consult your doctor, pharmacist or other health care professional for advice.

### **Driving and using machinery:**

Not relevant.

### **Important information about some of the ingredients of Epiduo 0,1 % / 2,5 %:**

Epiduo 0,1 % / 2,5 % also contains an ingredient known as propylene glycol (E1520) that may cause skin irritation.

### **Using other medicines with Epiduo 0,1 % / 2,5 %:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

## **4. HOW TO USE EPIDUO 0,1 % / 2,5 %**

Always use Epiduo 0,1 % / 2,5 % as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Epiduo 0,1 % / 2,5 % is only intended for use in adults and adolescents aged 12 years and over.

Apply a thin film of gel evenly over acne affected areas once a day at bedtime, avoiding the eyes, lips and nostrils.

The skin should be clean and dry before application. You should wash your hands thoroughly after you have used Epiduo 0,1 % / 2,5 %.

Your doctor will tell you how long you will need to use Epiduo 0,1 % / 2,5 %.

If you feel that the effect of Epiduo 0,1 % / 2,5 % is too strong or too weak, talk to your doctor or pharmacist.

If you experience persistent irritation when applying Epiduo 0,1 % / 2,5 %, contact your doctor.

You may be asked to apply a moisturiser to use the gel less often or to stop for a short time, or to stop using the gel altogether.

**If you use more Epiduo 0,1 % / 2,5 % than you should:**

In the event of overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you use more Epiduo 0,1 % / 2,5 % than you should on your skin, you will not get rid of your acne quicker, but your skin may become irritated and red.

Please contact your doctor, pharmacist or the nearest hospital:

- If you have used more Epiduo 0,1 % / 2,5 % than you should.
- If a child has accidentally swallowed Epiduo 0,1 % / 2,5 %.

Your doctor will advise you on action to be taken.

**5. POSSIBLE SIDE EFFECTS**

Epiduo 0,1 % / 2,5 % can have side effects.

Epiduo 0,1 % / 2,5 % may cause the following side effects at the site of application.

**Frequent side effects**

- dry skin
- local skin rash (irritative contact dermatitis)
- burning sensation
- irritation of the skin

**Less frequent side effects**

- itching of the skin (pruritus)
- sunburn

Unknown frequency of occurrence (cannot be estimated from the available data): swelling face, allergic contact reactions.

If skin irritation appears after application of Epiduo 0,1 % / 2,5 %, it is gently mild to moderate, with local signs as redness, dryness, scaling, burning and pain of skin (including stinging), which peak during the first week and resolve without additional treatment.

Not all side effects reported for Epiduo 0,1 % / 2,5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Epiduo 0,1 % / 2,5 %, please consult your doctor, pharmacist or other healthcare professional for advice.

**6. STORING AND DISPOSING OF EPIDUO 0,1 % / 2,5 %**

- Keep all medicines out of reach of children.
- Do not use Epiduo 0,1 % / 2,5 % after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- Discard the tube 6 months after first opening.
- Store at or below 25 °C.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**7. PRESENTATION OF EPIDUO 0,1 % / 2,5 %**

Epiduo 0,1 % / 2,5 % is presented in white multidose containers with an airless pump and snap on cap, made of polypropylene, low density polyethylene and high density polyethylene containing 30 g of gel. Each multidose container is packed in a carton box.

**8. IDENTIFICATION OF EPIDUO 0,1 % / 2,5 %**

Epiduo 0,1 % / 2,5 % is a white to very pale yellow opaque gel.

**9. REGISTRATION NUMBER**

44/13.12/0109

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

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**11. DATE OF PUBLICATION**

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