# EPIDUO® GEL

Adapalene / Benzoyl peroxide (0.1% w/w / 2.5% w/w)

# What is in this leaflet

- 1. What Epiduo® Gel is used for
- 2. How Epiduo<sup>®</sup> Gel works
- 3. Before you use Epiduo<sup>®</sup> Gel
- 4. How to use Epiduo<sup>®</sup> Gel
- 5. While you are using it
- 6. Side Effects
- 7. Storage and Disposal of Epiduo® Gel
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

# What Epiduo<sup>®</sup> Gel is used for EPIDUO<sup>®</sup> Gel is used for the treatment of acne.

# How Epiduo® Gel works

Epiduo<sup>®</sup> 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.

# Before you use Epiduo® Gel

- When you must not use it
Do not use Epiduo<sup>®</sup>Gel:
If you are allergic to any of the ingredients in Epiduo<sup>®</sup> Gel.

The safety and effectiveness of Epiduo<sup>®</sup> Gel have not been studied in children below 12 years of age.

Pregnancy and lactation
Do not use Epiduo<sup>®</sup> Gel if you are pregnant, trying to get pregnant or think you may be pregnant.

Use Epiduo<sup>®</sup> Gel with caution if you are breast-feeding. Ask your doctor or pharmacist for advice before using any medicine.

Application of Epiduo<sup>®</sup> Gel to the chest should be avoided when used during breast-feeding.

### - Before you start to use it

- You should not use Epiduo<sup>®</sup>
   Gel on areas where you have cuts, scrapes or eczema.
- Make sure Epiduo<sup>®</sup> Gel 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<sup>®</sup> Gel on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used the medicine.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- Do not use other acne products (containing benzoyl peroxide and/or retinoids) at the same time as Epiduo<sup>®</sup> Gel.
- Avoid using Epiduo<sup>®</sup> Gel at the same time as cosmetics that are irritant, drying or exfoliate the skin.

# How to use Epiduo® Gel

- <u>How much to use</u> Always use Epiduo<sup>®</sup> Gel exactly as your doctor has told you. You

as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Apply a thin film of gel evenly over acne affected areas once a day in the evening, avoiding the eyes, lips and nostrils. The skin should be clean and dry before application.

# - When to use it

Follow your doctor's instructions; with the fingertips spread evenly across each affected area of your face. Using more won't speed things up, and it's not a good idea to spot-treat. Stick with the right amount and stay consistent.

### - How long to use it

How long you will need to use Epiduo<sup>®</sup> Gel will depend on how quickly your condition improves. Persevere with your therapy as

Persevere with your therapy as acne can take time to improve.

After you have used it for one month, you should see your doctor or pharmacist again so they can check the improvement in your condition.

# - If you forget to use it

Skipping a day of treatment can allow new pimples to begin forming beneath the skin's surface. So try to make Epiduo<sup>®</sup> Gel part of your regular daily routine. If you miss a day, just start the next day with the same fingertips amount you always use on each of the affected areas of your face and you'll be back on track.

- <u>If you use too much (overdose)</u> If you use more Epiduo<sup>®</sup> Gel than you should on your skin, you will not get rid of your acne quicker,

not get rid of your acne quicker, but your skin may become irritated and red.

# While you are using it

- <u>Things you must do</u>
  The skin should be clean and dry before application. You should wash your hands thoroughly after you have used Epiduo<sup>®</sup> Gel.
- <u>Things you must not do</u> Do not use Epiduo<sup>®</sup> Gel after the expiry date.
- Things to be careful of Driving and using machines
  This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

# Side effects

Like other medicine, Epiduo<sup>®</sup> Gel can cause side effects, although not everybody gets them. Epiduo<sup>®</sup>

# EPIDUO® GEL

Adapalene / Benzoyl peroxide  $(0.1\% \, \text{w/w} \, / \, 2.5\% \, \text{w/w})$ 

Gel may cause following side effects at the site of application.

# Common side effects:

- Dry skin
- Irritant skin inflammation
- Burning sensation
- Irritation of the skin

### Uncommon side effects

- Itching of the skin (pruritus)
- Sunburn

# Unknown frequency of occurrence

- Swelling face
- Allergic skin inflammation

If skin irritation appears after application of Epiduo<sup>®</sup> Gel, it is generally mild to moderate, with local sign of redness, dryness, scaling, burning and pain on skin (stinging pain), which peak during the first week and resolve without additional treatment.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers—> Reporting)

# Storage and Disposal of Epiduo<sup>®</sup> Gel

### - Storage

Keep out of the reach and sight of children. Store below 30°C.

# - <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **Product Description**

- What it looks like
Epiduo is a white to very pale
yellow opaque gel.

- Ingredients
- Active Ingredients Adapalene 0.1% w/w, benzoyl peroxide 2.5% w/w
- Inactive Ingredients
  Disodium edetate, docusate
  sodium, glycerin, poloxamer,
  propylene glycol (E1520),
  simulgel 600PHA
  (copolymer of acrylamide
  and sodium
  acryloyldimethyltaurate,
  isohexadecane, polysorbate
  80, sorbitan oleate), purified
  water.
- <u>MAL number:</u> MAL 20102080A

### Manufacturer

Laboratoires Galderma Zl-Montdésir 74540 Alby-sur Chéran, France.

### **Product Registration Holder:**

Zuellig Pharma Sdn Bhd No 15, Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150, Shah Alam, Selangor.

# Date of revision:

10/12/2015

# **Serial Number:**

BPFK(R4/1)171115/00429