



## Patient Information Leaflet

# SureCure™ 0.1% w/w Gel Adapalene

### Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What SureCure™ is and what it is used for
2. Before you use SureCure™
3. How to use SureCure™
4. Possible side effects
5. How to store SureCure™
6. Further information

### 1. What SureCure™ is and what it is used for

- The active substance in SureCure™ is adapalene, which has an anti-inflammatory effect reducing soreness and irritation.
- It is used on the face, chest or back for acne, where the skin has lots of blackheads, spots and pimples.
- SureCure™ is only absorbed into the body in very small amounts and has little effect, except on the surface of the skin.

### 2. Before you use SureCure™

#### Do not use SureCure™ if you are:

- Allergic (hypersensitive) to adapalene or any of the other ingredients of SureCure™ (see section 6 for other ingredients).

#### Take special care with SureCure™

- Do not use SureCure™ on areas where you have cuts or scrapes or if you have a skin condition called eczema.
- Avoid contact with the eyes, mouth or nostrils, and avoid other very sensitive areas of the body. If accidental contact does occur, immediately wash with warm water.
- Avoid exposure to strong sunlight and artificial UV light.
- If you experience sensitivity or irritation when applying SureCure™, stop using it and tell your doctor. You may be asked to use the gel less often, or stop using it for a short time.

### Using other medicines

- Other acne products (containing benzoyl peroxide, erythromycin or clindamycin) may be used with SureCure™ but they must be applied in the morning and SureCure™ at night.
- Cosmetics may be used but they must not cause blackheads or dry the skin.
- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### Pregnancy and breast-feeding

- SureCure™ should not be used during pregnancy. If you fall pregnant while taking SureCure™, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.
  - SureCure™ can be used during breast-feeding. To avoid contact exposure of the infant, application of SureCure™ to the chest should be avoided.
- Ask your doctor or pharmacist for advice before taking any medicine.

### Important information about some of the ingredients of SureCure™

The ingredient propylene glycol may cause skin irritation.

### 3. How to use SureCure™

- Always use SureCure™ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- SureCure™ is only intended for use in adults and adolescents aged 12 years and over.
  - SureCure™ is for EXTERNAL USE ONLY.
  - SureCure™ is applied at night before going to bed, unless your doctor has told you otherwise.
  - Thoroughly wash the areas to be treated with water. Make sure the skin is clean and dry before using SureCure™.
  - Put on a thin film of the gel with your fingertips to the affected areas and rub in gently.
  - Don't forget to wash your hands afterwards.
  - How long you will have to use SureCure™ will depend on how quickly your acne improves. After you have used SureCure™ for three months, it is important that you see your doctor. He or she can then check the improvement of your acne.

### If you use more SureCure™ than you should or accidentally swallow the gel

- If you put too much SureCure™ on your skin, you will not get rid of your acne any quicker, but your skin may become irritated and red. Some peeling or discomfort could also occur.
- In the rare event that you accidentally swallow any of this product, seek medical advice.

### If you forget to use SureCure™

Don't worry if you forget to apply your SureCure™ at the right time. When you remember, start using the product again, in the same way as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, SureCure™ can cause side effects, although not everybody gets them.

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

#### Common side effects (occur in less than 1 in 10 patients)

- dry skin.
- irritation of the skin.
- burning sensation of the skin.
- redness of the skin (erythema).

#### Uncommon side effects (occur in less than 1 in 100 patients)

- local skin reaction (contact dermatitis).
- skin discomfort
- sunburn
- itching of the skin (pruritus)
- peeling skin (exfoliation)
- flare up of acne

Other effects include pain or swelling of the skin and irritation, redness, itching or swelling of the eyelids.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5. How to store SureCure™

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use SureCure™ after the expiry date which is stated on the tube and carton.

Advice to be used within 3 months of tube opening.

Keep the medicine in its original container.

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.

### 6. Further information

#### What SureCure™ contains

The active substance is adapalene 0.1% w/w.

The other ingredients are carbopol, disodium edetate, methylparaben, propylene glycol, propylparaben, sodium lauryl sulphate, diethanolamine and purified water.

#### What SureCure™ looks like and contents of the pack

SureCure™ is a white to slight yellowish, smooth gel.

SureCure™ Gel comes in aluminum collapsible tube of 30 grams.

### Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Ltd., Jeddah, Saudi Arabia.

Tel: +966-12-6081111, Fax: +966-12-6081222.

Website: www.jamjoompharma.com

### To report any side effect(s):

• Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Call NPC at +966-11-2038222,

Exts: 2317-2356-2353-2354-2334-2340.

Toll free phone: 8002490000

E-mail: npc.drug@sfd.gov.sa

Website: www.sfda.gov.sa/npc

• Other GCC States:

– Please contact the relevant competent authority.

This leaflet was last approved in 04/2014; Version number 02.

### THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



SureCure™ is a quality product manufactured by:



P.O.Box 6267 Jeddah - 21442- Saudi Arabia

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150 x 280 mm