,

CLINDOXYL GEL

PATIENT INFORMATION LEAFLET

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 further questions, please ask your doctor or your pharmacist.
- CLINDOXYL GEL 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

CLINDOXYL GEL

COMPOSITION OF THE MEDICINE, THAT IS, WHAT CLINDOXYL GEL CONTAINS:

The active substances in 100 g CLINDOXYL GEL are:

- Clindamycin phosphate equivalent to clindamycin 1,00 g
- Hydrous benzoyl peroxide equivalent to anhydrous benzoyl peroxide 5,00 g

The other ingredients are:

Carbomer, dimethicone, disodium lauryl sulfosuccinate, edetate disodium, glycerol, colloidal hydrated silica, poloxamer 182, purified water and sodium hydroxide.

APPROVED INDICATION AND USE, THAT IS, WHAT CLINDOXYL GEL IS USED FOR:

CLINDOXYL GEL belongs to a group of medicines known as anti-acne preparations.

Clindamycin is an antibiotic.

Benzoyl peroxide acts to reduce comedones (blackheads and whiteheads).

INSTRUCTION BEFORE USING CLINDOXYL GEL:

CLINDOXYL GEL may not be right for some people. If the answer to any of the following questions is YES, please check with your doctor or pharmacist before you start using the product.

- Are you allergic to any of the ingredients listed above?
- Are you using any other acne treatments which the doctor does not know about?
- Are you pregnant, or trying to become pregnant?
- Are you breastfeeding?

Do Not Use CLINDOXYL GEL:

- If you are allergic to any of the ingredients in this product.
- If you suffer from regional enteritis or ulcerative colitis, or antibiotic-associated colitis or have suffered from these conditions in the past.

Take special care with CLINDOXYL GEL:

Keep CLINDOXYL GEL away from your eyes, lips, mouth, other mucous membranes and from any irritated areas of your skin; for example, if you have cuts, grazes, sunburn or eczema.

Be careful not to use too much CLINDOXYL GEL on sensitive areas of skin.

The product can bleach coloured fabrics, including clothing, towels and bed linen. Be careful to avoid contact of the product with these materials.

The product may bleach hair.

It may take 4-6 weeks before you see the full effect of CLINDOXYL GEL.

Pregnancy and Breastfeeding:

If you are pregnant or trying to become pregnant, or breastfeeding, consult your doctor, pharmacist or other health care professional before using CLINDOXYL GEL.

Taking or using other medications:

Care must be taken when using other topical antibiotics, medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol and or astringents, as a cumulative irritant effect may occur. If you are taking or using other medications consult your doctor before using CLINDOXYL GEL.

INSTRUCTIONS ON HOW TO USE CLINDOXYL GEL:

Do not share medicines prescribed for you with any other person.

A thin film of gel should be applied to all of the area of the skin which has acne, not just to the individual spots. As a guide, one finger-tip (the amount of gel squeezed from the tube which reaches from the tip of your finger to the first joint) is enough to cover your face, two and one half finger tips of gel will cover your face and back. If the gel does not rub into your skin easily, you are using too much.

The usual dose is to apply CLINDOXYL GEL once daily in the evening.

The doctor will tell you how long your treatment will last.

Remove your make-up thoroughly before applying the gel. After it has dried, you can use a non-greasy make-up.

Do not exceed 12 weeks of use.

If you use more CLINDOXYL GEL than you should:

There has been no experience with overdose of CLINDOXYL GEL.

However, if you think that someone has accidentally swallowed the gel, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use CLINDOXYL GEL:

Do not use a double dose to make up for the forgotten individual doses. Apply the next dose at the usual time.

SIDE EFFECTS:

CLINDOXYL GEL can have side effects. The gel may cause slight itching and burning and make your skin feel warm, especially when it is first applied. You may also notice flaking and redness of your skin during the first few weeks of use. These effects are normal; if they bother you, try using the product less often for a while, or stop for a few days and then start again.

If you suffer severe burning, peeling or itching, or other effects not mentioned in this leaflet, you should stop using CLINDOXYL GEL and go back to your doctor for advice.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

Keep all medicines in a safe place where children cannot reach or see them.

Keep well closed.

Pharmacist: Store product in a refrigerator between +2 °C and +8 °C.

Do not freeze.

Patients: Store at or below 25 °C.

Use within 2 months after dispensing.

Do not use CLINDOXYL GEL after the expiry date printed on the tube and carton.

PRESENTATION:

CLINDOXYL GEL comes in 30 g tubes sealed with a white polyethylene screw cap. Each carton contains one tube of CLINDOXYL GEL.

IDENTIFICATION:

A white to slightly yellow homogenous gel.

REGISTRATION NUMBER:

42/13.11/0441

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

1 March 2013

Trademarks are owned by or licensed to the GSK group of companies.
© 2021 GSK group of companies or its licensor

GDS01