

ZINDACLIN GEL

Clindamycin Phosphate (1% w/w)

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What *Zindaclin Gel* is used for

Zindaclin Gel is used to treat mild to moderate acne (spots).

What is acne?

Acne is an extremely common skin condition most common in adolescence, but not restricted to this stage of life. During adolescence, glands in the skin produce extra grease in response to sex hormones in the body, and this can cause blocked pores, resulting in blackheads. When this happens the pores are invaded by bacteria. The chemicals produced by these bacteria go into deeper layers of the skin and produce red spots filled with pus.

How *Zindaclin Gel* works

Zindaclin Gel contains an antibiotic clindamycin that reduces the number of bacteria and stops the skin pores becoming blocked and new spots forming. *Zindaclin Gel* may also help to reduce the redness of the spots you already have. It will take some time once you have started using *Zindaclin Gel* before you see your acne improving.

Before you use *Zindaclin Gel*

When you must not use it

➤ If you are allergic (hypersensitive) to the active substance clindamycin phosphate or any of the other ingredients (see section *inactive ingredients*).

➤ If you are allergic (hypersensitive) to lincomycin, another type of antibiotic.

An allergic reaction may include a rash, red skin, itching, swelling or breathing difficulties. *Zindaclin Gel* should not be used by children under the age of 12 years.

Before you start to use it

➤ Before you use *Zindaclin Gel*, consult your doctor if you suffer from a condition known as inflammatory bowel disease (such as enteritis, ulcerative colitis or Crohns disease) or you have diarrhoea when you have taken antibiotics. If you do get diarrhoea, when using *Zindaclin Gel*, you must stop using it straight away and tell your doctor immediately.

➤ If you are taking other antibiotics, consult with your doctor before using *Zindaclin Gel*.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or recently taken or used any other medicines, including medicines you have bought without a prescription. Interactions with other antibiotics such as erythromycin are possible.

How to use *Zindaclin Gel*

How much to use

Zindaclin Gel must not be taken by mouth. It is for use on the skin only.

Always use *Zindaclin Gel* as your doctor has told you. You should

check with your doctor or pharmacist if you are not sure.

When to use it

➤ You should use *Zindaclin gel* once a day. Wash as normal, rinse well and pat your skin dry. Apply a small amount of gel in a thin layer to the whole of the area where you usually get the spots.

➤ It is important to replace the cap after you have used *Zindaclin Gel*.

Do not

➤ apply *Zindaclin Gel* to areas where you do **not** usually get spots.

➤ use *Zindaclin Gel* in an attempt to stop you getting acne, it does not work that way.

➤ just dab *Zindaclin Gel* onto individual spots.

➤ apply a thick layer of *Zindaclin Gel* in any particular area as this will not get rid of the spots any quicker.

➤ cover *Zindaclin Gel* with dressings (e.g. bandages or plasters) as this may increase the chance of irritation.

Take care to avoid *Zindaclin Gel* from getting into your eyes, inside your nose or mouth. If you accidentally put gel on these areas, wash them straight away with plenty of water.

How long to use it

Successful treatment of acne can take several months. You may not see any effect of treatment for several weeks. After that you should note a gradual but definite improvement but maximum benefit may take several months. Your doctor will normally arrange a check- up after 6 to 8 weeks of treatment. You may need to use more than one tube of *Zindaclin Gel* during each course of treatment. Use *Zindaclin Gel* for as long as your doctor tells you. Try not to pick or squeeze spots as this can make your acne worse and even lead to scarring.

If you forget to use Zindaclin Gel

Use it as soon as you remember and then continue to use as your doctor has told you. Do not apply a double dose to make up for a forgotten application. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use too much (overdose)

You do not need to worry, just wash your treated skin with plenty of water. Contact your doctor or your local hospital if you are worried.

While you are using it

Things you must do

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant, think you might be pregnant, or trying to become pregnant, before using Zindaclin Gel. Clindamycin can pass into breast milk, even if you only use it on your skin, so you should not breast feed while using Zindaclin Gel.

Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give Zindaclin Gel to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Clindamycin therapy has been associated with severe colitis which may end fatally.
- It should be reserved for serious infections where less toxic antimicrobial agents are inappropriate.
- It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infections.
- Its use in newborns is contraindicated.

Important information about some of the ingredients of Zindaclin gel

This product contains

- About 20% ethanol. Each gram contains about 0.2g of alcohol.
- Propylene glycol that may cause skin irritation.

Side effects

Like all medicines, Zindaclin Gel can cause side effects, although not everybody gets them.

Common (affecting fewer than 1 in 10 but more than 1 in 100)

- Dry skin
- Redness of the skin
- Skin burning
- Irritation around eyes
- Worsening of acne
- Itchy skin

Uncommon (affecting fewer than 1 in 100 but more than 1 in 1,000)

- Painful skin
- Scaly rash

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.

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 Zindaclin Gel

Storage

Keep out of the reach and sight of children. Store Zindaclin Gel below 30°C. Do not use Zindaclin Gel after the expiry date which is stated on the tube and box. The expiry date refers to the last day of that month.

Disposal

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

- **Ingredients**

-Active ingredient
Zindaclin Gel contains the active ingredient clindamycin phosphate. Each gram of gel contains 10mg clindamycin (1% w/w) equivalent to 11.88mg clindamycin phosphate.
-Inactive ingredients
Zindaclin Gel also contains propylene glycol, purified water, ethanol, zinc acetate, hydroxyethylcellulose and sodium hydroxide.

What it looks like

Zindaclin Gel is a white translucent gel. Zindaclin Gel is available in 30g laminate tubes with a seal covering the opening and a screwcap.

MAL number

MAL06041464AC

Manufacturer

Dr. August Wolff GmbH & Co. KG Arzneimittel, Sudbrackstraße 56, 33611 Bielefeld, Germany.

Product Registration Holder

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