

PACKAGE LEAFLET

Package leaflet: Information for the user

Zindaclin® 1% Gel Clindamycin Phosphate

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

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1. What Zindaclin is and what it is used for

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

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 normal amounts of 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.

2. Before you use Zindaclin

Do not use Zindaclin

- If you are allergic (hypersensitive) to the active substance clindamycin phosphate or any of the other ingredients (See Section 6).
 - 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 should not be used by children under the age of 12 years.

Take special care with Zindaclin

- Before you use Zindaclin consult your doctor if you suffer from a condition known as inflammatory bowel disease (such as colitis or crohns disease) or you have had diarrhoea when you have taken antibiotics. If you do get diarrhoea, when using Zindaclin, 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.

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, metronidazole and aminoglycosides are

possible.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking or using any medicine.

Tell your doctor if you are pregnant, think you might be pregnant, or trying to become pregnant before using Zindaclin.

Clindamycin can pass into breast milk, even if you only use it on your skin, so you should not breast feed while using Zindaclin.

Important information about some of the ingredients of Zindaclin

This medicine contains

- 200 mg alcohol (ethanol) in each gram which is equivalent to 20% w/w. It may cause burning sensation on damaged skin.
- 400 mg propylene glycol in each gram, which is equivalent to 40% w/w. Propylene glycol may cause skin irritation.

3. How to use Zindaclin

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

Always use Zindaclin as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- You should use Zindaclin 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.

Do not

- apply Zindaclin to areas where you do not usually get spots.
- use Zindaclin in an attempt to stop you getting acne, it does not work that way.
- just dab Zindaclin onto individual spots.
- apply a thick layer of Zindaclin in any particular area as this will not get rid of the spots any quicker.
- cover Zindaclin with dressings (e.g. bandages or plasters) as this may increase the chance of irritation.

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

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. Zindaclin should be used for a maximum of 12 weeks.

You may need to use more than one tube of Zindaclin during each course of treatment. Use Zindaclin 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 use more Zindaclin than you should

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.

If you forget to use Zindaclin

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.

4. Possible side effects

Like all medicines, Zindaclin 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

You can relieve these unwanted effects by using an oil free moisturiser on the affected area. When clindamycin (the active ingredient in Zindaclin) is given by mouth or injection it has been known to cause inflammation of the bowel, leading to diarrhoea with blood and mucus. This reaction is extremely rare when clindamycin is applied on the skin. However, if you get diarrhoea with blood and mucus, stop using Zindaclin and contact your doctor immediately. 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 Zindaclin

Keep out of the reach and sight of children.
Zindaclin does not require any special storage conditions.
Do not use Zindaclin after the expiry date which is stated on the tube and box after the abbreviation used for expiry date. The expiry date refers to the last day of that month.
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 Zindaclin contains

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

What Zindaclin looks like and contents of the pack

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

Product Authorisation Holder

Canute Pharma (Ireland) Ltd
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Manufacturer

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