

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Zindaclin 1% Gel

Composition:

Each gram of gel contains 10 mg clindamycin (1% w/w) equivalent to 11.88 mg clindamycin phosphate.

For a list of inactive ingredients and allergens in the preparation - see section 6 "Further Information".

Read the package insert carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for infants and children under the age of 12.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of acne vulgaris.

Therapeutic group:

Clindamycin is a lincosamide antibiotic.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:

- You are breastfeeding.
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
For the list of inactive ingredients - see section 6 "Further Information".
- You are sensitive (allergic) to lincomycin - another type of antibiotic.

Special warnings regarding use of the medicine:

☒ Before using Zindaclin 1% Gel, tell the doctor if:

- You are pregnant, think that you might be pregnant or are trying to become pregnant.
- You suffer, or have suffered in the past, from impaired function of the digestive system (e.g., ulcer), inflammation of the colon.
- You suffered from diarrhea while taking an antibiotic.
- You are sensitive to any food or medicine.

☒ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.

☒ Pregnancy and breastfeeding

- If you are pregnant, think that you might be pregnant or are trying to become pregnant, discuss with the doctor before using the medicine.
- Do not use the medicine when you are breastfeeding. Clindamycin can pass into breast milk, even though it is used only on the skin.

☒ Important information regarding some of the ingredients of the medicine

The preparation contains about 20% ethanol. Each gram contains about 0.2 gram alcohol.

Do not light a cigarette or come in contact with an open flame until the product has been completely dried off of the skin.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage in the absence of other instructions from the doctor is generally:

Spread a thin layer of Zindaclin 1% Gel on the affected area, once daily.

Do not exceed the recommended dose.

How to use:

- Do not swallow! For external use only.
- Wash, thoroughly rinse and dry the skin. Spread a small amount of the gel in a thin layer on the whole area where the pimples generally appear. Do not spread locally on only the pimples themselves.
- Do not spread on areas where pimples do not generally appear.
- Do not use in order to prevent the appearance of acne.
- Do not spread a thick layer of Zindaclin 1% Gel, since

- this does not make the pimples disappear faster.
- Do not squeeze the pimples, since this may cause worsening of the acne and may even lead to the development of scars.
- Avoid contact with the eyes, mucous membranes (mouth and nose). If the gel comes into contact with these areas, wash immediately with plenty of water.
- It is important to replace the cap on the tube after using Zindaclin 1% Gel.

This medicine is not intended for infants and children under the age of 12.

Improvement will be noticed after use for 4-6 weeks. If there is no improvement after 6 weeks or the acne condition worsens, report to the doctor.

If you took an overdose of the medicine, wash the skin with plenty of water. If you are worried about this - refer to a doctor.

If a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Zindaclin 1% Gel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop use and refer to a doctor immediately if:

You suffer from diarrhea (rare).

Additional side effects

- **Effects appearing frequently**
 - dry skin
 - redness of the skin
 - skin burning
 - irritation around the eyes
 - worsening of acne
 - itchy skin
- **Effects appearing infrequently**
 - sensitivity of the skin to touch
 - scaly rash

You can relieve these unwanted effects by using an oil-free moisturizing cream on the irritated area.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Propylene glycol, ethanol, hydroxyethylcellulose, zinc acetate dihydrate, sodium hydroxide, purified water.

- **What does the medicine look like and what are the contents of the package -** Zindaclin 1% Gel is a white translucent gel. Zindaclin 1% Gel is packaged in 15 gram or 30 gram sealed LDPE/HDPE tubes with a screw cap (PP).

License holder

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Manufacturer

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This leaflet was checked and approved by the Ministry of Health in June 2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 128.65.30648