

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Lindac Gel

Lindac contains 2 active ingredients:

clindamycin (as phosphate) 1% w/w

benzoyl peroxide 5% w/w

Inactive ingredients in this medicine – see section 6 in the leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your 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 to yours.

1. What is this medicine intended for?

Lindac is intended for treatment of mild to moderate acne vulgaris, particularly when accompanied by inflammatory lesions.

Therapeutic group:

Clindamycin is an antibiotic of the lincosamide class, which stops the bacteria involved in acne from reproducing.

Benzoyl peroxide is a mild keratolytic agent (causes separation and loosening of the outer layer of the skin) acting against comedones (acne sores) and reduces acne sores of the whitehead and blackhead types. In addition, it is an oxidizing agent acting against the bacteria involved in acne. Furthermore, it is a sebostatic agent acting against sebum production associated with acne.

The combination of these two ingredients together in Lindac makes it possible to:

- Fight the bacteria that can cause acne.
- Treat existing blackheads, whiteheads and spots.
- Lower the number of red, inflamed acne spots.

2. Before using this medicine

Do not use Lindac if:

- you are sensitive (allergic) to the active ingredients clindamycin and benzoyl peroxide as well as to lincomycin, or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

- **Lindac should be used on the skin only.** Keep it away from areas such as the eyes, lips, mouth or the inside of your nose.
- Do not use Lindac on irritated areas of your skin such as cuts, grazes, sunburn or broken skin.
- In case of contact with the eyes, mouth, lips or inside of your nose, rinse thoroughly with plenty of water.
- Do not apply too much Lindac on sensitive areas of the skin.
- Most patients will experience some skin redness and peeling during the first few weeks of the treatment. If your skin becomes irritated, you may need to use an oil-free moisturizer. In such a case, use Lindac less often or stop using it for a short period to allow your skin to recover and then resume the treatment.
- Stop the treatment and refer to a doctor if the skin irritation is severe (severe redness, dryness, itching, stinging or burning) or if the irritation does not improve.
- Do not let Lindac come into contact with coloured fabrics, including clothing, towels, bed linen, furniture or carpeting. Lindac may bleach these fabrics.
- Lindac may bleach hair.
- Lindac can make your skin more sensitive to the harmful effects of the sun. Avoid the use of sunbeds/lamps and minimize exposure time to the sun. You should use sunscreen and wear protective clothing while using Lindac.

Refer to the doctor or pharmacist before using Lindac if:

- You have ever had any intestinal problem such as regional enteritis, ulcerative colitis or antibiotic-associated colitis.
- You develop stomach cramps or severe diarrhoea that does not improve, stop using Lindac and refer immediately to the doctor. Antibiotics may cause a condition that results in severe diarrhoea or stomach cramps, although this is unlikely to happen with antibiotics applied to the skin.
- You have recently used other clindamycin- or erythromycin-containing medicines; there is an increased chance that Lindac will not work as well as it should. Tell your doctor or pharmacist if you have used any other clindamycin- or erythromycin-containing medicines recently.

Children

Lindac is not intended for children under the age of 12. It is not known whether Lindac is effective or safe for them.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are:

- taking any other acne treatment, including antibiotics used on your skin.
- using medicated soaps or cleansers that are abrasive to the skin.
- using soaps or cosmetics that overdry the skin.
- Using products which contain large amounts of alcohol or antiseptics.

This is because using these products in combination with Lindac may cause irritation of the skin over time.

Lindac may decrease the effectiveness of other medicines taken at the same time to treat acne, including certain acne medicines that contain tretinoin, isotretinoin or tazarotene.

You should tell the doctor if you are taking these medicines. You may need to use the two products at different times of the day (for example, one in the morning and the other in the evening). Using several acne products together increases the risk of skin irritation. Stop the treatment and refer to a doctor if the skin irritation becomes severe (severe redness, dryness, itching, stinging or burning).

- Do not use Lindac at the same time as erythromycin-containing medicines.
- Using Lindac together with medicines such as dapsone and sulfacetamide can cause a temporary colour change of facial skin and/or hair (yellow/orange color). This change will not be permanent.
- One of the active ingredients in Lindac can affect how certain general anaesthetics work. Tell your doctor or pharmacist if you are going to have surgery.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Lindac.

Pregnancy and breast-feeding

Pregnancy

There is limited information about the safety of Lindac in pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine.

Your doctor will consider the benefit to you and the risk to your baby of using Lindac while you are pregnant.

Breast-feeding

It is not known whether the ingredients of Lindac can pass into breast milk. One of the active ingredients in Lindac is clindamycin. When it is taken by mouth or injection, it may pass into breast milk.

If you are breast-feeding, you must check with your doctor before using Lindac.

If you are breast-feeding, do not apply Lindac on your breasts.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually to apply once a day in the evening.

It may take 2-5 weeks before you see the effect of Lindac.

How to use:

1. Completely remove makeup.
2. Wash the affected area well and then rinse with warm water and pat dry.
3. Apply a **thin layer** of gel on the entire affected area using your fingertips.
4. Apply to all of the areas on your skin which have acne, not just to the spots. If the gel is not absorbed into the skin easily, you are using too much.
 - For the face only, use an amount of gel from the tube which reaches from the tip of your finger to the first joint, namely, the fingertip.
 - For the face and back, use two and a half fingertips in total.
5. If the skin is very dry or peeling, you can use an oil-free, fragrance-free, hypoallergenic moisturizer. In addition, use Lindac less frequently or stop treatment for a short period, to allow your skin to adjust to treatment. This medicine may not be properly effective if it is not applied every day.
6. Wash your hands after using the gel.
7. After the gel has dried, oil-free makeup can be used.

Duration of treatment – do not use for a period exceeding 12 weeks without consulting the doctor. Your doctor will instruct you about the treatment duration.

Do not exceed the recommended dose.

Do not swallow, for external use only.

If you have accidentally applied a higher dosage

Pay attention not to apply too much gel. Applying too much gel or applying it more frequently will not help the spots to clear up more quickly and may cause skin irritation. If this does happen, use the gel less often or stop the treatment for a few days and then resume the treatment.

If a child or someone else has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. They may experience symptoms identical to those associated with antibiotics by mouth (stomachaches).

If you forgot to apply Lindac

If you forgot to apply Lindac at the designated time, do not apply a double dose, apply it at the regular time.

Adhere to the treatment as recommended by your doctor.

If you stop the treatment with this medicine too soon contrary to the doctor's instructions, your acne may return.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Lindac may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop the treatment with Lindac and refer to the doctor immediately if the following signs appear - you may require urgent medical treatment:

- Signs of an allergic reaction (such as swelling of the face, eyes, lips or tongue, hives, difficulty breathing, collapse).
- Prolonged or severe diarrhoea, abdominal cramps.
- Severe burning, peeling or itching.

Other possible side effects

If you notice any of these side effects, try using Lindac less frequently or temporarily stop using the gel and then start again.

Very common side effects (appear in more than 1 in 10 users):

In the treatment area: redness, peeling and dryness. These side effects are usually mild.

Common side effects (appear in 1-10 in 100 users):

Headaches.

In the treatment area: burning, pain, sensitivity to sunlight.

Uncommon side effects (appear in 1-10 in 1,000 users):

Tingling (paraesthesia), worsening acne, red and itchy skin, rash (dermatitis, erythematous rash).

Additional side effects

Side effects of unknown frequency (the frequency of these effects has not been established yet)

Allergic reactions, intestinal inflammation, diarrhoea, including bloody diarrhoea, stomach pain.

In the treatment area: skin reactions, skin discoloration, raised and itchy rash.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

You can also report to Trima using the following e-mail address: safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and tube. The expiry date refers to the last day of that month.
- Before first opening, Lindac should be refrigerated (2-8°C). Do not freeze.
- After first opening, store Lindac at a temperature below 25°C. It can be used for 45 days from first opening.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Carbomer homopolymer type C, dimethicone, edetate disodium, glycerin, silicone dioxide, poloxamer 182, sodium hydroxide, purified water.

• What the medicine looks like and contents of the pack:

Lindac is an opaque, white to yellowish watery gel with no lumps packed in a tube containing 45 grams.

- **Registration holder, importer's name and address:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in June 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 173-88-37528-99

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Israel Pharmaceutical Products
Maabarot Ltd.



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