

Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed with a doctor's prescription only

Duac Gel

Duac Gel contains 2 active ingredients:

Clindamycin (as phosphate) 1% W/W
Benzoyl peroxide (as hydrous) 5% W/W
Inactive ingredients and allergens in the medicine – see section 6 in the leaflet

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any 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.

This medicine is intended for adults and adolescents above the age of 12.

1. What is the medicine intended for?

Duac Gel is intended for treatment of mild to moderate acne vulgaris, particularly when accompanied by inflamed 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 (causes separation and loosening of the outer layer of the skin) acting against comedones (acne sores) and reduces acne sores of the blackhead and whitehead 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 Duac Gel allows 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 the medicine

Do not use Duac Gel:

- if you are hypersensitive (allergic) to the active ingredients clindamycin and benzoyl peroxide, as well as to lincomycin, or to any of the additional ingredients this medicine contains (see section 6).

Special warnings regarding use of the medicine

- **Duac Gel should be used only on the skin.** Keep it away from areas such as: the eyes, lips, mouth or the inside of your nose.
- Do not use Duac Gel 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 Duac Gel 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 Duac Gel less often, or stop using it for a short period to allow your skin to recover and then re-start the treatment.
- Stop the treatment and refer to a doctor if the skin irritation is severe (severe redness, dryness, itching, stinging or burning) or does not improve.
- Do not let Duac Gel come into contact with colored fabrics, including clothing, towels, bed linen, furniture or carpeting. Duac Gel may bleach these fabrics.
- Duac Gel may bleach hair.
- Duac Gel 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 a sunscreen and wear protective clothing while using Duac Gel.

Refer to the doctor or pharmacist before using Duac Gel if:

- You have ever had any intestinal problem such as: regional enteritis, ulcerative colitis or antibiotic-associated colitis.

- If you develop stomach cramps or severe diarrhea that does not improve, stop using Duac Gel and refer immediately to the doctor. Antibiotics may cause a condition that results in severe diarrhea or stomach cramps, although this is unlikely to happen with antibiotics applied to the skin.
- If you have recently used other clindamycin or erythromycin-containing medicines, there is an increased chance that Duac Gel 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

Duac Gel is not intended for children under the age of 12 years. It is not known whether Duac Gel is efficient or safe for them.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular inform the doctor or pharmacist 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 have a strong drying effect of the skin.
 - using products which contain large amounts of alcohol or antiseptics.
- This is because using these products in combination with Duac Gel may cause irritation of the skin over time.

Duac Gel may decrease the efficacy of other medicines taken at the same time to treat acne, including: some acne medicines that contain tretinoin, isotretinoin or tazarotene.

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

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

Pregnancy and breast-feeding

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

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

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

It is not known whether the ingredients of Duac Gel can pass into breast milk. One of the active ingredients in Duac Gel is clindamycin. When clindamycin is taken by mouth or injection, it may pass into breast milk. If you are breast-feeding, you must check with your doctor before you use Duac Gel.

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

3. How should you use Duac Gel?

Always use Duac Gel according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The usual recommended dosage is: apply once a day in the evening.

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

How to use:

1. Completely remove make-up.
2. Wash the affected area well and then rinse with warm water and gently pat dry.
3. Apply a **thin film** of gel on the entire affected area using your finger tips.
4. Apply to all of the areas of your skin which have acne, not just to the individual spots. If the gel does not rub into your 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 finger tip.
 - For the face and back, use two and a half finger tips in total.
5. If the skin is very dry or peeling, you can use an oil-free, fragrance-free, hypoallergenic moisturizer. In addition, use Duac Gel less frequently or stop treatment for a short period, to allow your skin to adjust to the 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 make-up 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 start again.

If a child or someone else has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. They may experience symptoms identical to those associated with taking antibiotics by mouth (an upset stomach).

If you forgot to apply Duac Gel

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

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop the treatment with this medicine without consulting the 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 the dose each time you take the medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, the use of Duac Gel may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Stop the treatment with Duac Gel 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, urticaria, difficulty breathing, collapse).
- Prolonged or severe diarrhea, abdominal cramps.
- Severe burning, peeling or itching.

Other possible side effects

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

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

At the site of application: redness, peeling and dryness. These side effects are usually mild.

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

Headaches.

At the site of application: burning, pain, sensitivity to sunlight.

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

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

Other side effects:

Side effects for which a frequency cannot be determined from the available data:

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

At the site of application: skin reactions, skin discoloration, raised and itchy rash.

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

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link:

<https://sideeffects.health.gov.il>

Additionally, side effects can be reported to Padagis via following address: Padagis.co.il

5. How should the medicine be stored?

• Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

• Do not use the medicine after the expiry date (exp. date) that appears on the package and tube. The expiry date refers to the last day of that month.

• Before first opening, store Duac Gel in a refrigerator (2°C-8°C). Do not freeze.

• After first opening, store Duac Gel at a temperature below 25°C. It can be used for two months from first opening.

6. Additional information

In addition to the active ingredients, the medicine also contains –

Glycerol, Carbomer, Sodium Hydroxide, Silica, Colloidal Hydrated, Poloxamer 182, Dimeticone, Disodium Edetate, Disodium Lauryl Sulfosuccinate, Purified Water.

• **What the medicine looks like and contents of the package:**

Duac Gel is a white to yellowish-white gel packed in an aluminum tube containing 25 grams, or 30 grams. For multiple use.

Not all package sizes may be marketed.

• **Registration holder:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

• **Manufacturer:** Glaxo operations UK Limited, Barnard Castle, UK.

• Revised in February 2022 according to MOH guidelines.

• **Drug registration number at the National Medicines Registry of the Ministry of Health:** 140-92-31439

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