

Package leaflet: Information for the user

Clindamycin + Benzoyl Peroxide 10 mg/g + 50 mg/g gel clindamycin + anhydrous benzoyl peroxide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you use this medicine
3. How to use this medicine
4. Possible side effects
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1. What this medicine is and what it is used for

Clindamycin + Benzoyl Peroxide Gel contains two medicines: clindamycin and benzoyl peroxide. Clindamycin + Benzoyl Peroxide Gel belongs to a group of medicines known as ‘anti-acne preparations’.

This medicine is used for treating mild to moderate acne on your skin.

- Clindamycin is an antibiotic which stops the bacteria involved in acne from reproducing
- Benzoyl peroxide reduces blackheads and whiteheads. It also kills the bacteria involved in acne.

Used together in Clindamycin + Benzoyl Peroxide Gel, these work by:

- fighting the bacteria that can cause acne
- treating existing blackheads, whiteheads, and spots
- lowering the number of red, inflamed acne spots

This medicine is for use by adults and adolescents aged 12 years or over.

2. What you need to know before you use this medicine

Do not use Clindamycin + Benzoyl Peroxide Gel:

- if you are allergic to clindamycin, lincomycin, benzoyl peroxide or any of the other ingredients of this medicine (listed in Section 6)

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you start using Clindamycin + Benzoyl Peroxide Gel.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine.

- **Check with your doctor or pharmacist before using this medicine if** you have ever had any of the following **gut problems**: ‘regional enteritis’, ‘ulcerative colitis’, or ‘antibiotic-associated colitis’.

- **If you develop stomach cramps or diarrhoea** that does not improve or is severe, **stop using Clindamycin + Benzoyl Peroxide Gel** and contact your doctor immediately. Antibiotics may cause a condition that results in severe diarrhoea and stomach cramps, although this is unlikely to happen with antibiotics applied to the skin.
- **Only use Clindamycin + Benzoyl Peroxide Gel on your skin.** Keep it away from areas like your eyes, lips, mouth or inside your nose.
- **Do not use the gel on any irritated areas of your skin.** For example, if you have cuts, grazes, sunburn or broken skin.
- ➔ If you accidentally get this medicine in your eyes, mouth, lips, or inside your nose rinse with plenty of water.
- Do not to use too much Clindamycin + Benzoyl Peroxide Gel on sensitive areas of skin.
- Most patients will experience some skin redness and peeling during the first few weeks of treatment. **If your skin becomes irritated**, you may need to use an oil-free moisturiser, use this medicine less often, or stop using it for a short period to allow your skin to recover and then re-start treatment.
- Stop treatment and see your doctor if skin irritation is severe (severe redness, dryness, itching, stinging, or burning) or does not improve.
- Clindamycin + Benzoyl Peroxide Gel can make your skin more sensitive to the harmful effects of the sun. Avoid the use of sunbeds/lamps and minimise the time you spend in the sun. You should use a sunscreen and wear protective clothing while using this medicine.
- If you have recently used other clindamycin or erythromycin-containing medicines, there is an increased chance that Clindamycin + Benzoyl Peroxide 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.
- Try not to let Clindamycin + Benzoyl Peroxide Gel come into contact with coloured fabrics, including clothing, towels, bed linen, furniture or carpeting. **This medicine can bleach these materials.**
- This medicine may bleach hair.

Children

Do not give this medicine to children under 12 years. It is not known if it works or if it is safe for them.

Other medicines and <Invented name>

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Tell your doctor or pharmacist if you are using any of the following:

- any other acne treatments including antibiotics used on your skin
- medicated or 'abrasive' soaps and cleansers
- soaps or cosmetics that have a strong drying effect
- products which contain large amounts of alcohol or 'astringents'

This is because when used together with Clindamycin + Benzoyl Peroxide Gel, they may irritate your skin over time.

Clindamycin + Benzoyl Peroxide Gel may make some acne medicines less effective when used at the same time. This includes:

- Some acne medicines that are applied to the skin which contain **tretinoin, isotretinoin** or **tazarotene**
- ➔ Tell your doctor or pharmacist if you are also using one of these medicines. You may need to use the two products at different times of the day (e.g. one in the morning and the other in the evening). Using other acne medicines at the same time as Clindamycin + Benzoyl Peroxide Gel can increase the risk of skin irritation.

- ➔ **Stop treatment and see your doctor** if skin irritation becomes severe (severe redness, dryness, itching, stinging or burning).

Clindamycin + Benzoyl Peroxide Gel should not be used at the same time as erythromycin-containing medicines.

Applying Clindamycin + Benzoyl Peroxide Gel at the same time as medicines such as **dapsone** and **sulfacetamide** can cause a temporary colour-change of skin or facial hair (yellow/orange colour). This will not be permanent.

One of the medicines in Clindamycin + Benzoyl Peroxide Gel can affect how certain general anaesthesia medicines work (called “neuromuscular blocking agents”).

- ➔ **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 this medicine.

Pregnancy and breast-feeding

There is only limited information about the safety of this medicine in pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Your doctor will consider the benefit to you and the risk to your baby of using Clindamycin + Benzoyl Peroxide Gel while you're pregnant.

It is not known whether the ingredients of Clindamycin + Benzoyl Peroxide Gel can pass into breast milk. One of the medicines in Clindamycin + Benzoyl Peroxide 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 Clindamycin + Benzoyl Peroxide Gel.

Do not use this medicine on your breast if you are breast-feeding.

3. How to use this medicine

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Use Clindamycin + Benzoyl Peroxide Gel once a day in the evening.
- It may take 2 to 5 weeks before you see the effect of this medicine.
- Do not use for more than 12 weeks at one time. Your doctor will tell you how long your treatment will last.

How to apply this medicine

1. Completely remove any make-up.
2. Wash the affected area of skin well. Then rinse with warm water and gently pat dry.
3. Put a **thin film** of gel on the **entire** area of affected skin, using your fingertips.
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 your face only, use an amount of gel from the tube which reaches from the tip of your finger to the first joint (the first crease on your finger). This is a ‘finger tip’.
 - For your face and back, use two and a half ‘finger tips’ in total.
5. If you get a lot of dryness or skin peeling, you can use an oil-free, fragrance free, hypoallergenic moisturiser, use Clindamycin + Benzoyl Peroxide Gel less frequently or stop treatment for a short

period, to allow your skin to adjust to the treatment. This medicine may not work properly if it is not applied every day.

6. **Wash your hands** after using the gel.

7. After it has dried, you can use a non-greasy make-up.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you use more Clindamycin + Benzoyl Peroxide Gel than you should

- **Take care not to apply too much.** Applying too much gel or applying it more frequently will not help your spots clear up more quickly, and may cause skin irritation. If this does happen, use the gel less often, or stop using it for a few days and then start again.

If you accidentally swallow this medicine

- **If you do accidentally swallow the gel, seek medical advice.** You may get symptoms similar to when you take antibiotics by mouth (an upset stomach).

If you forget to use this medicine

- Do not use a double dose to make up for forgotten individual doses.
- Apply the next dose at the usual time.

If you stop using Clindamycin + Benzoyl Peroxide Gel

Don't use the gel for more than 12 weeks at one time, without talking to your doctor. Use Clindamycin + Benzoyl Peroxide Gel for as long as your doctor recommends. Don't stop unless your doctor advises you to.

It is important to continue to use the gel as prescribed by your doctor. If you stop too soon, your acne may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Clindamycin + Benzoyl Peroxide Gel and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- signs of an allergic reaction (such as swelling of your face, eyes, lips or tongue, nettle rash or difficulty breathing, collapse)
- severe or prolonged diarrhoea, or abdominal cramps
- severe burning, peeling or itching.

Very common side effects

(may affect more than 1 in 10 people)

At site of application:

- Redness, peeling, dryness

These side effects are generally mild.

Common side effects

(may affect up to 1 in 10 people)

- Headache

At site of application:

- Burning, pain, sensitivity to sunlight

Uncommon side effects

(may affect up to 1 in 100 people)

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

Other side effects

Other side effects with not known frequency (frequency cannot be estimated from the available data) include:

- Allergic reactions
- Inflammation of the intestine, diarrhoea, including bloody diarrhoea, stomach pain

At the site of application:

- Skin reactions, discoloration of the skin
- Raised itchy rash (hives)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance;

Website: www.hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).

After first opening of Clindamycin + Benzoyl Peroxide Gel, do not store it above 25°C and discard after 2 months.

Do not use this medicine after the expiry date which is stated on the package after "EXP".

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clindamycin + Benzoyl Peroxide Gel contains

- The active substances are: clindamycin and anhydrous benzoyl peroxide. 1 g of gel contains 10 mg clindamycin (as clindamycin phosphate) and 50 mg anhydrous benzoyl peroxide (as hydrous benzoyl peroxide).
- The excipients are: carbomer 980, dimeticone, disodium lauryl sulfosuccinate, disodium edetate, glycerol, poloxamer (poloxamer 182), silica, colloidal hydrated, sodium hydroxide 2N, purified water.

What this medicine looks like and contents of the pack

White to slightly yellow homogenous gel with visible fine particles.

Each pack contains 25 g, 30 g, 50 g or 60 g of gel in an aluminium tube closed with white plastic screw cap, in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspire Pharma (Malta) Limited
Trident Park, Notabile Gardens
No. 2 – Level 3, Mdina Road, Zone 2, Central Business District
Birkirkara CBD2010, Malta

Manufacturer:

Jadran-Galenski Laboratorij d.d.
Svilno 20
51000 Rijeka
Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

Slovenia: Aperox 10mg/50 mg v 1 g gel
Croatia: Aknet Duo 10 mg/g + 50 mg/g gel

This leaflet was last revised in March 2024