

PACKAGE LEAFLET: INFORMATION FOR THE USER



PanOxyl[®] 2.5 Aquagel

2.5% w/w Gel

Benzoyl Peroxide

PanOxyl[®] 5 Aquagel

5% w/w Gel

Benzoyl Peroxide

PanOxyl[®] 10 Aquagel

10% w/w Gel

Benzoyl Peroxide

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use PanOxyl carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve.
- 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.

In this leaflet:

1. What PanOxyl is and what it is used for
2. Before you use PanOxyl
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1. What PanOxyl is and what it is used for

The name of your medicine is PanOxyl-Aquagel (called PanOxyl in this leaflet). PanOxyl contains an active ingredient called benzoyl peroxide.

Benzoyl peroxide works by killing the bacteria on your skin that can cause acne.

PanOxyl is used to treat acne (spots).

PanOxyl is for use by adults and adolescents with acne. **It is not for use by children.**

2. Before you use PanOxyl

Do not use PanOxyl if:

- you are allergic (*hypersensitive*) to benzoyl peroxide or any of the other ingredients (listed in Section 6).
- Do not use PanOxyl if the above applies to you. If you are not sure, ask your pharmacist or doctor before you use this medicine.

Take special care with PanOxyl

- Only use PanOxyl on your skin. Avoid contact with the eyes, eyelids, mouth, lips and inside the nose. If contact occurs, rinse with water.
- **Take care not to use PanOxyl on areas of broken skin**, such as cuts or grazes. If contact with these areas occurs, wash the affected area immediately with water.

- Take care when applying this product to the neck and other sensitive areas, since skin irritation is more likely to occur.
- PanOxyl 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 PanOxyl.
- PanOxyl may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

Using other medicines with PanOxyl

Please tell your pharmacist or doctor if you are using or have recently used any other medicines. This includes medicines you get without a prescription, such as herbal medicines.

Some medicines can affect how PanOxyl works, or make it more likely that you'll have side effects such as redness, peeling and skin irritation.

In particular, tell your doctor or pharmacist:

- If you are using other acne treatment. If used at the same time, it may make skin irritation worse.
- If you are using other acne medicines containing tretinoin, isotretinoin or tazarotene. If used at the same time, PanOxyl may make these treatments less effective.
- If you are using sulphonamide-containing medicines such as dapsone and sulfacetamide. If used at the same time as PanOxyl, your skin or facial hair may turn yellow or orange. This will not be permanent.

Tell your doctor or pharmacist if you are taking any of these. Your doctor or pharmacist will decide if you should take PanOxyl with these medicines or may advise you to use the medicines at different times of the day (for example, one in the morning and the other at bedtime).

Pregnancy and breast-feeding

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

- **Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.**
- **If you do become pregnant during treatment with PanOxyl tell your doctor.**

It is not known whether the ingredients of PanOxyl can pass into breast milk. If you are breast-feeding, you must check with your doctor or pharmacist before you use PanOxyl.

- **Don't use PanOxyl on your breast** if you are breast-feeding.

Important information about some of the ingredients of PanOxyl

PanOxyl contains propylene glycol. Propylene glycol may cause skin irritation.

3. How to use PanOxyl

If this medicine is from your pharmacist or doctor, follow their instructions. Otherwise, follow the instructions below. If you do not understand the instructions or are not sure, ask your pharmacist or doctor.

- **Use PanOxyl once a day.**
- Most people start by using PanOxyl 2.5 Aquagel and only use the stronger PanOxyl 5 or 10 Aquagel only if needed. The pharmacist or doctor will advise you.
- **During the first weeks of treatment a sudden increase in peeling and reddening of the skin can occur.** If they cause you a problem, try using PanOxyl less often or stop using it for a few days until the irritation goes away then start again. Stop using PanOxyl if the irritation does not go away.
- After 6-8 weeks if your acne is no better or it gets worse, talk to your doctor or pharmacist.
- Use PanOxyl for as long as your doctor or pharmacist tells you to. Continue using this medicine until the acne has gone.
- Do not stop using it without asking advice. If you stop too soon your acne may come back.

How to apply PanOxyl

1. Completely remove any make-up.
2. Wash the affected area and gently dry.
3. Put a thin film of the gel on the affected skin, using your fingertips and smooth in.
4. Apply to all of the area of your skin that has acne, not just to the individual spots. You may notice a mild burning sensation. If this becomes severe, stop using and see your doctor.
5. Take care not to apply too much gel. Applying too much, or applying it more often than advised, will not help your acne clear up more quickly and may cause skin irritation.
6. Wash your hands after using the gel.

If you forget to use PanOxyl

- Do not use a double dose to make up for forgotten doses.
- Skip the dose and apply the next dose at the usual time.

If you accidentally swallow PanOxyl

The ingredients of PanOxyl are not expected to be harmful if swallowed in the small amounts normally applied to the face. However, if you do accidentally get a larger amount of PanOxyl in your mouth, rinse immediately with plenty of water.

Contact your doctor or pharmacist for advice.

4. Possible side effects

Like all medicines, PanOxyl can cause side effects, although not everybody gets them:

Severe allergic reactions:

Signs may include:

- raised and itchy rash (*hives*)
- swelling of the face or mouth (*angioedema*), causing difficulty in breathing
- collapse.

Contact a doctor immediately if you get these symptoms.
Stop using PanOxyl immediately.

Very common side effects:

These may affect more than 1 in 10 people:

- redness and peeling of the skin

Common side effects:

These may affect up to 1 in 10 people:

- dryness, itching or sensitivity of the skin.

Uncommon side effects:

These may affect up to 1 in 100 people:

- burning sensation

Other side effects may include:

- rash
- allergic reaction
- discoloration of the skin
- other skin reactions such as irritation and pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5. How to store PanOxyl

- Keep out of the sight and reach of children.
- PanOxyl should be stored at room temperature (below 25°C).
- Do not use PanOxyl after the expiry date which is printed on the tube and carton.
- 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 PanOxyl contains

- The active ingredient is benzoyl peroxide. The amount of benzoyl peroxide in your medicine is indicated by the number after the name 'PanOxyl Gel': PanOxyl 2.5 Aquagel contains 2.5% w/w benzoyl peroxide. PanOxyl 5 Aquagel contains 5% w/w benzoyl peroxide. PanOxyl 10 Aquagel contains 10% w/w benzoyl peroxide.
- The other ingredients are: carbomer, di-isopropanolamine, propylene glycol, macrogol lauryl ether, sodium laurilsulfate and purified water.

What PanOxyl looks like

PanOxyl Aquagel is a white gel and comes in either 40g or 50g tubes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Stiefel, 980 Great West Road, Brentford, Middlesex, TW8 9GS, U.K.

Manufacturer:

Stiefel Laboratories (Ireland) Ltd.,
Finisklin Business Park, Sligo, Ireland

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