

Package Leaflet: Information for the User

PanOxyl 10 Wash

10% w/w Lotion

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.

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1. What PanOxyl is and what it is used for

The name of your medicine is PanOxyl 10 Wash (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). It is a lotion that you use to wash your affected skin.

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 products 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.

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, in the morning if possible.
- 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. Wet the areas of the skin to be treated with warm water
3. Apply PanOxyl and gently massage for one or two minutes.
4. Cover **all of the area of your skin which has acne**, not just each spot. You may notice a mild burning sensation. If this becomes severe, stop using and see your doctor.
5. Rinse the skin well with warm water and gently dry.
6. **Take care not to use too much PanOxyl.** Washing too much, or more often than advised, will not help your acne clear up more quickly and may cause skin irritation..
7. Wash your hands after using PanOxyl.

If you forget to use PanOxyl

- Do not worry if you forget to use PanOxyl.
- 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

Tell your doctor or pharmacist if any of these side effects become **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5. How to store PanOxyl

- Keep out of the reach and sight 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 bottle and carton after Exp.
- 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. PanOxyl Wash contains 10% w/w benzoyl peroxide.
- The other ingredients are: magnesium aluminium silicate, hypromellose, polyoxyethylene lauryl ether, sodium alkyl aryl polyether sulphonate, sodium dihexyl sulphosuccinate, sodium lauryl sulphoacetate, citric acid monohydrate, imidurea and purified water.

What PanOxyl looks like

PanOxyl 10 Wash is a lotion that comes in 150ml bottles.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Avianta Pharma Limited, Unit H, Ashbourne Drive, Leamington Spa, England, CV31 3SS, United Kingdom

PL 49226/0018

Manufacturer:

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

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