

BREVOXYL®

4% w/w cream

Benzoyl peroxide

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Brevoxyl. This leaflet answers some common questions about Brevoxyl. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using Brevoxyl against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Brevoxyl is used for

Brevoxyl is a water based cream containing 4% w/w benzoyl peroxide. Benzoyl peroxide is an antibacterial and mild peeling agent. This medicine belongs to a group of medicines called keratolytics (peeling agents). This medicine also works by fighting the bacteria that can cause acne.

Brevoxyl is used on the skin to treat acne. It helps to:

- reduce the bacteria or germs, which are implicated in acne
- reduce the number of acne spots or pimples
- stop new blackheads, whiteheads and spots from forming, and
- make your skin less oily.

Your doctor or pharmacist may have recommended Brevoxyl for another purpose.

Ask your doctor or pharmacist if you have any questions about why Brevoxyl has been recommended for you.

Brevoxyl is only available from your pharmacy.

Before you use Brevoxyl

When you must not use it

Do not use Brevoxyl if:

- you have ever had an allergic reaction to benzoyl peroxide or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- the expiry date (EXP) printed on the pack has passed.

If you are not sure whether you should start using Brevoxyl, contact your doctor or pharmacist.

Before you start to use it

Keep Brevoxyl away from your eyes, eyelids, mouth, lips, and inside the nose.

Take care not to use Brevoxyl on areas of broken skin, such as cuts or grazes. If contact with these areas occurs, wash the affected area immediately with water.

Care should be taken when applying Brevoxyl to the neck or other sensitive areas of the skin.

Brevoxyl may cause a slight stinging sensation and make your skin feel warm, especially when it is first applied. You may also notice moderate redness and peeling of your skin during the first few weeks of use. Excessive drying of the skin may also occur. These effects are normal; if they bother you:

- try using the product less often for a while (for example once daily instead of twice daily); or
- stop using Brevoxyl temporarily for one or two days; or
- stop using and consult your doctor or pharmacist for advice.

Brevoxyl can make your skin more sensitive to sunlight. 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 Brevoxyl.

Brevoxyl may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

Do not use this medicine on a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Using other medicines

Tell your doctor or pharmacist if you are using other creams, ointments, gels or lotions for acne or are taking any other medicines. This includes any other medicines that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines can affect how Brevoxyl works, or make it more likely that you may experience side effects such as skin irritation, redness, peeling and drying.

These include:

- acne medicines that are applied to the skin which contain tretinoin, isotretinoin or tazarotene
- some other acne medicines that are applied to the skin
- sulphonamide or sulfone-containing medicines applied to the skin such as dapson and sulfacetamide - applying Brevoxyl at the same time as these medicines can cause a temporary discoloration of skin or facial hair (yellow/orange colour)
- abrasives
- products containing alcohol
- chemical peels

You may need different amounts of your medicine or the medicines may need to be applied at different times of the day (e.g. one in the morning and the other in the evening) or you may need to use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using Brevoxyl.

How to use Brevoxyl

Brevoxyl is for external use only.

Follow all directions given to you by your doctor or pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, tube or this leaflet, ask your doctor or pharmacist for help.

How to use Brevoxyl

Apply Brevoxyl to the affected area once or twice daily, preferably after washing and drying the skin.

As excessive drying of the skin may occur, you should start with applying the cream once daily and then increase to twice daily if needed.

How to apply Brevoxyl:

- Completely remove any make-up.
- Wash your hands and the affected areas of the skin with suitable cleansers and water prior to application of Brevoxyl. Gently pat dry.
- Apply a thin film of Brevoxyl with your fingertips to the whole affected area of your skin which has acne, not just individual spots or pimples.
- Wash your hands after using Brevoxyl.
- After the Brevoxyl has dried, you can use non-greasy make-up.

If the Brevoxyl cream does not rub into the skin easily, you are using too much.

If you are breastfeeding, Brevoxyl cream should not be applied to the breast area to avoid accidental ingestion by the infant.

It is important to use Brevoxyl according to these directions or exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your acne may not improve.

Using it more often than you should may not improve your acne any faster and may cause or increase side effects.

When to use Brevoxyl

Use Brevoxyl at the same time every day.

How long should you use Brevoxyl for

It can take a few weeks before you see the full effects of Brevoxyl on your acne. You should continue treatment for at least 3 months unless your doctor or pharmacist tells you otherwise.

If you are not sure of how long you need to use Brevoxyl, talk to your doctor or pharmacist.

If you use too much (overdose)

Using too much Brevoxyl can result in severe skin irritation. If this happens, wash off the cream and stop using the cream. Cold compresses can provide relief from skin irritation. Contact your doctor or pharmacist or the Poisons Information Centre (In Australia 13 11 26; In New Zealand 0800 POISON or 0800 764 766) for further advice.

If you swallow Brevoxyl

Immediately telephone your doctor or the Poisons Information Centre (In Australia 13 11 26; In New Zealand 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have swallowed Brevoxyl. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep this telephone number handy.

While you are using Brevoxyl

Things you must do

Tell your doctor who is treating you that you are using Brevoxyl. If you feel that Brevoxyl is not helping your condition, tell your doctor or pharmacist. Tell your doctor or pharmacist if for any reason, you have not used Brevoxyl exactly as recommended.

Otherwise, your doctor or pharmacist may think that it was not effective and change your treatment unnecessarily.

Things to be careful of

Avoid excessive exposure to sunlight and other sources of ultra violet light. Avoid using at high altitudes or where the ground is snow-covered. Sunlamps should not be used. When exposure to sunlight cannot be avoided, protective clothing should be worn and a sunscreen should be used.

Brevoxyl can bleach hair and coloured fabrics, such as clothing, towels, bed linen, furniture and carpeting. Be careful to avoid contact of Brevoxyl with these materials.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Brevoxyl.

This medicine helps most people with acne, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Brevoxyl may cause a slight stinging sensation and make your skin feel warm, especially when it is first applied. You may also notice moderate redness and peeling of your skin during the first few weeks of use. Excessive drying of the skin may also occur.

These effects are normal; if they bother you:

- try using the product less often for a while (for example once daily instead of twice daily); or
- stop using Brevoxyl temporarily for one or two days; or
- stop using and consult your doctor or pharmacist for advice.

The most commonly reported side effects are:

- redness and peeling of the skin at the site of application.
- dryness, itching or sensitivity of the skin at the site of application.

Some people may also experience a burning sensation at the site of application.

If you suffer severe burning, redness, peeling, itching or other unwanted effects, stop using Brevoxyl and consult your doctor or pharmacist.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice wheezing, swelling of the lips/mouth, difficulty in breathing, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction. Stop using Brevoxyl immediately.

Tell your doctor or pharmacist if you notice any other side effects not listed in this leaflet.

After using Brevoxyl

Storage

Keep Brevoxyl in a cool dry place where the temperature stays below 25°C.

Do not store Brevoxyl or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep Brevoxyl where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Brevoxyl or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Brevoxyl is a white to off-white cream which is available in a 50 gram tube in a carton.

Ingredients

The active ingredient in Brevoxyl is benzoyl peroxide 4% w/w.

Brevoxyl contains the following inactive ingredients:

- cetyl alcohol
- stearyl alcohol
- simethicone
- propylene glycol alginate
- dimethyl isosorbide
- purified water
- fragrance X-23304

Supplier

Brevoxyl is supplied in Australia by:

GlaxoSmithKline Pty Ltd Consumer Healthcare Division
82 Hughes Avenue
Ermington
NSW 2115
Australia

Brevoxyl is supplied in New Zealand by:

GlaxoSmithKline NZ Ltd
Auckland, New Zealand

Australian Registration Number:

AUST R 58220

Brevoxyl® is a registered trade mark of Stiefel Laboratories, Inc.

This leaflet was prepared on:
2 December 2013

Version 4.0

