

LEAFLET

Brevoxyl[®] 40mg/g Cream
Benzoyl peroxide

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- keep this leaflet You may need to read it again.
- ask your pharmacist if you need more information or advice.
- if you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- you must talk to your doctor if you do not feel better or if you feel worse after 4 to 6 weeks

WHAT IS IN THIS LEAFLET:

1. What Brevoxyl is and what it is used for
 2. what you need to know before you use Brevoxyl
 3. How to use Brevoxyl
 4. Possible side effects
 5. How to store Brevoxyl
- Contents of the pack and other information

1. What Brevoxyl is and what it is used for

The name of your medicine is Brevoxyl 40mg/g Cream (called Brevoxyl in this leaflet). Brevoxyl contains the active ingredient benzoyl peroxide which works by fighting the bacteria that can cause spots.

Brevoxyl is used to treat mild to moderate acne vulgaris in adults and adolescents. It is not for use by children. It helps to:

- reduce the number of spots
- stop new blackheads, whiteheads and spots from forming

2. What you need to know before you use Brevoxyl

Do not use Brevoxyl if you are allergic to benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6). If you are not sure, ask your doctor or pharmacist before you use this medicine.

Warnings and precautions

- avoid contact with the eyes, eyelids, mouth, lips, other mucous membranes and broken skin.
- take care when applying the product to the neck and other sensitive areas.
- Propylene glycol alginate may cause skin irritation.
- stearyl alcohol and cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).
- do not apply too much as this may increase the risk of skin irritation.
- stop using Brevoxyl if severe local irritancy occurs (e.g. redness, dryness and itching or severe stinging/burning sensation).
- during the first weeks of treatment, a sudden increase in peeling and reddening will occur in most patients; this is not harmful and will normally subside in a day or two if treatment is temporarily discontinued.

Sunlight

As benzoyl peroxide may cause increased sensitivity to sunlight, try to limit the amount of time that

your treated skin is in the sun and do not use sun beds. When exposure to strong sunlight cannot be avoided, use a sunscreens product and wear protective clothing.

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

Children

DO not use this medicine on children under 12 years of age because the safety and efficacy have not been established.

Other medicines and Brevoxyl

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

Some acne treatments can affect how Brevoxyl works, or make it more likely that you'll have side effects such as skin irritation. These include:

- other acne treatments that are applied to the skin
- other acne treatments that are applied to the skin which contain tretinoin, isotretinoin or tazarotene.

Applying Brevoxyl at the same time as other topical sulphonamide-containing medicines may cause a temporary discolouration of skin and facial hair (yellow/orange).

If you are not sure if the above applies to you, check with your doctor or pharmacist before using Brevoxyl.

Pregnancy and breastfeeding

There is only limited information about the safety of Brevoxyl in pregnant women. It is not known whether the ingredients of Brevoxyl can pass into breast milk.

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

Brevoxyl contains propylene glycol alginate, stearyl alcohol and cetyl alcohol.

Propylene glycol alginate may cause skin irritation. Stearyl alcohol and cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. How to use Brevoxyl

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

Check with your doctor or pharmacist if you are not sure.

- apply Brevoxyl only to the skin
- use Brevoxyl once or twice a day
- it may take 4 to 6 weeks before you see an improvement of your skin. You may need to use this treatment for longer before you see the full treatment effects. This is normal for acne treatments.

How to apply Brevoxyl

1. completely remove any make up
2. wash the affected area of skin. Then rinse with warm water and gently pat dry.
3. put a thin layer of the cream on the affected skin, using your fingertips and smooth in. Apply to the area of your skin that has acne, not just to the individual spots.
4. if the cream does not rub into your skin easily, you are using too much.
5. take care not to apply too much as it may cause skin irritation.
6. wash your hands after using the cream
7. after it has dried, you can use non-greasy make up.

If you forget to use Brevoxyl

- do not use a double dose to make up for the forgotten doses
- apply the next dose at the usual time

If you accidentally swallow Brevoxyl

The ingredients of Brevoxyl 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 Brevoxyl in your mouth, rinse immediately with plenty of water and seek medical advice.

If you stop using Brevoxyl

Use Brevoxyl for as long as your doctor or pharmacist recommends. It is important to continue to use this medicine until all the acne has gone. If you stop too soon, your acne may return. If after 4-6 weeks you see no improvement or if your acne gets worse after this time period, return to your doctor or pharmacist for further advice.

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.

Severe allergic reactions: These are rare in people taking Brevoxyl. 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 immediately.

Very common side effects (these may affect up to 1 in 10 people):

- application site redness
- application site peeling.

During the first few weeks of using Brevoxyl, you may notice some peeling and reddening of the skin. If this happens, stop using for one or two days.

Common side effects (these may affect up to 1 in 100 people):

- application site dryness
- application site itching
- sensitivity of the skin at the application site.

Uncommon side effects (these may affect up to 1 in 1,000 people):

- application site burning sensation.

Rare side effects (these may affect up to 1 in 1,000 people):

- application site discolouration of the skin
- application site reactions such as irritation and apin
- skin allergy
- application site skin rash.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Brevoxyl

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use this medicine after the expiry date which is printed on the tube and carton after (EXP). The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Brevoxyl contains

The active ingredient is benzoyl peroxide. Each gram of Brevoxyl cream contains 40mg of benzoyl peroxide as the hydrate. The other ingredients are: cetyl alcohol, stearyl alcohol, macrogol cetostearyl ether, simethicone emulsion, propylene glycol alginate, dimethyl isosorbide, fragrance (X-23304) and water.

What Brevoxyl looks like and contents of the pack

Brevoxyl Cream is a white to off white cream and comes in 5g, 15g, 30g, 40g and 50g tubes. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer.

Marketing authorisation holder:

Avianta Pharma EU Limited, Inniscarra, Main Street, Rathcoole,
Dublin D24
Ireland

Manufacturer:

Glaxo Operations UK Ltd. (trading as Glaxo Wellcome Operations) Hamire Road, Barnard Castle, Co. Durham, DL12 8DT, UK

This leaflet was last revised in May 2022.

Other sources of information

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.