

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Brevoxyl 4% Cream** 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 Brevoxyl 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 contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Brevoxyl is and what it is used for
2. Before you use Brevoxyl
3. How to use Brevoxyl
4. Possible side effects
5. How to store Brevoxyl
6. Further information

### **1. WHAT BREVOXYL IS AND WHAT IT IS USED FOR**

The name of your medicine is Brevoxyl 4% Cream (called Brevoxyl in this leaflet). Brevoxyl contains an active substance called **benzoyl peroxide**.

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

Brevoxyl is used to treat moderate acne (spots).

It helps to:

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

Brevoxyl is for use by adults and adolescents aged twelve years or over.

### **2. BEFORE YOU USE BREVOXYL**

#### **Do not use Brevoxyl if:**

- if you are allergic (hypersensitive) to benzoyl peroxide or any of the other ingredients (listed in Section 6). Do not use Brevoxyl 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 Brevoxyl**

- Only use Brevoxyl on your skin. Keep it away from areas like your eyes, eyelids, lips, mouth and inside the nose. If contact with these areas occurs, immediately wash the affected area with water.
- **Take care to avoid using** Brevoxyl on broken skin; for example, if you have cuts or grazes.
- **Take care when using** Brevoxyl **on areas of sensitive skin** such as your neck
- Brevoxyl 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 Brevoxyl.
- Avoid contact with hair, dyed or coloured fabrics (including clothing, towels and bed linen) furniture or carpeting. **Brevoxyl can bleach these materials.**

## **Children**

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

## **Using other medicines**

**Tell your pharmacist or doctor if you are taking any other medicines**, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

### **In particular, please tell your doctor or pharmacist:**

- if you are using any 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, Brevoxyl 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 Brevoxyl, your skin or facial hair may turn yellow or orange. This will not be permanent.

**Check with your doctor or pharmacist** if you think any of these may apply to you. Your doctor or pharmacist will decide if you should take Brevoxyl with these medicines or you may need to use your medicines at different times of the day (for example, one in the morning and the other at bedtime).

## **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before using Brevoxyl, if you are pregnant or breast-feeding.

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

- **Tell your doctor or pharmacist if you are pregnant**, planning to become pregnant or become pregnant during treatment with Brevoxyl.

It is not known whether benzoyl peroxide can pass into breast milk. If you are breast-feeding, you must check with your doctor or pharmacist before you use Brevoxyl

- **Do not use Brevoxyl on your breast** if you are breast-feeding.

## **Important information about some of the ingredients of Brevoxyl**

- Brevoxyl contains propylene glycol alginate. This may cause skin irritation.
- Brevoxyl also contains stearylalcohol and cetyl alcohol. These may cause local skin reactions (e.g. contact dermatitis).

## **3. HOW TO USE BREVOXYL**

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

- **Use Brevoxyl once or twice a day as instructed by your doctor or pharmacist.**
- Start with one application daily, preferably in the evening, then gradually increase to twice daily (morning and evening) as instructed.
- During the first weeks of treatment a sudden increase in peeling and reddening of the skin will occur in most people. If this causes you problems, try using Brevoxyl less often, or stop using it for a few days until the irritation goes away then start again. Stop using Brevoxyl if the irritation does not go away.
- 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 effects. This is normal for acne treatments.
- After 6 to 8 weeks if your acne is no better or it gets worse, talk to your doctor or pharmacist.
- Use Brevoxyl 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 for advice. If you stop too soon your acne may come back.

### **How to apply Brevoxyl**

1. Completely remove any make-up.
2. Wash your hands and the affected area and gently dry.
3. Put a **thin layer** of Brevoxyl cream on the affected skin, using your fingertips. If the cream does not rub into your skin easily, you are using too much.
4. Apply to **all of the area of your skin that has acne**, not just each spot. You may notice a mild burning sensation. If this becomes severe, stop using Brevoxyl and see your doctor.
5. **Take care not to use too much** Brevoxyl. Applying too much, or 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 cream.

### **If you forget to use Brevoxyl**

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

### **If you accidentally swallow Brevoxyl**

- Contact your doctor or pharmacist for advice. If you accidentally get Brevoxyl in your mouth, rinse it with plenty of water.

## **4. POSSIBLE SIDE EFFECTS**

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

### **Severe allergic reactions:**

Severe allergic reactions have occurred in a very small number of people but their exact frequency is not known. Signs include:

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

**Contact a doctor immediately** if you get these symptoms. Stop taking Brevoxyl immediately.

### **Other side effects include:**

Very common: may affect **more than 1 in 10 people**

- peeling of the skin and redness at the site of application

Common: may affect **up to 1 in 10 people**

- dryness, itching or sensitivity of the skin at the site of application

Uncommon: may affect **up to 1 in 100 people:**

- burning sensation.

Not known (cannot be estimated from the available data)

At site of application:

- rash
- 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 BREVOXYL**

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use Brevoxyl 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 Brevoxyl contains**

- The active ingredient is benzoyl peroxide. Brevoxyl contains 4% w/w benzoyl peroxide.
- 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 50g tubes.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Stiefel  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom

Manufacturer:  
Stiefel Laboratories (Ireland) Ltd  
Finisklin Business Park  
Sligo  
Ireland

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