

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aphtheal 5% w/w Oromucosal Paste amlexanox

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or dentist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 dentist.
- Aphtheal 5% Oromucosal Paste will be known as Aphtheal throughout this leaflet.

In this leaflet:

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

1. WHAT APHTHEAL IS AND WHAT IT IS USED FOR

Aphtheal contains the active ingredient amlexanox, which belongs to a group of medicines called anti-allergic and anti-inflammatory agents.

Aphtheal is used for the treatment of minor mouth ulcers (minor aphthous ulcers) in adults. It works by speeding up the healing and relieving the pain of minor mouth ulcers.

2. BEFORE YOU USE APHTHEAL

Do not use Aphtheal if:

- You are allergic (hypersensitive) to amlexanox or any of the other ingredients of Aphtheal. A full list of ingredients is provided in Section 6 “Further Information”
- You are under 18 years of age
- You are over 65 years of age.

Take special care with Aphtheal

Talk to your doctor or dentist before using Aphtheal if:

- You are being treated for kidney (renal) conditions
- You are being treated for liver (hepatic) conditions.

Taking or using other medicines

Please tell your doctor or dentist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Aphtheal should not be used if you are pregnant or breast-feeding.

Ask your doctor or dentist for advice before taking any medicine.

Driving and using machines

Aphtheal is unlikely to affect your ability to drive and use machines.

3. HOW TO USE APHTHEAL

Always use Aphtheal exactly as your doctor has told you. You should check with your doctor or dentist if you are not sure.

Adults

The usual dose is 0.5 cm of paste for each mouth ulcer.

Aphtheal should be applied as soon as possible after first noticing the symptoms of a mouth ulcer. Treatment with Aphtheal must be started no later than 48 hours after the first symptoms develop.

The paste should be applied four times daily after meals and cleaning your teeth. Suggested times are after breakfast, lunch, dinner and at bedtime.

How to apply Aphtheal:

- Before using Aphtheal you should wash your hands
- Dry the ulcer by gently patting with a soft clean cloth
- Squeeze 0.5 cm (a pea sized amount) of paste onto a wet finger tip
- Dab the paste onto the ulcer – do not rub it into the ulcer as this will cause irritation
- Repeat with a further 0.5 cm of paste for each further ulcer, up to a maximum of 3 ulcers
- After applying Aphtheal you should wash your hands.

IMPORTANT

- Do not treat more than three ulcers at a time unless your doctor or dentist has advised you differently.
- If Aphtheal comes into contact with your eyes, bathe your eyes with water several times.

How long to use Aphtheal for

You should use Aphtheal until the ulcer has healed, for up to a maximum of 7 days.

Consult your doctor or dentist if your mouth ulcer does not heal or if you are still in pain 10 days after you started treatment with Aphtheal.

If you use more Aphtheal than you should

If you swallow excessive amounts of Aphtheal, contact your doctor or go to the nearest hospital casualty department. Take the Aphtheal tube and pack with you.

Symptoms of overdose include feeling and being sick and diarrhoea.

If you forget to use Aphtheal

Apply the paste as soon as you remember and then continue with your next dose as normal.

Do not use a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

Immediately contact your doctor if you experience rapid swelling of the face or throat. You may be having a serious allergic reaction. This is a very rare side effect (likely to affect less than 1 in 10,000 people).

Most people find using Aphtheal causes no problems, however the following side effects have been reported:

Common side effects (likely to affect less than 1 in 10 people and more than 1 in 100)

- Temporary pain, stinging or burning sensation at the site of application.

Uncommon side effects (likely to affect less than 1 in 100 people and more than 1 in 1,000)

- Reddening and tenderness of the mouth lining (oral mucositis)
- Dry lips
- Bumps on the lips
- Feeling unwell or sick (nausea)
- Diarrhoea
- Allergic reaction at the site of application.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, dentist or pharmacist.

5. HOW TO STORE APHTHEAL

- Keep out of the reach and sight of children.
- Do not use Aphtheal after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 Aphtheal contains

Each 1 g of Aphtheal contains 50 mg of the active ingredient amlexanox.

The other ingredients are liquid paraffin, gelatin, pectin, carmellose sodium, glyceryl monostearate 40-55, soft white paraffin, benzyl alcohol.

What Aphtheal looks like and contents of the pack

Aphtheal is a granular, beige-coloured, paste. Aphtheal comes in plastic tubes containing either 3 or 5 grams of paste, with a screw cap. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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~~IrelandMeda Health Sales Ireland Limited,~~
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If this leaflet is difficult to see or read or you would like it in a different format, please contact:

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