PATIENT INFORMATION LEAFLET

APHTIN

(Borax)

200 mg/g mouth lotion

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

Use this medicine exactly as described in this leaflet or as your doctor or pharmacists has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or need advice, ask your pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- If your condition does not improve after 3–10 days or if your child's condition does not improve after 3–5 days or if you or your child feel worse, talk to your doctor.

What is in this leaflet

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

1. What Aphtin is and what it is used for

Aphtin is a solution to be used inside the mouth. Borax – the active ingredient, has a mild antiseptic effect. It disinfects the mucous membrane of the mouth.

Indications

Thrush – candidiasis on the mucous membranes of the mouth.

2. What you need to know before you use Aphtin

Do not use Aphtin

- if you are allergic to borax or any of the other ingredients of this medicine (listed in section 6);
- if your mucous membrane is damaged.

Warnings and precautions

Do not use the medicine when your mucous membrane of the mouth is extensively damaged.
Discontinue using it if you notice any lesions at the site where the solution is applied.
Do not swallow.
Use with caution if you have renal dysfunction.
Avoid long-term use.

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant or breastfeeding.

Ability to drive and use machines

The medicine does not affect the ability to drive or use machines.

Taking other medications

If you are using Aphtin, do not use any other topical medications inside the mouth, do not rinse your mouth with hygiene mouthwashes and do not chew gums.

3. HOW TO USE APHTIN

The medicine is intended for use in the mouth.
If your doctor has not told you otherwise, apply 1 or 2 drops of the medicine on the lesions in your mouth 2 or 3 times daily. Duration of treatment: 3 to 10 days.
Children older than 1 year old should not use this medicine longer than 3–5 days.

Use in children

Talk to your doctor before you use this medicine in a baby younger than 1 year-old.

If you feel that the effects of Aphtin are too strong of too weak, ask your doctor for advice.

If you forget to use Aphtin

If you forget to use Aphtin, continue using it as usual, according to the recommendations.

If you take more Aphtin than you should

It is unlikely to overdose Aphtin when used topically. If you use more than you should, wash it off of the mucous membrane with water or rinse your mouth and tell your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aphtin can cause side effects, although not everybody gets them.
If you use the medicine for a long time on damaged mucous membrane you may experience a rash, loss of appetite, vomiting, diarrhoea, menstrual disorders, convulsions or anaemia.
If any of the effects exacerbate or if you get any side effects not listed in this leaflet, talk to your doctor or pharmacist.

You can also report side effects directly to the Department for Monitoring Adverse Reactions of Medicinal Products of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:

ul. Ząbkowska 41
03-736 Warsaw, Poland
Tel.: + 48 22 49 21 301
Fax: + 48 22 49 21 309
e-mail: adr@urpl.gov.pl.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE APHTIN

Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the packaging.

Store in a closed packaging.

Do not use after the expiry date which is stated on the packaging. 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 what to do with medicines you no longer use. These measures will help protect the environment.

6. OTHER INFORMATION

What Aphtin contains
The active substance is borax.
1 g of the solution contains 200 mg of borax.
The remaining ingredient is glycerine – 86%.

What Aphtin looks like and contents of the pack
Aphtin is a colourless and odourless solution.

Available packsizes:
Polyethylene or amber glass bottles with a dropper and a cap for 10 g, 15 g or 30 g of the product.

Marketing Authorisation Holder and Manufacturer
Farmaceutyczne Przedsiębiorstwo Produkcyjno-Analityczno-Handlowe „PROLAB" Halkiewicz i Ratajczyk sp.j. Paterek, ul. Przemysłowa 3, 89-100 Nakło n/Notecią, Poland
Tel.: 52 386 73 10 Fax: 52 386 73 23

For more detailed information, contact the Marketing Authorisation Holder.

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