

Package leaflet: Information for the patient

Balpic 1 mg/g, gel
Dimetindene maleate

Please read this leaflet carefully before you start using this medicine, as it contains important information for you.

Take this medicine exactly as described in this leaflet, or as your doctor or pharmacist has told you.

Keep this leaflet. You may need to read it again.

If you need clarification or advice, please consult your pharmacist.

If you get any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

If you don't feel better or if it gets worse, you have to see a doctor.

What's in this leaflet:

1. What Balpic is and what it is used for
2. What you need to know before you use Balpic
3. How to use Balpic
4. Possible side effects
5. How to store Balpic
6. Package contents and other information

1. What Balpic is and what it is used for

Balpic is a gel for application to the skin. Balpic contains as active substance dimethindene maleate which has antihistamine effects.

The product reduces swelling, acts strongly as an antipruritic (with the exception of cholestatic itching), relieves skin irritations.

The drug has local anesthetic properties.

Therapeutic indications:

Insect bites, 1st degree burns, including solar ones.

Localized symptomatic treatment of eczema and dermatitis with prior medical diagnosis.

2. What you need to know before you use Balpic

Do not use Balpic

- if you are allergic (hypersensitive) to dimethindene maleate or any of the other ingredients of this medicine (listed in section 6);
- in case of second- and third-degree burns.

Warnings and precautions

Talk to your doctor or pharmacist before using Balpic.

If Balpic gel is applied to large areas of skin, prolonged exposure of the treated areas to sunlight should be avoided.

Tell your doctor if you have very severe itching or extensive changes.

Children

In infants and children (under 2 years of age) avoid use on large areas of the skin, especially in cases of skin injury and inflammation.

Other medicines and Balpic

Tell your doctor or pharmacist if you are using, or have recently used, or might use any other medicines.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

Do not use Balpic during the first three months of pregnancy. During the rest of pregnancy and while breastfeeding, Balpic should not be applied to large areas of the skin, especially in cases of skin injury or inflammation.

The gel should not be applied to the nipples while breastfeeding.

Driving and using machines

Balpic does not affect the ability to drive and use machines.

Balpic contains benzalkonium chloride and propylene glycol

Balpic contains benzalkonium chloride which is irritating and may cause skin reactions (skin reactions). It also contains propylene glycol which can cause skin irritation (skin irritation).

3.How to use Balpic

Use this medicine exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Balpic should be applied as a thin layer to the affected and itchy skin area 2-4 times a day.

If you use more Balpic than you should

No cases of overdose have been reported with dimethindene maleate applied topically to the skin.

If you take the medicine, you should contact your doctor immediately.

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.

Uncommon (may affect up to 1 in 100 people):
burning sensation on the skin, dry skin.

Very rare (may affect up to 1 in 10,000 people):
allergic dermatitis.

Reporting of side effects

If you get any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you will help provide more information about the safety of this medicine.

INFARMED, I.P.

Directorate of Drug Risk Management

Parque da Saúde de Lisboa, Av. Brazil

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Lisbon

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Drug Line: 800222444 (free of charge)

Fax: +351 21798 73 97

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>

E-mail: farmacovigilancia@infarmed.pt

5. How to store Balpic

Keep this medicine out of the sight and reach of children.

The medicinal product does not require any special storage precautions.

Store in the original packaging to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date corresponds to the last day of the month indicated.

After opening, it must be used within 36 months.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Balpic contains

The active substance is dimethindene maleate. Each gram of gel contains 1 mg of dimethindene maleate.

The other ingredients are carbomer (type 974 P), disodium edetate, sodium hydroxide, propylene glycol, benzalkonium chloride and purified water.

What Balpic looks like and contents of the pack

Balpic is a homogeneous, transparent and colourless gel.

Aluminum tube with diaphragm and HDPE screw closure in a cardboard package.

Tube: 30 g or 50 g

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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