PACKAGE LEAFLET: INFORMATION FOR THE USER

Blistex

Cold Sore Cream

100mg/g cream, Docosanol

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 Blistex Cold Sore Cream 100mg/g cream 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 stop using the cream and contact a doctor if your symptoms worsen or do not improve after 10 days.
- 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 pharmacist.

In this leaflet:

1. What is Blistex Cold Sore Cream 100mg/g cream and what it is used for
2. Before you use Blistex Cold Sore Cream 100mg/g cream
3. How to use Blistex Cold Sore Cream 100mg/g cream
4. Possible side effects
5. How to store Blistex Cold Sore Cream 100mg/g cream
6. Further information

1. WHAT Blistex Cold Sore Cream 100mg/g cream IS AND WHAT IT IS USED FOR

Docosanol is an antiviral agent. Blistex Cold Sore Cream 100mg/g cream is a white cream used for the treatment of early stages of recurrent labial herpes simplex infection (cold sores)) in adults and adolescents (over 12 years old).

To be effective, treatment with Blistex Cold Sore Cream 100mg/g cream should start in the early stages of a cold sore, before the blisters appear. Start using Blistex Cold Sore Cream 100mg/g cream as soon as you get any of the symptoms of a cold sore, such as redness, itching, pain, tingling or prickling. Continue using until the cold sore is healed, usually 4-6 days.

The cause of cold sores is a herpes simplex virus infection. The infection may break out when the immune system is weakened, during stress or during a menstrual period. The virus causes blisters or sores, mainly on the lips.

2. BEFORE YOU USE Blistex Cold Sore Cream 100mg/g cream

Do not use Blistex Cold Sore Cream 100mg/g cream

If you are allergic (hypersensitive) to docosanol or any of the other ingredients in the cream listed at the end of this leaflet (see section 6).

Take special care with Blistex Cold Sore Cream 100mg/g cream

- Blistex Cold Sore Cream 100mg/g cream is intended for cutaneous use only. Avoid getting the cream in or close to your eyes as this may cause irritation. If you accidentally get cream in your eyes rinse them thoroughly with plenty of water.

- Do not use this product if you have been told you are immunocompromised (if your immune system's ability to fight infectious diseases is known to be reduced, e.g. by a serious illness such as leukaemia or AIDS or if you may have had an organ transplant). If you are immunocompromised and you develop a cold sore you should consult your doctor immediately.
- Do not apply the cream if the cold sore has already formed a blister or ulcer like appearance.

Children

Children under 12 years should not use Blistex Cold Sore Cream 100mg/g cream.

Using other medicines

Blistex Cold Sore Cream 100mg/g cream should not be used with other topical products (medicines, cosmetic products, creams) at the same application site".

It is unlikely that Blistex Cold Sore Cream 100mg/g cream affects or is affected by other medicines since Blistex Cold Sore Cream 100mg/g cream is intended for cutaneous use only, however do not apply other cold sore medicines whilst using Blistex Cold Sore Cream 100mg/g cream.

Ask your pharmacist if you have any questions regarding how Blistex Cold Sore Cream 100mg/g cream is affected by, or affects, other medicines.

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

Pregnancy and breast-feeding

Blistex Cold Sore Cream 100mg/g cream can be used during pregnancy and breast-feeding.

Driving and using machines

Blistex Cold Sore Cream 100mg/g cream has no effect on driving or using machines.

Important information about some of the ingredients of Blistex Cold Sore Cream 100mg/g cream

Blistex Cold Sore Cream 100mg/g cream contains propylene glycol which can cause skin irritation.

3. HOW TO USE Blistex Cold Sore Cream 100mg/g cream

- Adults and adolescents over 12 years: Start treatment as soon as you notice the first symptoms or signs of a cold sore, for instance itching, stinging, burning or prickling in the affected area.
- Wash your hands thoroughly before and after treatment to avoid spreading the infection.
- Apply a thin film carefully over the entire cold sore five times a day. (Approximately every 3 hours during waking hours).
- Use a fingertip or, preferably, a cotton bud and avoid touching the end of the tube after you have touched the cold sore.
- Continue treatment until healing is complete, usually between 4 and 6 days.
- If you notice no difference after 10 days you should stop the treatment and contact your doctor.

- Remember that Blistex Cold Sore Cream 100mg/g cream is your medicine. If you lend the tube to anyone you risk spreading the infection to others.

If you use more Blistex Cold Sore Cream 100mg/g cream than you should

No serious problem should arise if you have used a large amount of the cream on your skin. No special treatment is necessary.

If you forget to use Blistex Cold Sore Cream 100mg/g cream

If you forget to use Blistex Cold Sore Cream 100mg/g cream, use it as soon as you remember.

If you have any further questions on the use of this product, ask your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Blistex Cold Sore Cream 100mg/g cream can cause side effects, although not everybody gets them.

For the frequency of occurrence of side effects, the following phrases are used: very common (more than 1 in 10 users), common (between 1 in 100 users and 1 in 10 users), uncommon (between 1 in 1000 users and 1 in 100 users), rare (between 1 in 10000 users and 1 in 1000 users), very rare (in less than 1 in 10000 users).

Nervous system problems:

Very common***:*** headache.

Skin problems:

Common: skin disorders including dry skin, skin rashes and facial swelling occurring where the cream has been applied.

If a more severe skin reaction occurs you should cease treatment, and if the problem does not disappear you should contact your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE Blistex Cold Sore Cream 100mg/g cream

Keep out of the reach and sight of children.

Do not use Blistex Cold Sore Cream 100mg/g cream after the expiry date which is stated on the carton and on the tube as “Expiry date month/year”. The expiry date refers to the last day of that month.

Discard 6 months after first opening the tube.

Do not store above 25ºC.

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 Blistex Cold Sore Cream 100mg/g cream contains

The active substance is docosanol. One gram of cream contains 100 mg docosanol.

The other ingredients are sucrose stearates, light mineral oil, propylene glycol, benzyl alcohol and purified water.

What Blistex Cold Sore Cream 100mg/g cream looks like and contents of the pack

Blistex Cold Sore Cream 100mg/g cream is a white cream.

It is available in pack sizes of 2 g, 5 g and 15 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

DDD Ltd., 94 Rickmansworth Road,
Watford, Herts, WD18 7JJ, UK.

Manufacturers

Fleet Laboratories Limited,
94 Rickmansworth Road, Watford,

Hertfordshire, WD18 7JJ, England.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	ERAZABAN 100 mg/g Creme
Belgium	ERAZABAN 100 mg/g Crème
Bulgaria	ERAZABAN 10 % Cream
Croatia	ERAZABAN 100 mg/g krema
Czech Republic	ERAZABAN 10 % Krém
France	ERAZABAN 10% crème
Germany	Muxan
Hungary	ERAZABAN 100 mg/g krém
Ireland	Blistex Cold Sore Cream, 100mg/g Cream
Poland	ERAZABAN 10 % Krem
Portugal	Erazaban 100 mg/g Creme
Romania	Erazaban 100 mg/g Cremă
Slovakia	ERAZABAN 10 % Krém
Slovenia	ERAZABAN 100 mg/g krema

Spain	ERAZABAN 100 mg/g crema
Sweden	Healip 10% Kräm
United Kingdom	Docosanol 10% Cream

This leaflet was last revised in June 2017