

PACKAGE LEAFLET: INFORMATION FOR THE USER

Anthisan cream 2% w/w

mepyramine maleate

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

Always use 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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

In this leaflet:

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

1. What Anthisan Cream is and what it is used for

Anthisan Cream contains a medicine called mepyramine maleate. This belongs to a group of medicines called antihistamines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction.

Anthisan Cream is used for treating:

Pain, itch and inflammation caused by insect stings, bites and nettle rash in adults and children aged 2 years and over.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you use Anthisan Cream

Do not use Anthisan Cream:

- If you are allergic to mepyramine maleate or any of the other ingredients of this medicine (listed in Section 6). The signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are pregnant, might become pregnant, or think you may be pregnant.
- If you are breast feeding or planning to breast feed.
- In premature infants and neonates

- With adhesive dressings

Do not apply the cream on:

- Eczema, acute dermatitis including inflamed, blistering or oozing skin.
- Cut, grazed or extensively broken skin.
- Areas of sunburnt skin
- Large areas of skin

Do not use this medicine if any of the above applies to you. If you are not sure talk to your doctor or pharmacist before using Anthisan Cream.

Warning and Precautions

Repeated application for periods longer than three days is not recommended and treatment should be discontinued immediately if skin sensitization occurs. If symptoms persist, consult a doctor.

Pregnancy and breast-feeding

Do not use Anthisan if you are pregnant or breast feeding.

Driving and using machines

If this medicine is used over large areas of skin, it may cause sleepiness and disorientation. If this happens do not drive or use any tools or machines.

Anthisan Cream contains

- Methyl parahydroxybenzoate. This may cause an allergic reaction (possibly delayed).
- Ceto-stearyl alcohol and Macrogol 600 Monostearate may cause local skin reactions (e.g. contact dermatitis).
- Castor oil. This may cause skin reactions.
- Silicone MS Antifoam. This may cause local irritation and local skin reactions, (e.g. contact dermatitis).
- Fragrance with benzyl benzoate, benzyl alcohol, benzyl salicylate, citral, Citronellol Coumarin, Farnesol, Geraniol, Hexyl cinnamal, Isoeugenol, Limonene and Linalool. These may cause allergic reactions.

3. How to use Anthisan Cream

- Apply the cream directly to the affected area of skin.
- Do not swallow the cream.
- Do not apply the cream on eczema, larger areas of skin, cut, grazed, badly broken or sunburnt skin.
- Apply the cream two to three times a day.
- Do not use the cream for longer than 3 days.
- For best results, use as soon as possible after the bite or sting.
- If your symptoms worsen or do not improve after 3 days talk to your doctor or pharmacist.

Children:

Do not use on children under 2 years of age.

If you use more Anthisan Cream than you should

If you use more Anthisan Cream than you should, contact your doctor. If the medicine is swallowed, seek immediate medical attention particularly in young children. Contact a doctor or go to a hospital casualty department immediately. Take the medicine pack with you. This is so the doctor knows what you or your child has taken.

The following effects could happen if the medicine is swallowed: loss of consciousness and fits (seizures).

If you forget to use Anthisan Cream

Do not apply a double amount of cream to make up for a forgotten application. Apply the cream as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

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

4. Possible side-effects

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

Stop using Anthisan Cream and see a doctor or go to a hospital straight away if you notice any of the following side effects:

- A severe allergic reaction. The signs may include rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Stop using Anthisan Cream and tell your doctor or pharmacist as soon as possible if you notice any of the following side effects:

- An increase in skin redness, swelling and itching in the area where the cream was used. This might be due to a mild allergic reaction.
- An increase in the sensitivity of the skin to sunlight in the area where the cream was used.
- Drowsiness and disorientation can occur if Anthisan Cream is applied to large areas of the skin.

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 Website: www.hpra.ie

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

5. How to store Anthisan Cream

Store below 25°C. Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

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

For external use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Anthisan Cream contains

The active substance is Mepyramine maleate 2%w/w.

The other ingredients are:

Cetostearyl alcohol, macrogol 600 monostearate, castor oil, methyl parahydroxybenzoate (E218), foin coupe (36% benzyl benzoate, 21% oil of cedarwood, other aromatic and essential oils), silicone MS antifoam (a mixture of liquid dimethicones containing finely divided silicone dioxide), purified water.

What Anthisan Cream looks like and contents of the pack

The cream is off-white to pale in colour with a smooth, fairly firm consistency. The tube contains 25g of cream and is packed in an outer carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Anthisan is a registered trademark.

This leaflet was last revised in June 2025