

SANOFI PACKAGING TEAM	
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Anthisan[®]

cream 2%w/w
mepyramine maleate

**Is this leaflet hard to see or read?
Phone +353 1 4035600 for help.**

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 Anthisan 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 contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ANTHISAN CREAM

Do not use this medicine and tell your doctor or pharmacist if:

- You are allergic (hypersensitive) to mepyramine maleate or any of the other ingredients of Anthisan Cream (listed in Section 6 below). 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.

Do not use this medicine:

- In premature infants and neonates.
- With adhesive dressings.

Do not apply the cream on:

- Eczema
- 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without prescription, including herbal medicines.

Pregnancy and breast-feeding

This medicine should not be used 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 or disorientation. If this happens do not drive or use any tools or machines.

Important information about some of the ingredients of Anthisan Cream

This product contains:

- Methyl parahydroxybenzoate. This may cause an allergic reaction. This allergy may happen some time after starting the medicine.
- Ceto-stearyl alcohol. This may cause local skin reactions (eg. contact dermatitis).
- Castor oil. This may cause skin reactions.
- Benzyl benzoate. This can be a mild irritant to the skin, eyes and mucous membranes.



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3. HOW TO USE ANTHISAN CREAM

If you are not sure how to use this medicine, check with your doctor or pharmacist.

- Apply the cream directly to the affected area of skin.
- 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.

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 accidentally 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, Anthisan Cream 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.
- Occasionally drowsiness 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, pharmacist or nurse.

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: www.hpra.ie; email: medsafety@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 30°C. Do not use Anthisan Cream 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 OUT OF THE REACH AND SIGHT OF CHILDREN.

FOR EXTERNAL USE ONLY.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Anthisan Cream contains

The active substance is Mepyramine maleate 2%w/w. Other ingredients include:

Cetostearyl alcohol, macrogol 600 monostearate, castor oil, methyl parahydroxybenzoate (E218), foin coupe (36% benzyl benzoate, 21% oil of cedarwood, other aromatics 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:

Opella Healthcare France SAS, T/A Sanofi,

82 Avenue Raspail,

94250 Gentilly, France.

Tel: +353 1 4035600

Email: IMedinfo@sanofi.com

Manufacturer:

Sanofi -Winthrop Industrie,

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45200 Amilly,

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