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PACKAGE LEAFLET: INFORMATION FOR THE USER Anthisan[®] 2%w/w Cream Mepyramine maleate

PHOENIX LABS

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, pharmacist or nurse has told you.

- · Keep this leaflet. You may need to read it again
- · Ask your pharmacist if you need more information or advice
- · You must talk to a doctor if do not feel better or if you feel worse after 3 davs
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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What is 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 may be provided directly by a pharmacist for use in the following situation:

• Pain, itching and inflammation caused by insect stings, bites and nettle rash

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

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

Do not use this medicine if:

imes 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: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue



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Do not apply the cream on:

X Eczema

× Extensively broken 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.



0ther medicines and Anthisan Cream

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, talk to your doctor, pharmacist or nurse for advice before using this medicine.



Driving and using machines

You may feel drowsy or sleepy while using this medicine. If this happens, do not drive or use any tools or machines.

Anthisan Cream contains ceto-stearyl alcohol, castor oil and methyl hvdroxybenzoate.

This medicine contains:

- Ceto-stearyl alcohol and castor oil. These may cause local skin reactions (such as "contact dermatitis" which may include the following symptoms: skin redness, swelling and itching, pain or burning sensation).
- Methyl hydroxybenzoate. This may cause an allergic reaction, possibly delayed. This reaction may happen some time after starting the medicine

3. How to use Anthisan Cream

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

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Adults, Elderly and Children

The recommended dose is two or three times a day for up to three days:

- Apply the cream directly to the affected areas of skin
- · Do not apply the cream on eczema and badly broken skin
- For best results, use as soon as possible after the bite or sting
- Repeated use of the cream for periods longer than a few days is not recommended
- If your symptoms worsen or do not improve after 3 days talk to your doctor or pharmacist

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor or pharmacist.

If you use more Anthisan Cream than you should

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

The following effects may happen: 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, then carry on as before.

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

4. Possible side effects

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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:

• An allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Stop using Anthisan Cream and tell a pharmacist if you notice the following side effect:

• An increase in skin redness, swelling and itching in the area where you have used the cream. This might be due to a mild allergic reaction

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 Yellow Card Scheme at: "http://www.mhra. gov.uk/yellowcard" or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

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5. How to store Anthisan Cream

- · Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton flap or tube after EXP. The expiry date refers to the last day of that month
- Do not store above 30°C

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 to protect the environment.

6. Contents of the pack and other information

What Anthisan Cream contains:

- Each 1g of cream contains 20mg of the active substance, mepyramine maleate
- The other ingredients are ceto-stearyl alcohol, polyethylene glycol 600 monostearate, castor oil, methyl hydroxybenzoate, foin coupe (fragrance), silicon antifoam and purified water

What Anthisan Cream looks like and contents of the pack

A smooth off-white cream contained within a collapsible aluminium tube with extended nozzle and polypropylene cap. The tube contains 25 grams of cream.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co.Meath, Ireland. Tel: +353-1-5742410 email: medicalinformation@phoenixlabs.ie

<u>Manufacturer</u> Sanofi Winthrop Industrie 196, Rue du Maréchal Juin 45200 Amilly France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in June 2023