

PACKAGE LEAFLET: INFORMATION FOR THE USER

SYNOPE

10 mg / g Ointment

CHLOROPYRAMINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What SYNOPE is and what it is used for
2. Before you take SYNOPE
3. How to take SYNOPE
4. Possible side effects
5. How to store SYNOPE
6. Further information

1. WHAT SYNOPE IS AND WHAT IS IT USED FOR

The active substance of SYNOPE ointment is chloropyramine. It is antihistamine that has a very strong effect. Chloropyramine works by blocking the action of histamine, a substance that is produced in our bodies which participates in the development of allergic reaction. When applied to the skin, it alleviates symptoms of allergies.

Ointment soothes and relieves itching 5-10 minutes after application.

SYNOPE ointment is used for insect bites and itching, for short-term alleviation of localized itching or symptoms resulting from insect bites.

2. BEFORE YOU TAKE SYNOPE

Do not take SYNOPE

- If you are allergic (hypersensitive) to chloropyramine or any of the other ingredients in this medicine
- If your skin is infected and wet, or if you have eczema.

Take special care with SYNOPE

SYNOPE ointment should not be used on large areas of skin and open wounds.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During pregnancy and breastfeeding, SYNOPEN should be applied only if it is necessary, in small quantities, and during a short period of time.

Driving and using machines

SYNOPEN has no effect on your ability to drive or operate machinery.

3. HOW TO USE SYNOPEN

Always take SYNOPEN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

SYNOPEN ointment is applied in a thin layer and rubbed on the diseased part of the skin two or three times a day.

After applying the ointment, wash your hands!

If during the use of SYNOPEN your symptoms get worse or if they do not alleviate after 3 days of the application of the medicine, it is necessary to consult a doctor.

If you use more SYNOPEN than you should

The overdose during the use of SYNOPEN ointment has not been recorded.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

There is a possibility that you may develop photosensitivity (sensitivity of the skin when exposed to sunlight), hypersensitivity reactions (allergic reactions), and particularly allergic reactions on the skin (hives).

After applying to large areas of the skin, systemic side effects were reported.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE SYNOPEN

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Storage conditions:

Do not store above 25 °C.

Shelf life: 3 years.

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 SYNOPEN contains

The active substance is chloropyramine hydrochloride.

1 g of ointment contains 10 mg of chloropyramine hydrochloride.

Other ingredients: stearic acid 50; glycerol; paraffin, solid; wax, white; trolamine; ethylene glycol monopalmitostearate; stearyl; ammonia, concentrated solution; sodium lauryl sulfate; methyl; smell: Chemoderm 839; propyl; oksihinolin sulfate.

What SYNOPEN looks like and contents of the pack

Homogeneous ointment, white in color.

Aluminum tube; 20 g.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Pliva Croatia doo, Access Barona Filipovica 25, Zagreb, Croatia