

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xepin 5% w/w Cream

doxepin hydrochloride



Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 Xepin 5% w/w Cream is and what it is used for
2. Before you use Xepin 5% w/w Cream
3. How to use Xepin 5% w/w Cream
4. Possible side effects
5. How to store Xepin 5% w/w Cream
6. Further information

1. WHAT XEPIN 5% w/w CREAM IS AND WHAT IT IS USED FOR

Xepin 5% w/w Cream is a white moisturising cream for application to the skin. Xepin 5% w/w Cream is applied to relieve itching associated with eczematous dermatitis.

2. BEFORE YOU USE XEPIN 5% w/w CREAM

Do not use Xepin 5% w/w Cream if you

- are allergic (hypersensitive) to doxepin hydrochloride or any of the other ingredients of Xepin 5% w/w Cream (see section 6).

Take special care with Xepin 5% w/w Cream

Before treatment with Xepin 5% w/w Cream if you have any of the following please talk to your doctor before using the cream

- glaucoma
- a tendency to retain urine
- severe liver disease
- depression
- severe heart disease including disorders of the rhythm of the heartbeat.

Xepin 5% w/w Cream can cause drowsiness or sleepiness. You should not drink alcohol while you are using Xepin 5% w/w Cream, as this can make the drowsiness worse.

Taking 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.

- If you are taking medication for depression called monoamine-oxidase inhibitors, you should have stopped taking this medicine before starting to use Xepin 5% w/w Cream.
- Tell your doctor if you are taking a medicine called Cimetidine before using Xepin 5% w/w Cream.

Do not stop taking your medicine unless your doctor has told you to.

Tell your doctor, pharmacist or dentist that you are using Xepin 5% w/w Cream before having general or local anaesthesia.

Pregnancy and breast-feeding

Do not use Xepin 5% w/w Cream if you are pregnant, think that you may be pregnant or if you are breast-feeding. Please ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive if you feel drowsy after using Xepin 5% w/w Cream.

Do not use any tools or machines if you feel drowsy after using Xepin 5% w/w Cream.

Important information about some of the ingredients of Xepin 5% w/w Cream

Xepin 5% w/w Cream contains cetyl alcohol which can cause local skin reactions such as contact dermatitis.

3. HOW TO USE XEPIN 5% w/w CREAM

Always use Xepin 5% w/w Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Xepin 5% w/w Cream should not be used on children under the age of 12 years.

Usual Dose

Apply a thin film of cream only to the affected areas of the skin, 3 to 4 times a day or as directed by your doctor.

Do not cover the cream with a bandage or with tight clothing, unless your doctor has told you to do this. Do not apply near the eyes.

Do not apply the cream to more than 10% of the surface area of the body as it will increase the likelihood of drowsiness and dryness in the mouth. The diagram below shows how to estimate 10% of the surface area of the body. A total area equivalent to 10% of the body surface area is approximately:

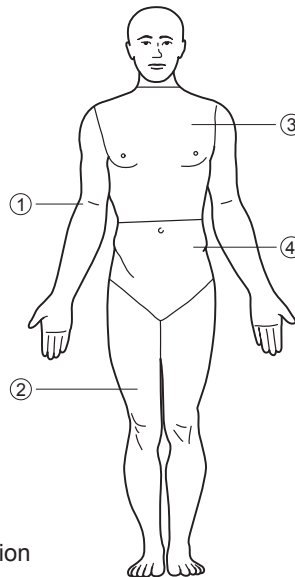
one whole arm (1) the front or back of a leg (2) half the torso (3 and 4)

However this 10% can be made up of several smaller patches (for example knees, face and hands).

If you use more Xepin 5% w/w Cream than you should

If you use more Xepin 5% w/w Cream than you should, wash it off immediately. If you are at all worried, contact your doctor.

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



4. POSSIBLE SIDE EFFECTS

Like all medicines, Xepin 5% w/w Cream can cause side effects, although not everybody gets them.

Xepin 5% w/w Cream can cause drowsiness or sleepiness, especially during the first few days of treatment.

Other possible side effects include:

- Skin reactions such as burning, stinging, irritation, tingling and rash.

More rare side effects include:

- dry mouth
- blurred vision
- fever
- indigestion
- depression, suicidal thoughts
- changes in taste
- difficulty passing urine
- dizziness
- vomiting
- dry eyes
- headaches
- nausea
- diarrhoea or constipation

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 the Yellow Card Scheme at: www.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE XEPIN 5% w/w CREAM

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use Xepin 5% w/w Cream after the expiry date that is stated on the tube and the carton after EXP. The expiry date refers to the last day of the month.

If your doctor tells you to stop using Xepin 5% w/w Cream, take the tube back to the pharmacist for safe disposal. Medicines should not be disposed of via household waste. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Xepin 5% w/w Cream contains

- The active substance is doxepin hydrochloride, 5% w/w
- The other ingredients are sorbitol solution 70%, cetyl alcohol, isopropyl myristate, PEG 100 stearate, glyceryl stearate, white soft paraffin, benzyl alcohol, titanium dioxide and purified water.

What Xepin 5% w/w Cream looks like and contents of the pack

Xepin 5% w/w Cream comes in aluminium tubes containing 30g, 60g or 120g Xepin 5% w/w Cream. Not all pack sizes may be available.

Marketing Authorisation Holder: Cambridge Healthcare Supplies Ltd, Chestnut Drive, Wymondham, Norfolk NR18 9SB, UK

Manufacturer: Bioglan AB, PO Box 50310, Borrkatan 31, S – 202 13, Malmö, Sweden.

Date of revision: March 2015.

910623