

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zipzoc°

20% zinc Oxide Impregnated Dressing (Stocking)

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 have told you.

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

In this leaflet

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1 What Zipzoc is and what it is used for

ZIPZOC is a sterile rayon stocking impregnated with an ointment containing 20% w/w Zinc Oxide. Zinc Oxide has a soothing and protective effect.

ZIPZOC is used:

- as an aid in the treatment of chronic venous leg ulcers
- if you have poor circulation in your veins (causing poor return of circulating blood from the feet and legs to the heart, known as chronic venous insufficiency), as a primary contact layer under compression bandaging or hosiery.

2 What you need to know before you use ZIPZOC

DO NOT use ZIPZOC if you:

- are allergic to zinc oxide or any of the other ingredients of this medicine (listed in section 6)
- have used ZIPZOC before and suffered a reaction to it
- suffer from arterial leg ulcers (ulcers caused by poor circulation in arteries rather than veins).

Consult your doctor, pharmacist or nurse immediately if you are unsure what kind of ulcer you have.

Warning and precautions

If the outer bandage is inappropriate or the stocking is not changed often enough it can cause the stocking to dry out.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and ZIPZOC

Please tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Pregnancy and breast-feeding

There is no evidence to suggest that ZIPZOC should not be used during pregnancy or breast-feeding.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Driving and using machines

ZIPZOC is unlikely to affect driving or the use of machines.

3 How to use ZIPZOC

Always use ZIPZOC exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure. The length of time you will need to use ZIPZOC for and the number of times you will need to change it will depend on your circumstances. Your doctor, pharmacist or nurse will advise you.

Wash your hands thoroughly before applying the stocking.

- slip your foot into the stocking and draw it up on the lower part of the leg from the base of the toes to the knee
- smooth out any folds or wrinkles
- fold any excess stocking below the knee
- if you have a larger than normal calf size you must take care to apply the stocking without constricting the lower leg
- an outer bandage may be applied by the nurse to compress the leg if you have poor circulation and/or to prevent soiling of clothes
- change the dressing at least once a week to avoid the risk of infection and also to avoid the stocking drying out

4 Possible side effects

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

Very rare (affect less than 1 person in 10 000)

- pain at the site of the ulcer
- swelling of the leg (oedema)
- local skin reactions such as rash, reddening and itching
- further deterioration of the wound

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This

includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store (UK). And HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: HYPERLINK "http://www.hpra.ie" www.hpra.ie; E-mail: HYPERLINK "mailto:medsafety@hpra.ie" medsafety@hpra.ie (IE). By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store your ZIPZOC

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

Do not use after the expiry date, which is stated on the pouch or the outer carton. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicine 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 ZIPZOC contains

- the active substance is zinc oxide 20% w/w
- each stocking also contains white soft paraffin and liquid paraffin

What ZIPZOC looks like and the contents of the pack

- ZIPZOC is a sterile rayon stocking, length 80cm
- Each medicated stocking is wrapped in a polyethylene foil laminated pouch in a printed carton
- ZIPZOC is supplied in outer cartons which may contain 4 or 10 bouches

Marketing Authorisation Holder (UK):

Evolan Pharma AB Box 120 182 12 Danderyd, Sweden

Product Authorisation Holder (Eire):

Evolan Pharma AB Box 120 182 12 Danderyd, Sweden

Manufacturer:

Purna Pharmaceuticals NV Rijksweg 17 2870 Puurs, Belgium

Marketing Authorisation Numbers:

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