

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zipzoc 20%, Impregnated Dressing

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

20 % Zinc Oxide

Each stocking (80 cm x 7 cm) contains about 41.5g of ointment

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Impregnated dressing.

Zipzoc is a sterile rayon stocking impregnated with an ointment containing Zinc Oxide.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To be used as an aid in the treatment of chronic venous leg ulcers. Where chronic venous insufficiency exists the stocking can be used as a primary contact layer under compression bandaging or hosiery.

4.2 Posology and method of administration

Posology

Zipzoc should be applied to cover the lower leg from the base of the toes to below the knee. All folds should be smoothed out. In the case of excessive calf size care should be taken to apply the stocking without constricting the lower leg. A suitable outer bandage or dressing should be used to prevent soiling of clothes. If chronic venous insufficiency exists, Zipzoc can be used as a primary contact layer under suitable compression bandaging.

The duration and frequency of application will depend on the clinical circumstances, but Zipzoc must be changed no less frequently than weekly.

Method of administration

For cutaneous use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Arterial leg ulcers.

4.4 Special warnings and precautions for use

If the outer bandage is inappropriate or the stocking is not changed with sufficient frequency it can cause the stocking to dry out.

4.5 Interaction with other medicinal products and other forms of interactions

None known

4.6 Fertility, pregnancy and lactation

There is no evidence to suggest Zipzoc should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

It is unlikely to have an effect.

4.8 Undesirable effects

General disorders and administration site conditions

Very rare: Application site pain

Very rare: Oedema

Skin and subcutaneous tissue disorders

Very rare: Application site folliculitis

Very rare: Erythema.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Website: www.hpra.ie;

4.9 Overdose

None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC-code: D09A B01

The stocking consists of tubular rayon gauze impregnated with zinc oxide Ph Eur 20% in an ointment base. Zinc oxide has a soothing and protective effect. Zipzoc has no effect on the underlying condition of chronic venous leg ulcers, but can be used under appropriate compression bandaging where chronic venous insufficiency is the problem.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Nothing relevant to add to the prescribing information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ointment base consists of:

Liquid Paraffin
White Soft Paraffin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Polyethylene aluminium foil laminated pouches, each pouch containing a single stocking.
The outer carton will contain 1, 4 or 10 pouches.

Each pouch contains a tubular rayon gauze stocking impregnated with about 41.5g of ointment.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Evolan Pharma AB
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182 12 Danderyd
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8 MARKETING AUTHORISATION NUMBER

PA2262/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 1998
Date of last renewal: 01 October 2006

10 DATE OF REVISION OF THE TEXT

November 2020