Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Desenex Ointment Zinc Undecylenate 20% w/w Undecylenic Acid 5% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Undecylenate 20.0 % w/w
Undecylenic Acid 5.0 % w/w

Excipients with known effect
Contains wool fat 3.0 % w/w, methyl parahydroxybenzoate (E218) 0.3 % w/w, propyl parahydroxybenzoate (E216) 0.075 % w/w and benzyl benzoate (Max 0.25% w/w).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment
A white to cream coloured smooth ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Desenex is recommended in the prophylaxis and treatment of mycotic superficial dermatophytoses of feet and the relief of itching and scaling produced by these fungal infections. Is it also used to remove foot odour and prevent sweating.

4.2 Posology and method of administration

Posology:
For topical administration only.

General directions:
Apply a smooth even coating of ointment to affected areas as required or use as directed by the physician

Feet:
Twice daily, wash and dry the infected area, apply ½ inch (12.7 mm) ribbon of ointment and rub gently between toes and on feet. Spread evenly.

Continue treatment for two weeks after symptoms disappear. If there is no improvement after 2 weeks treatment or symptoms worsen consult your doctor or pharmacist.

To prevent reinfection, use Desenex Powder daily.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Not recommended for nail or scalp infections.

Do not use on children under 2 years of age, except under the advice and supervision of a doctor.

If there is no response within 2 weeks, or the condition is aggravated, use of the product should be stopped and the physician should be consulted.

Desenex ointment contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may be mildly irritant to the skin, eyes and mucous membranes and may cause allergic reactions, possibly delayed.

Desenex ointment also contains benzyl benzoate which may cause local irritation.

Desenex ointment also contains wool fat which may cause local skin reactions e.g. contact dermatitis.

Do not apply to broken skin

4.5 Interaction with other medicinal products and other forms of interactions

There are no known interactions.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Zinc Undecylenate and Undecylenic Acid in pregnant women, pregnancy and lactation

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Summary of the safety profile.

Adverse reactions have been ranked under headings of frequency using the following convention:
1. Very common (≥ 1/10);
2. Common (≥ 1/100, < 1/10);
3. Uncommon (≥ 1/1000, < 1/100);
4. Rare (≥ 1/10000, < 1/1000);
5. Very rare (< 1/10000)
6. Not known (cannot be estimated from the available data).

System Organ Class	Incidence	Adverse reaction
Skin and subcutaneous tissue disorders	Not known	Mild irritation of the skin. Local skin reactions e.g. contact dermatitis. Allergic reactions. Irritant to the mucous membranes
Eye disorders	Not known	Mild irritation to the eyes

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Undecylenic Acid, combination
ATC Code: D01AE54

Zinc undecylenate and undecylenic acid have antifungal properties and are applied topically in the prophylaxis and treatment of mycotic superficial dermatophytoses and the relief of itching and scaling produced by these fungal infections. Applied topically for superficial treatment of fungal infections.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid sorbitol (non-crystallising) (E420)
Polyoxyethylene laurate
White soft paraffin
Wool fat
Polyethylene glycol monostearate 616
Ethylene glycol monostearate MN
Stearic acid
Trolamine
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Perfume undeca 4875*
Purified water

*contains : Benzyl benzoate, eugenol, isoeugenol and phenyl ethyl alcohol white

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Aluminium tube lined with epoxy/phenolic resin lacquer and fitted with a white polythene cap. The tube is presented in an outer carton.

Pack size: 30g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/154/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th March 1998

Date of last renewal: 20th March 2008

10 DATE OF REVISION OF THE TEXT

June 2020