

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Morhulin Ointment
Cod Liver Oil 11.4% w/w
Zinc Oxide 38% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients: The ointment contains 38.0 % w/w Zinc Oxide and 11.4 % w/w Cod Liver Oil.

Excipients with known effect: Contains 10% w/w wool fat

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

Smooth, white homogenous ointment with the characteristic odour of cod liver oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Morhulin Ointment promotes the healing of nappy rash, protects irritated skin and soothes minor skin irritations and superficial trauma.

4.2 Posology and method of administration

Posology

Nappy rash: To help prevent nappy rash, apply a smooth even coating of ointment at each nappy change.

Method of administration

Apply to the affected area after cleansing and drying.
For cutaneous use only.

4.3 Contraindications

Hypersensitivity to the active ingredients, lanolin or to any of the other ingredients of the ointment listed in section 6.1.

4.4 Special warnings and precautions for use

If symptoms persist, the doctor should be consulted. In rare cases, rashes may occur.

This product contains wool fat (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Morhulin Ointment may be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Morhulin Ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

In rare cases, rashes may occur.

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

In the case of deliberate or accidental ingestion, large quantities of Morhulin Ointment, symptomatic and supportive treatment should be provided.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Emollients and Protectives, Zinc Products.ATC code: D02AB

Zinc Oxide has mild astringent and protective properties. Morhulin Ointment protects irritated skin and soothes minor skin irritations and superficial trauma. Cod liver oil promotes healing of wounds. The oil contains glyceryl ethers which have a direct action on tissues of mesenchymal origin which may explain the healing properties of cod liver oil. Cod liver oil also contains vitamin A which contributes to its healing effects.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Yellow soft paraffin
Wool fat
Castor oil
Dilute sodium hypochlorite solution

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube with a screw cap (high density polypropylene) containing 50 g of product.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

8 MARKETING AUTHORISATION NUMBER

PA1380/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983
Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

July 2015