

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Unguentum M Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients: None.

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Cream

A white water –miscible cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

1. Unguentum M is used as a diluent for topical corticosteroid formulations in those instances where a lower strength preparation is considered desirable by the physician.
2. As an adjunct to topical steroid therapy.
3. As an emollient to protect the skin during remissions of various dermatoses, against contact irritants and older agents likely to damage the skin and to treat the symptoms of dry skin associated with dermatitis, pruritus, ichthyosis etc.

4.2 Posology and method of administration

A thin application of the cream should be gently massaged into the skin two or three times daily.

When used as a protective cream Unguentum M should be applied sparingly to the affected areas before, or immediately after, exposure to a potentially harmful factor.

4.3 Contraindications

Sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Unguentum M contains the excipient cetostearyl alcohol, 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 Pregnancy and lactation

No evidence of any harmful effect on the use of Unguentum M in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

No effect.

4.8 Undesirable effects

Allergic reactions and allergic contact dermatitis.

4.9 Overdose

None.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Unguentum M is an ambiphilic topical preparation with emollient properties which maintains the high lipid content of an ointment but has the water mixable characteristics of a cream. The high lipid content reduces water loss from the skin and therefore has a hydrating effect which permits the recovery from dermatitis, eczema, and dry or scaly skin conditions. Unguentum M also contains sorbic acid which has an antibacterial effect.

5.2 Pharmacokinetic properties

Unguentum M is for topical use only and contains no specific active ingredient. There are no pharmacokinetic data for this product.

5.3 Preclinical safety data

Since Unguentum M is intended for topical use only and contains no active ingredients, toxicological data is limited.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide solution 32%
Colloidal anhydrous silica
White soft paraffin
Liquid paraffin
Cetostearyl alcohol
Polysorbate 40
Glycerol monostearate 40-55
Medium chain triglycerides
Sorbic acid
Propylene glycol
Purified water

6.2 Incompatibilities

No compatibility studies with other topical medications have been performed.

6.3 Shelf Life

Unopened: 5 years.

Any remaining contents should be discarded 6 months after first opening.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Collapsible aluminium tubes of 10,30,50,60 and 100 grams.
Not all pack sizes may be marketed.

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

Crookes Healthcare Limited
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8 MARKETING AUTHORISATION NUMBER

PA 43/32/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 November 1975

Date of last renewal: 27 November 2005

10 DATE OF REVISION OF THE TEXT

April 2006