

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Quellada-M Cream Shampoo 1.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Malathion 1.0% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Shampoo

A smooth, light orange, pearlescent cream shampoo.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of head lice and pubic lice infestation.

This product is intended for treatment only and not prevention of lice or scabies.

4.2 Posology and method of administration

For topical external use only

Adults, the elderly and children aged 6 months and above

For Head Lice

1. Wet the hair thoroughly with warm water and apply sufficient shampoo to work up a rich lather and ensure that no part of the scalp is left uncovered. Pay special attention to the back of the neck and the area behind the ears. Take care to avoid the eyes.
2. Leave for at least five minutes.
3. Rinse thoroughly with clean water and repeat procedure.
4. While the hair is still wet, comb with an ordinary comb. The fine-toothed louse comb can then be used to remove the dead lice and eggs.
5. This treatment should be carried out a total of three times at three day intervals.

For Pubic Lice

Application and dosage are as for the head. Apply the lotion to the pubic hair and the hair between the legs and arms.

4.3 Contraindications

Known hypersensitivity to active constituents.

Not to be used on infants less than six months old except on medical advice.

4.4 Special warnings and special precautions for use

1. The eyes should be well protected during application and washing of hair.
2. Persons applying this product should wear rubber gloves so that their continued direct contact is avoided.
3. All members of the household of the patient should be treated, preferably simultaneously.
4. The source of the infestation should be sought and treated.
5. This product is poisonous if ingested. If accidentally swallowed, contact your local doctor or hospital immediately.
6. Prolonged continued application should be avoided.
7. Keep out of the reach of children.
8. Children under the age of 6 months should only be treated under medical supervision.
9. The lotion should not be applied to damaged skin except after medical consultation.

4.5 Interaction with other medicinal products and other forms of interaction

None stated

4.6 Pregnancy and lactation

No known effects in pregnancy and lactation. However, as with all medicines, use with caution.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Very rarely skin irritation has been reported with malathion products

4.9 Overdose

It is most unlikely that a toxic dose of malathion will be ingested. Treatment consists of gastric lavage, assistant respiration and, if necessary in the event of massive ingestion, administration of atropine together with pralidoxime.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Quellada-M Cream Shampoo contains malathion, a widely used organophosphorus insecticide which is active by cholinesterase inhibition. It is effective against a wide range of insects, but is one of the least toxic organophosphorus insecticides since it is rapidly detoxified by plasma carboxylesterases.

5.2 Pharmacokinetic properties

Quellada-M Cream Shampoo is applied topically to the affected area.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium laurilsulfate paste
Cetostearyl alcohol
Lauric diethanolamide
Ethyoxylated lanolin 50%
Propyl Parahydroxybenzoate (E216)
Methyl Parahydroxybenzoate (E218)
Hydrochloric acid
Citric acid anhydrous
Dibasic sodium phosphate
FD&C Yellow (E110)
Sodium Edetate
Perfume M&B 1658
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

18 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Cartoned, internally lacquered aluminum tube with polyethylene cap containing 40g of product.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ultra Chemicals Limited
Tubiton House,
Oldham,
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UK.

8 MARKETING AUTHORISATION NUMBER

PA 858/1/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th November 1998

Date of last renewal: 13th November 2003

10 DATE OF REVISION OF THE TEXT

April 2005