

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Quellada-M Liquid Cutaneous Emulsion 0.5% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Malathion 0.5% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous emulsion

A white, creamy, perfumed cutaneous emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of severe infestation of scalp or pubic hair with lice (T. Pediculosis).
For the treatment of scabies.

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

4.2 Posology and method of administration

Topical external use only

Adults including the elderly and children over 6 months of age

Treatment of Head Lice

Rub the liquid into the scalp until all the hair and scalp is thoroughly moistened. Leave the hair to dry naturally in a warm but well ventilated room. After 12 hours, or the next day, if preferred, shampoo hair in the normal way. Rinse the hair and comb whilst wet to remove dead lice and eggs (nits) using the louse comb.

Treatment of Crab (Pubic) Lice

Apply Quellada-M Liquid to the entire skin surface. Pay particular attention to all the hairy areas including beards and moustaches. Avoid any other areas above the neck. Leave on for at least one hour before washing but preferably Quellada-M Liquid should be left on overnight. Wash off in the usual manner.

Treatment of Scabies

Apply Quellada-M Liquid to the entire skin surface. In adults it may not be necessary to apply above the neck but children under the age of two years should have a thin film of Quellada-M Liquid applied to the scalp, face and ears, avoiding the eyes and mouth.

Do not wash off or bathe for 24 hours. If hands or any other parts must be washed during this period, the treatment must be re-applied to those areas immediately.

No special sterilisation of clothing is necessary, ordinary laundering or dry-cleaning with hot-iron pressing are sufficient.

The infestation is cleared by the treatment. However, the itching and rash may persist for up to 7 days. An anti-irritant

cream can be applied if necessary.

Family members and close contacts should be also treated simultaneously.

Children aged 6 months and under

On medical advice only.

4.3 Contraindications

Known sensitivity to active constituents. Not to be used on infants less than 6 months except on medical advice.

4.4 Special warnings and special precautions for use

The eyes should be well protected during the application and washing of hair.

Persons applying this product should wear rubber gloves so that their continued direct contact is avoided.

All members of the household of the patient should be treated, preferably simultaneously.

The source of infestation should be sought and treated.

This product is poisonous if ingested. If accidentally swallowed, contact your local doctor or hospital immediately.

Prolonged continued application should be avoided.

Keep out of the reach of children.

Children under the age of 6 months should only be treated under medical supervision.

The emulsion 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, assisted 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 Liquid 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 Liquid is applied topically to the affected area.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Emulsifying Wax

(Contains cetostearyl alcohol)

Potassium citrate

Citric Acid Monohydrate

Perfume HT 52

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

30 months.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Cartoned, clear or amber glass bottles with polyethylene caps and polypropylene faced wad, containing 50, 55, 100, 200 or 210ml.

Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ultra Chemical Ltd,
Tubiton House,
Oldham,
Lancashire, OL1 3HS,
UK.

8 MARKETING AUTHORISATION NUMBER

PA 858/1/1

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