Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Calamine Lotion, cutaneous suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine 15% w/v
Zine Oxide 5% w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous Suspension.

Calamine Lotion is a pale pink lotion which separates on standing. It has a faint characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Calamine Lotion is a mild astringent lotion recommended for the topical treatment of mild skin irritation and inflammation, including mild sunburn.

4.2 Posology and method of administration

Calamine Lotion is applied topically to the affected area with cotton wool and allowed to dry.

4.3 Contraindications

Calamine Lotion is contraindicated in patients with a known sensitivity to its ingredients.

4.4 Special warnings and precautions for use

No adverse effects reported.

4.5 Interaction with other medicinal products and other forms of interaction

Zinc oxide is incompatible with benzylpenicillin. Zinc oxide reacts slowly with fatty acid in oils and fats to produce the corresponding fatty acid esters.

4.6 Fertility, pregnancy and lactation

No adverse effects reported.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

None reported.

4.9 Overdose

No special procedures or anti-dote is likely to be necessary. In case of over use wash off with soap and hot water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc oxide and calamine have similar properties. Calamine has mild astringent, antipruritic and soothing actions. Zinc oxide is mildly astringent has covering, protective and cooling properties.

Calamine and zinc oxide produce astringent effects in the skin or mucous membranes by coagulating protein. The protein precipitates which forms serve as a protective coat, allowing new tissue to regenerate underneath. They are commonly used to reduce the extent of weeping in dermatitis and to check oozing and discharge in other mild disorders.

Phenol functions as a preservative in Calamine Lotion.

Bentonite is used as a stabilising and suspending agent in Calamine Lotion.

5.2 Pharmacokinetic properties

Zinc oxide or calamine are unlikely to be absorbed through the skin. Zinc salts are poorly absorbed from the gastrointestinal tract. Only a small proportion of dietary zinc is absorbed. Zinc is widely distributed throughout the body and is excreted in the faeces with only traces appearing in the urine.

Phenol is absorbed through the skin and mucous membrane. It is metabolised to phenylglucuronide and phenyl sulphate and small amounts are oxidised to catechol and quinol, which are mainly conjugated. The metabolites are excreted in the urine which may tint the urine green.

5.3 Preclinical safety data

No preclinical studies carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bentonite
Sodium Citrate
Liquefied Phenol
Glycerol
Purified Water

6.2 Incompatibilities

Phenol is incompatible with camphor, methanol, resorcinol, thyrinol and other substances.

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

100ml and 200ml PET container with HDPE tamper evident cap.

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

Shake the bottle before use.

7 MARKETING AUTHORISATION HOLDER

Ovelle Ltd,
Industrial Estate,
Coe's Road,
Dundalk,
Co. Louth.

8 MARKETING AUTHORISATION NUMBER

PA0206/016/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th October 1992

Date of last renewal: 14th October 2007

10 DATE OF REVISION OF THE TEXT

March 2015