SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength> lotion

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calamine 15.0% w/v

Zinc oxide 5.0% w/v

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Lotion

1. CLINICAL PARTICULARS
   1. Therapeutic indications

For relief of the symptoms of mild sunburn and other minor skin conditions.

* 1. Posology and method of administration

Topical.

Applied directly to the skin.

Recommended dose and dosage schedule

The product is suitable for use by adults, children and the elderly.

Apply gently with a pad of cotton wool to the affected parts as required.

* 1. Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

* 1. Special warnings and precautions for use

Shake the bottle.

For external use only.

Keep all medicines away from children.

* 1. Interaction with other medicinal products and other forms of interaction

May mask x-ray pictures under certain circumstances.

* 1. Fertility, pregnancy and lactation

No evidence has been found as to the safety of the product when used during pregnancy and lactation. However, the product has been used for many years without any apparent ill effects.

* 1. Effects on ability to drive and use machines

None known.

* 1. Undesirable effects

Occasional hypersensitivity or irritant reactions.

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 Health Product Vigilance Center; HPVC, Thai FDA.

* 1. Overdose

Overdose is considered unlikely with this product. However, if large quantities have been ingested, vomiting, inflammation of mucous membranes of the mouth and stomach, weakness, mental confusion, cold sweats, depression of pulse and leg cramps may occur.

Where phenol has been swallowed it may be necessary to empty the stomach by aspiration and lavage. Castor oil or olive oil may be added to the water to dissolve the phenol and delay absorption: 50ml of oil may be left in the stomach.

The patient should be kept warm, and pulmonary oedema, systemic acidosis, respiratory failure and circulatory failure should be treated symptomatically. Respiration may have to be assisted.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Calamine has a mild astringent action of the skin and is used as a dusting powder, cream, lotion or ointment in a variety of skin conditions.

Zinc oxide has a mildly antiseptic action and is a mild astringent, it has soothing and protective properties.

* 1. Pharmacokinetic properties

No information available.

* 1. Preclinical safety data

None.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

<Regarding the approval>

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>