# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Ascabiol Emulsion 25 % w/v

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzyl Benzoate 25 % w/v.

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

A cutaneous emulsion
A homogeneous white emulsion with a characteristic odour.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Treatment of scabies and pediculosis.

### 4.2 Posology and method of administration

**Scabies:** After total bathing 'Ascabiol' emulsion should be applied to the whole body except the head and face. A second application may be repeated within 5 days or alternatively it may be applied on three occasions at 12 hourly intervals.

**Pediculosis:** The affected region should be coated with 'Ascabiol' emulsion followed by a wash 24 hours later. This may be repeated two or three times in severe cases.

For use in children the emulsion should be diluted with an equal volume of water. For infants the proportion of emulsion to water should be 1:3.

### 4.3 Contraindications

Use in patients with a known hypersensitivity to benzyl benzoate.

### 4.4 Special warnings and precautions for use

Benzyl benzoate must not be allowed to come into contact with the eyes.

'Ascabiol' causes little skin irritation, but may cause a transient burning sensation. This is usually mild, but can occasionally be severe in sensitive individuals. In the event of a severe skin reaction the preparation should be washed off using soap and water.

### 4.5 Interaction with other medicinal products and other forms of interaction

If this preparation is accidentally taken by mouth, treatment should consist of gastric lavage or the administration of an emetic. An anticonvulsant should be given as necessary, otherwise treatment is symptomatic.

## 4.6 Pregnancy and lactation

There is an inadequate evidence of the safety of ‘Ascabiol’ in human pregnancy, but it has been in widespread use for many years without apparent ill consequences. Nevertheless ‘Ascabiol’ should not be used during pregnancy unless considered essential. Breast feeding should be suspended during treatment with ‘Ascabiol’. Feeding may be restarted after the emulsion has been washed off the body.

## 4.7 Effects on ability to drive and use machines

None when used as recommended.

## 4.8 Undesirable effects

Ascabiol causes little skin irritation, may cause a transient burring sensation. This is usually mild but can occasionally be severe in sensitive individuals. In the event of a severe skin reaction the preparation should be washed off using soap and warm water. Ascabiol is also irritating to the eyes therefore these should be protected if it is applied to the scalp.

## 4.9 Overdose

If Ascabiol is accidentally taken by mouth, treatment should consist of gastric lavage or the administration of an emetic. An anticonvulsant should be given if necessary, otherwise treatment is symptomatic.

Urinary retention in adults and convulsions in infants, have been reported following excessive use of topical benzyl benzoate. The body should be washed to remove excess benzyl benzoate. Otherwise treatment is symptomatic.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Benzyl benzoate is an acaricide, which eliminates *Acarus scabiei*, and is used in the treatment of scabies and pediculosis in man.

## 5.2 Pharmacokinetic properties

No data available.

## 5.3 Preclinical safety data

No animal data are available relating to ‘Ascabiol’. The active ingredient has been used widely for many years, without apparent ill effects. When ingested, benzyl benzoate may cause stimulation of the CNS and convulsions.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Stearic acid
Trolamine
Terpineol
Oil cinnamon leaf Ceylon
Silicone MS antifoam A
Purified water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

3 years.

## 6.4 Special precautions for storage

Store below 25°C.

## 6.5 Nature and contents of container

100 ml Type III amber glass bottle with aluminium pilfer-proof, screw 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 well before use.

## 7 MARKETING AUTHORISATION HOLDER

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50 Kings Hill Avenue
West Malling
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## 8 MARKETING AUTHORISATION NUMBER

PA 40/62/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2003

## 10 DATE OF REVISION OF THE TEXT

February 2005