

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ayrtons Antiseptic Ointment Zinc Oxide 5.0% w/w & Dichlorobenzyl Alcohol 0.5% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc oxide	5.0 % w/w
Dichlorobenzyl alcohol	0.5 % w/w

Excipients:	
Wool fat	20.0 % w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

Smooth, soft, homogenous, pink ointment with a faint smell of methyl salicylate.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Ayrtons Antiseptic Ointment is an ointment for the treatment and relief of cuts, sores, burns, wounds, rough and chapped skin.

4.2 Posology and method of administration

By external application.
Apply to affected parts.

4.3 Contraindications

Wool fat may cause local skin reactions (e.g. contact dermatitis).

4.4 Special warnings and precautions for use

For external use only.
Keep out of reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None stated.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

1. Zinc Oxide has a mild astringent action on the skin and acts as a soothing and protective application.
2. Dichlorobenzyl Alcohol (Myacide SP) is an antiseptic and at higher used concentrations (0.5%) has fast broad anti-microbial action. It is non-irritant even up to levels of 2.5% in ointment formulation.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

This product has been used over a long period of time with no adverse side effects reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool fat
Methyl salicylate
Terpineol
Pigment certolake ponceau 4R (E124)
Yellow soft paraffin
White beeswax

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.
Keep the container tightly closed.

6.5 Nature and contents of container

Polypropylene container/lid - 30 g or 500 g.
Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ayrton Saunders Ltd.
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8 MARKETING AUTHORISATION NUMBER

PA 501/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 November 1991

Date of last renewal: 26 November 2006

10 DATE OF REVISION OF THE TEXT

December 2006