

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Meted 3% & 5% w/w Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic acid	3.0% w/w
Colloidal sulphur	6.25%* w/w
(*equivalent to sulphur 5.0%)	

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Shampoo

A yellow viscous liquid with a characteristic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of itching, irritation, redness, flaking and/or scaling due to dandruff, seborrhoeic dermatitis, or psoriasis of the scalp.

4.2 Posology and method of administration

For topical administration.

Adults:

The hair should be thoroughly wetted and sufficient Meted Shampoo applied to produce an abundant lather. The hair should be rinsed and the procedure repeated.

Children:

As for adults.

Elderly:

As for adults.

4.3 Contraindications

Meted Shampoo is contra-indicated in persons with a sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. If shampoo gets into the eyes rinse thoroughly with water.

If the condition worsens or does not improve after regular use of the product as directed, consult a physician.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No limitations to the use of Meted Shampoo during pregnancy or lactation are known.

Safety has not been established in either humans or animals during pregnancy and lactation. However, with the small amounts of salicylic acid absorbed transdermally from Meted it is unlikely that use will cause any adverse effects.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

There have been no reports of adverse effects following the use of Meted Shampoo. However, salicylic acid is a mild irritant and may cause dermatitis.

As with other topical preparations containing salicylic acid excessive prolonged use may result in symptoms of salicylism.

4.9 Overdose

There is no evidence of systemic absorption following the use of this shampoo. There are no reports available of its ingestion.

Early symptoms are ringing in the ear tinnitus with deafness, epistaxis, nausea, vomiting, sensitivity and dryness of the mucous membranes. If this occurs treatment must be stopped immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sulphur is a keratolytic and mild antiseptic.
Salicylic acid has keratolytic and fungicidal properties.

5.2 Pharmacokinetic properties

There is no evidence of systemic absorption of sulphur or salicylic acid following use of Meted Shampoo.

5.3 Preclinical safety data

None presented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium aluminium silicate
Hypromellose
Panthenol
Sodium laureth sulphate
Sodium cocoyl sarcosinate
Cocamido propyl betaine
Fragrance - 430 015
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Meted Shampoo is supplied in a white HDPE bottle with a white polypropylene screw cap. Each bottle contains either 30ml or 120ml of Meted Shampoo.

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

Alliance Pharmaceuticals Limited
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8. MARKETING AUTHORISATION NUMBER

PA 943/11/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th October 1995/26th October 2005

10. DATE OF REVISION OF THE TEXT

11th March 2009