Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Metrotop 8mg/ml Topical Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains metronidazole 0.8%w/v (equivalent to 8mg/ml)
Also contains 0.02%w/v benzalkonium chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
A sterile, clear, colourless gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the management of fungating tumours.

For the topical treatment of acute inflammatory exacerbations of rosacea.

4.2 Posology and method of administration

Tumours

Following adequate cleansing, a liberal application of the gel should cover the area and in turn be covered with a loosely packed paraffin gauze and bandage as indicated.

Acne Rosacea

The gel should be applied twice daily to the affected areas. The usual duration of treatment is 1 month, but up to 2 months may be required in some cases.

Contact with the eyes should be avoided.

Elderly: instructions apply as for other adults with care.
Children: not recommended.

For topical administration.

4.3 Contraindications

- Use in patients with disease of the peripheral nervous system.
- Use in patients known to be hypersensitive to metronidazole or other constituents.

4.4 Special warnings and precautions for use

If prolonged therapy is required, the physician should bear in mind the possibility of peripheral neuropathy or leucopenia.

High oral or parental dosage regimens have been associated with transient epilepiform seizures. Caution is required with active disease of the central nervous system. No reports of such effects have been noted to date with topical use.

Prolonged or repeated course of metronidazole therapy should be conducted only under conditions of close surveillance for clinical and biological effects and under specialist direction.

Strong sunlight should be avoided since metronidazole is unstable under ultra violet light.

4.5 Interaction with other medicinal products and other forms of interactions

Some potentiation of anticoagulant activity has been reported when oral metronidazole has been used with certain anticoagulants.

4.6 Fertility, pregnancy and lactation

Metronidazole should only be used during pregnancy or lactation if considered essential by the physician.
Studies in animals have shown no teratogenic effect. If used, high dosage regimes should be avoided.
The drug crosses the placenta and is excreted in breast milk in which concentrations equal those in serum.
If pregnancy occurs, metronidazole should be stopped.
Breast feeding should also cease if use is considered necessary during lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Side effects include gastrointestinal disturbances, dry mouth, headache, rash, drowsiness and rarely neuropathy following oral therapy but not to date with topical use.

4.9 Overdose

There is no specific treatment for gross overdosage of metronidazole. Gastric lavage is recommended in cases of accidental ingestion. Uneventful recovery has followed overdosage of up to 12g taken orally. Metronidazole is readily removed from the plasma by dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Metronidazole is a potent agent against anaerobic bacteria, which are believed to produce odorous metabolites as a result of localised tissue colonisation.

The aim of the product is to provide a high concentration of metronidazole at and around the site of colonisation in a water-miscible base. This form allows surface spread and penetration within the wound accompanied by ease of aseptic application and up to 24 hours duration of action.

5.2 Pharmacokinetic properties

There is presently no evidence of any significant systemic concentrations of metronidazole following topical application.

5.3 Preclinical safety data

Metronidazole and a metabolite have been shown to be mutagenic in some tests with non-mammalian cells.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Benzalkonium Chloride Solution
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years.
Once opened, the contents should be used within 28 days of opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene tubes each fitted with a plastic screw cap and tamper-evident seal and enclosed within a printed cardboard box.
Packs sizes: 15g, 30g and 60g tubes available singly or in boxes of 12.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

The normal precautions involved in aseptic dressing should be observed to prevent contamination.
It is recommended that each patient should have an individual tube of Metrotop.

7 MARKETING AUTHORISATION HOLDER

Ayrton Saunders (Ireland) Limited
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Blackthorn Avenue
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8 MARKETING AUTHORISATION NUMBER

PA22906/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 19April 2006

10 DATE OF REVISION OF THE TEXT

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