Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anabact

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Metronidazole 0.75% w/w

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Gel.

Pale yellow clear gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the deodorisation of malodorous fungating tumours.

4.2 Posology and method of adminstration

Adults and Elderly:

Clean the wound thoroughly. Apply the gel over the complete area with a non-adherent dressing. Use once or twice as necessary.

Children:

Not recommended

4.3 Contraindications

In patients known to be sensitive to metronidazole, Bronopol, hydroxybenzoic acid esters, hydroxyethylcellulose, propylene glycol or phosphoric acid.
Use in patients with disease of the peripheral nervous system.

4.4 Special warnings and special precautions for use

Strong sunlight should be avoided because metronidazole is unstable under ultra-violet light. Contact with the eyes should be avoided. If contact with the eyes occurs, the gel should be carefully washed out with water.

4.5 Interaction with other medicinal products and other forms of interaction

A disulfiram-like reaction has been reported in a small number of patients taking oral metronidazole and alcohol concomitantly. Anticoagulants and antiepileptics may also interact. Concurrent use with keratolytics is not recommended.

4.6 Pregnancy and lactation

The safety of metronidazole in pregnancy and lactation has not been adequately established. The gel should not therefore be used in these circumstances unless the physician considers it essential. Medication should be stopped if pregnancy occurs.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

May cause local dryness of the skin, itching and peeling.

4.9 Overdose

Overdose is extremely unlikely. If necessary, medication should be removed by washing with warm water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Metronidazole is an established antibacterial agent. It is effective against a variety of organisms including anaerobic bacteria which are responsible for the distressing symptoms of malodorous full thickness wounds.

5.2 Pharmacokinetic properties

The systemic concentration of Metronidazole following the topical administration of 1g of a 0.75% Metronidazole gel has been demonstrated to range from 25ng/ml (limit of detection) to 66ng/ml, with a mean c/max of 40.6ng/ml.

The corresponding mean c/max following the oral administration of a solution containing 30mg of Metronidazole was 850ng/ml (equivalent to 212ng/ml if dose corrected). The mean Tmax for the topical formulation was 6.0 hours compared to 0.97 hours for the oral solution. These levels following topical administration are clinically insignificant.

5.3 Preclinical safety data

No published data are available on the irritancy and tolerance of topical metronidazole in animals.

It was, therefore, considered more appropriate to investigate the potential irritancy and tolerance of topical application of the proposed marketing formulation of metronidazole 0.75% gel in human volunteers.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bronopol
Hydroxybenzoic acid esters
Hydroxyethylcellulose
Propylene glycol
Phosphoric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep container in outer carton.

6.5 Nature and contents of container

Internally lacquered membrane sealed aluminium tubes each fitted with a low density polyethylene cap. The product is available in packs of 5g, (professional sample) 10g, 15g, 25g, 30g and 40g, though the availability of certain pack sizes may be limited.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 980/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 13th November 2003

10 DATE OF REVISION OF THE TEXT

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