SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Anabact 0.75% w/w Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient
Metronidazole 0.75% w/w

Other ingredients
The preservative agent Bronopol (2, bromo-2-nitro propan-1, 3-diol) and hydroxybenzoic acid esters, incorporated at a level of 0.06% w/w, and 0.13% respectively together with hydroxyethylcellulose, propylene glycol, and purified water

3. PHARMACEUTICAL FORM

A pale yellow water-based clear gel containing 0.75% w/w metronidazole for topical application

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The deodorisation of malodorous fungating tumours, gravitational ulcers and decubitus ulcers

4.2. Posology and method of administration

Children: Not recommended for children under 12 years of age.

Adults: Clean the wound thoroughly. Apply the gel over the complete area and cover with a non-adherent dressing. Use once or twice daily until the odour has been completely eradicated. Studies have shown that offensive odour is usually controlled with application of topical metronidazole gel 0.75% within two weeks.

Elderly: As detailed for other adults

4.3. Contraindications

In patients known to be sensitive to metronidazole, Bronopol, hydroxybenzoic acid esters, hydroxyethylcellulose, phosphoric acid or propylene glycol.

4.4. Special warnings and precautions for use

Strong sunlight should be avoided because metronidazole is unstable under ultraviolet light. Contact with the eyes should be avoided.
Anabact 0.75% w/w Gel contains Bronopol which can cause local skin reactions such as contact dermatitis; propylene glycol which may cause skin irritation, and hydroxybenzoic acid esters that may cause allergic reactions (possibly delayed).

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

A disulfiram-like reaction in a small number of patients taking oral metronidazole and alcohol concomitantly. Anticoagulants and antiepileptics may also interact.

4.6. Fertility, 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 dryness of the skin, local stinging or irritation.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

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 to 10 patients with rosacea ranged from 25ng/ml (limit of detection) to 66ng/ml, with a mean c/max of 40.6ng/ml. The corresponding mean c/max following 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. The proposed formulation would be expected to afford minimal serum concentrations of metronidazole.

5.3. Preclinical safety data

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

None known.

6.3. Shelf life

The unopened shelf-life is 2 years.
The opened shelf-life is 28 days.

6.4. Special precautions for storage

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

6.5. Nature and contents of container

The gel is packaged in internally lacquered membrane sealed aluminium tubes each fitted with a low density polyethylene cap.
Anabact is licensed in 5g, 10g, 15g, 25g, 30g and 40g pack sizes.

6.6. Special precautions for disposal

None stated

7. MARKETING AUTHORISATION HOLDER

Cambridge Healthcare Supplies Ltd
Unit 1 Chestnut Drive
Wymondham Business Park
Wymondham
Norfolk
NR18 9SB

8. MARKETING AUTHORISATION NUMBER

PL 16794/0006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st Oct 2000 / 18/11/2005

10. DATE OF REVISION OF THE TEXT

December 2016