Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Clonamp 250 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains ampicillin trihydrate equivalent to 250 mg ampicillin.

For full list of excipients, see section 6.1.

Excipients:

Amaranth (E123)	0.150 mg
Tartrazine (E102)	0.071 mg
Brilliant Black (E151)	0.008 mg

3 PHARMACEUTICAL FORM

Capsule, hard. (Capsule).

Size ‘2’ hard gelatin capsules with a red body and a grey cap marked ‘CLON AMP 250’ containing an off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For treatment of infections due to organisms sensitive to ampicillin.

4.2 Posology and method of administration

Adults and children over 20Kg b.w.:
The usual dose is 250mg every six hours.

For treatment of severe infections the dosage may be increased at the discretion of the physician.

Children under 20Kg b.w.:
50 to 100mg/Kg per day in divided doses.

Route of administration
Oral.

4.3 Contraindications

Ampicillin is penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillins, cephalosporins) or excipients.

4.4 Special warnings and precautions for use

(i) Prolonged use of an anti-infective may result in the development of superinfection due to organisms resistant to that anti-infective.
(ii) Ampicillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin.
(iii) The dosage should be reduced in patients with renal impairment.
(iv) Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity.

4.5 Interaction with other medicinal products and other forms of interaction

Ampicillin may decrease the efficacy of oral contraceptives and patients should be warned accordingly.

Probenecid decreases the renal tubular secretion of ampicillin. Concurrent use with ampicillin may result in increased and prolonged blood levels of ampicillin.

Concurrent admisitration of allopurinol during treatment with ampicillin can increase the likelihood of allergic skin reactions.

It is recommended that when testing for the presence of glucose in urine during ampicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of ampicillin, false positive readings are common with chemical methods.

Bacteriostatic drugs may interfere with the bactericidal action of ampicillin.

4.6 Pregnancy and lactation

Pregnancy:
Animal studies with ampicillin have shown no teratogenic effects. Ampicillin has been in extensive clinical use since 1961 and its use in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, ampicillin may be considered appropriate.

Lactation:
During lactation, trace quantities of penicillins can be detected in breast milk. Adequate human and animal data on use of ampicillin during lactation are not available.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Hypersensitivity reactions:
If any hypersensitivity reaction occurs, the treatment should then be discontinued.

Skin rash, pruritis and urticaria have been reported occasionally. The incidence is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin. Purpura has also been reported. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.

As with other antibiotics, anaphylaxis *(see section 4.4)* has been reported rarely.

Renal effects:
Interstitial nephritis can occur rarely.

Gastrointestinal reactions:
Effects include nausea, vomiting and diarrhoea. Pseudomembraneous colitis has been reported rarely.

Hepatic effects:
As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely. As with most other antibiotics, a moderate and transient increase in transaminases has been reported.

Haematological effects:
As with other beta-lactams, haematological effects including transient leucopenia, transient thrombocytopenia and haemolytic anaemia have been reported rarely.

Prolongation of bleeding time and prothrombin have also been reported rarely.

4.9 Overdose

Problems of overdosage with ampicillin are unlikely to occur; if encountered they may be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Penicillins with extended spectrum
ATC Code: J07CA

Ampicillin is bactericidal and has a similar mode of action to that of benzylpenicillin, although it has a broader spectrum of activity. It resembles benzylpenicillin in its action against Gram-positive organisms, including Streptococcus pneumoniae and other streptococci but, apart perhaps from Enterococcus faecalis, it is slightly less potent than benzylpenicillin. Ampicillin is an aminopenicillin with an amino group side chain attached to the basic penicillin structure, which enables ampicillin to penetrate the outer membrane of some Gram-negative bacteria.

5.2 Pharmacokinetic properties

Ampicillin is relatively stable in the acid gastric secretion and is moderately well absorbed from the gastro-intestinal tract after oral administration. Peak concentrations in plasma are obtained in about 1 to 2 hours. About 20% is bound to plasma proteins and the plasma half-life is about 1 to 2 hours, but this may be increased in neonates and the elderly; in renal failure half-lives of 7 to 20 hours have been reported. About 20 to 40% of an orally administered dose is excreted unchanged in the urine in 6 hours; urinary concentrations range from 0.25 to 1mg per ml following a dose of 500mg.

5.3 Preclinical safety data

No information submitted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate

Capsule shell
Amaranth (E123)

Tartrazine (E102)
Brilliant black (E151)
Titanium dioxide (E171)
Gelatin
Erythrosine (E127)

Printing Ink
Shellac
Black iron oxide (E172)
Propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Polypropylene tubes with low density polyethylene caps.
High density polyethylene film may be used as packing material.

Pack size: 250 mg:
30's, 50's, 100's, 250's, 500's, and 1000's.

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

Clonmel Healthcare Ltd.,
Waterford Road,
Clonmel,
County Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 0126/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 July 1981

Date of last renewal: 02 July 2006

10 DATE OF REVISION OF THE TEXT

February 2007