SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BRITCIN/Ampicillin 250 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ampicillin Trihydrate equivalent to 250.00 mg Ampicillin

3 PHARMACEUTICAL FORM

Capsule

Hard two-piece two-tone Gelatine Capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ampicillin is a broad-spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin-sensitive organisms. Typical indications include: ear, nose and throat infections, bronchitis, pneumonia, urinary tract infections, skin and soft tissue infections, gonorrhoea, gynaecological infections, septicaemia, peritonitis, endocarditis, meningitis, enteric fever, gastro-intestinal infections.

4.2 Posology and method of administration

Usual adult dosage (including elderly patients):

Ear, nose and throat infections:	250 mg, four times a day
Skin and soft tissue infections:	250 mg, four times a day
Bronchitis:	Routine therapy: 250 mg, four times a day
	High-dosage therapy: 1 g, four times a day
Pneumonia:	500 mg, four times a day
Urinary tract infections:	500 mg, three times a day
Enteric fever:	Acute: 1-2 g, four times a day for 2 weeks
	Carriers: 1-2 g, four times a day for 4-12 weeks
Gastro intestinal infections:	500-750 mg, three to four times daily
Gonorrhoea:	2 g orally with 1 g probenecid as a single dose
	Repeated doses are recommended for the treatment of females

Usual children's dosage (under 10 years):

Half the adult dose.

All recommended dosages are a guide only. In severe infections the above dosages may be increased. Oral doses of ampicillin should be taken half to one hour before meals.

Renal impairment:

In the presence of severe renal impairment (creatinine clearance <10 ml/min) a reduction in dose or extension of dose interval should be considered. In cases of dialysis, an additional dose should be administered after the procedure.

Route of Administration: Oral

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Before initiating therapy with ampicillin, careful enquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.

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.

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.

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

Dosage should be adjusted in patients with renal impairment (see section 4.2).

4.5 Interaction with other medicinal products and other forms of interaction

Bacteriostatic drugs may interfere with the bactericidal action of ampicillin.

In common with other oral broad-spectrum antibiotics, ampicillin may reduce the effect 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 administration 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.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Animal studies with Ampicillin have shown no teratogenic effects. The product 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

Gastrointestinal reactions:

Effects include nausea, vomiting and diarrhoea. Pseudomembraneous colitis and haemorrhagic colitis have been reported rarely they usually resolve rapidly when treatment is stopped. If they persist they may indicate overgrowth of resistant organisms, requiring specific treatment.

Hypersensitivity reactions:

If any hypersensitivity reaction occurs, the treatment should 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 – Warnings) has been reported rarely.

Renal effects:

Interstitial nephritis can occur 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.

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 at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

Ampicillin may be removed from the circulation by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ampicillin is a broad spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms. It has a similar mode of action to that of benzylpenicillin. It is effective against gram-positive organisms including streptococcus faecalis. Str. Pneumonia, and haemolytic streptococci but, apart perhaps from Str. Faecalis, it is less potent than benzylpenicillin. Listeria monocytogenes is also highly sensitive. Its action is similar to that of the tetracyclines and chloramphenicol against Gram-negative organisms particularly Haemophilus influenzae, salmonellae, and most strains of Escherichia coli; highly resistant strains of H. influenzae have been reported. Neisseria gonorrhoea, N. meningitidis, Bordetella pertussis, Proteus mirabillis, and Brucella spp. are also sensitive. Ampicillin is effective against some shigellae but strains can acquire resistance rapidly.

Minimum inhibitory concentrations for Gram-positive organisms have been reported to range from 0.02 to 5 ug per ml for Gram-negative organisms from 0.02 to 8 ug per ml. It is inactive against most strains of Pseudomonas aeruginosa.

It has been reported that Ampicillin inhibits side-wall synthesis in susceptible bacteria. Ampicillin is inactivated by penicillinase and complete cross resistance has been reported between Amoxicillin and Ampicillin.

5.2 Pharmacokinetic properties

Ampicillin Trihydrate is rapidly absorbed when given orally. It is widely distributed and is reported to produce peak anti-biotic plasma concentrations that are up to twice as high as those from the same dose of ampicillin. Peak plasma Ampicillin concentrations of about 5 nonagrams per ml have been observed two hours after a dose of 250 mg with detectable amounts present for up to eight hours. Doubling the dose can produce double the concentration.

The presence of food in the stomach does not appear to diminish absorption significantly.

Up to 20% is bound to plasma proteins in the circulation and plasma half-lives of about one hour have been reported. Ampicillin diffuses across the placenta; little appears to be excreted in breast milk. It penetrates well into purulent and mucoid sputum and low concentrations have been found in ocular fluid. Concentrations of the anti-biotic have been detected in the CSF of patients with inflamed mengines when given Ampicillin intra-venously.

About 60% of an oral dose of Ampicillin is excreted unchanged in the urine in 6 hours by glomerular filtration and tubular secretion. Urinary concentrations range from about 0.3 - 1.3 mg per ml after a dose of 250 mg. Up to 75% of a parental dose has been reported to be excreted unchanged in the urine within six hours. High concentrations have been reported in bile.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate

Gelatine

Iron Oxide Red E172

Iron Oxide black E172

Erythrosine E127

Titanium Dioxide E171

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a dry place below 25°C.

6.5 Nature and contents of container

High density polystyrene with polythene lids and/or polypropylene containers with polypropylene or polythene lids and polyurethane or polythene inserts.

Pack sizes: 100, 500

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
11 Boumpoulinas Street,
3rd floor, 1060 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/10/2009

10 DATE OF REVISION OF THE TEXT

13/05/2016