

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Ampicillin Capsules BP 500 mg

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Ampicillin Trihydrate, equivalent to 500mg of Ampicillin (anhydrous).

For excipients, see 6.1

#### 3 PHARMACEUTICAL FORM

Hard capsule

Red/dark grey size 0+ capsules marked 'AN 500' and 'G', containing white granular powder.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the treatment of infections due to organisms sensitive to ampicillin.

##### 4.2 Posology and method of administration

For oral administration.

<u>Adults:</u>	The usual dose is 250mg every six hours. For treatment of severe infections the dosage may be increased at the discretion of the physician.
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<u>Children:</u>	<u>Over 10 years old</u> As for adults.
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	<u>up to 10 years old</u> This strength is unsuitable for the appropriate dosage.
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##### 4.3 Contraindications

Use in patients with hypersensitivity to penicillins or ampicillin.

##### 4.4 Special warnings and special precautions for use

Prolonged use of an anti-infective may result in the development of superinfection due to organisms resistant to that anti-infective.

Patients with infectious mononucleosis are particularly prone to develop rashes with ampicillin.

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

None have been reported.

## 4.6 Pregnancy and lactation

Anti-infectives should not be used during pregnancy or lactation unless considered essential by the physician.

The drug has been shown to cross the placenta and is excreted in breast milk. Studies in animals and experience of human use to date have shown no evidence of teratogenic effects.

## 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

Side effects include maculopapular rashes, urticaria and other evidence of hypersensitivity, gastrointestinal disturbances, and diarrhoea. Transiently raised liver enzymes occur occasionally and Pseudomembranous colitis has been reported in a few cases.

## 4.9 Overdose

Overdose would be unlikely; an exacerbation of the side effects may be seen, which should be treated symptomatically.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

A broad spectrum antibiotic activity.

## 5.2 Pharmacokinetic properties

A broad spectrum antibiotic, well absorbed after oral administration, reaching peak plasma levels after 1 to 2 hours. It is excreted in the bile and urine with a plasma half-life of 1 to 2 hours.

## 5.3 Preclinical safety data

None stated.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

### Capsule Core:

Talc  
Magnesium Stearate  
Sodium Starch Glycollate  
Microcrystalline Cellulose

### Capsule Shell

Gelatin  
Iron oxides (E172)  
Titanium Dioxide (E171)

Erythrosine (E127)

**Printing Ink**

Opacode S-1-8100HV containing Iron oxide (E172),

Soya lecithin

Polydimethylsiloxane

Shellac

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf Life**

2 Years

**6.4 Special precautions for storage**

Do not store above 25°C.

Store in the original container.

**6.5 Nature and contents of container**

Polypropylene capsule container with tamper-evident polyethylene cap.

Pack sizes:- 20, 50, 100, 250, and 500.

Not all pack sizes may be marketed.

**6.6 Instructions for use and handling**

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Generics [UK] Limited,

Station Close,

Potters Bar,

Herts EN6 1TL,

England

**8 MARKETING AUTHORISATION NUMBER**

PA 405/8/2

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 12<sup>th</sup> May 1988

Date of last renewal: 12<sup>th</sup> May 2003

**10 DATE OF REVISION OF THE TEXT**

March 2005



