Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Nemecillin® Capsule.

2. Qualitative and quantitative composition

Each capsule contains: 250mg ampicillin as Ampicillin Trihydrate

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Capsule: Black and red capsules with “Nemel” and “Nemecillin®” 250mg overprinted on the capsule shell

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, gonorrhoea, gynaecological infections, septicaemia, peritonitis, endocarditis, meningitis, enteric fever, gastro-intestinal infections.

Parenteral usage is indicated where oral dosage is inappropriate.

4.2 Posology and method of administration

Posology

Usual adult dosage (including elderly patients):

Ear, nose and throat infections:	250mg four times a day.
Bronchitis:	Routine therapy: 250mg 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.

Gonorrhoea:	2 g orally with 1 g probenecid as a single dose. Repeated doses are recommended for the treatment of females.
Gastro-intestinal infections:	500-750 mg three to four times daily.
Enteric:	*Acute:* 1-2 g four times a day for two weeks. *Carriers:* 1-2 g four times a day for four to twelve weeks

Usual children's dosage (under 10 years):

Half adult routine dosage.

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

Renal Impairment:

In the presence of severe renal impairment (creatinine clearance <10ml/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.

Method of administration

oral administration.

4.3 Contraindications

Ampicillin is a 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

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 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 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

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 Item 4.4 – Warnings) has been reported rarely.

Renal effects:

Interstitial nephritis can occur rarely.

Gastrointestinal reactions:

Effects include nausea, vomiting and diarrhoea. Pseudomembraneous colitis and haemorrhagic colitis have 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.

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.

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.

5.2 Pharmacokinetic properties

Ampicillin is excreted mainly in the bile and urine with a plasma half life of 1-2 hours.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Smpc.

6. Pharmaceutical particulars

6.1 List of excipients

Capsule:

Corn starch

Magnesium stearate

Hard black and red gelatin shell

Purified Talcum powder

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C

Plastic containers: Keep the container tightly closed to protect from light and moisture.

6.5 Nature and contents of container

Aluminium/PVC blister pack of 10 capsules per blister. 10 of such blisters packed in a box with a patient information leaflet

6.6 Special precautions for disposal and other handling

No special instructions.

7. Marketing authorisation holder

NEMEL Pharmaceuticals Limited

Plot 35 Emene Industrial Layout

Enugu, Nigeria.

8. Marketing authorisation number(s)

A4-4148

9. Date of first authorisation/renewal of the authorisation

28th January, 2016

10. Date of revision of the text

1st February, 2021.

4

4.3 Contraindications

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Pregnancy and lactation

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

5. Pharmacological properties

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

No further information of relevance to add.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium stearate, gelatin, black and red iron oxides (E172), titanium dioxide (E171) and erythrosine (E127).

6.2 Incompatibilities

None.

6.3 Shelf life

Blister packs: five years
Others: three years

6.4 Special precautions for storage

Containers: Do not store above 25°C. Keep the container tightly closed.

Blisters: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Aluminium canister

Glass bottle fitted with a screw cap

Polypropylene tube with a polyethylene closure - 4, 16, 50, 100, 500

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

Chemidex Pharma Ltd

T/A Essential Generics or Chemidex Generics

Chemidex House

Egham Business Village

Crabtree Road

Egham

Surrey

TW20 8RB

United Kingdom

8. Marketing authorisation number(s)

PL 17736/0072

9. Date of first authorisation/renewal of the authorisation

4th March 2005

10. Date of revision of the text

21/10/2015