AUSTRALIAN PRODUCT INFORMATION

AUSTRAPEN®

(ampicillin (as sodium)) powder for Injection

1 NAME OF THE MEDICINE

Ampicillin (as sodium).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each AUSTRAPEN 1000 mg powder for injection contains 1000 mg of ampicillin (as sodium) as the active ingredient.

3 PHARMACEUTICAL FORM

Powder for injection.

AUSTRAPEN powder for injection is a white to almost white powder.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Treatment of infections due to susceptible strains of Gram-positive and Gram-negative organisms (see Section 5.1 PHARMACODYNAMIC PROPERTIES - Mechanism of action, Microbiology). Bacteriological studies to determine the organism and its sensitivity should be undertaken.

4.2 DOSE AND METHOD OF ADMINISTRATION

AUSTRAPEN may be given by intramuscular injection, by intravenous infusion or by SLOW intravenous injection.

Respiratory Tract Infections

Adults: 250 to 500 mg six hourly.

Children: 25 to 50 mg/kg/day in equally divided doses, six hourly.

Chronic Bronchitis

Adults: 500 mg six hourly. (High dosage therapy - 1g six hourly).

Urinary Tract Infections

Adults: 500 mg six hourly.

Children: 50 mg/kg/day in equally divided doses, six hourly.

Gastrointestinal Tract Infections

Adults: 500 to 750 mg six hourly.

Children: 50 to 70 mg/kg/day in equally divided doses, six hourly

The children's dosage is intended for individuals whose weight will not cause a dosage to be calculated greater than that recommended for adults. Children weighing more than 20 kg should be dosed according to the adult recommendations. It should be recognised that frequent bacteriological and clinical appraisals are necessary in the treatment of chronic urinary tract and intestinal infections.

Smaller doses than those recommended above should not be used. Higher doses may be needed at times. The usual duration of therapy is 5 to 10 days but in some cases therapy may be required for longer durations.

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least 10 days treatment for any infection caused by haemolytic streptococci to help prevent the occurrence of acute rheumatic fever or glomerulonephritis.

Bacterial Meningitis and Septicaemia

Adults and children: 200 mg/kg/day in equally divided doses, four to six hourly, intravenously, with an upper limit of 12 g daily.

Intraperitoneal Use

At least 500 mg per 10 mL water for injections daily.

Intrapleural Use

500 mg in 5 to 10 mL water for injections daily.

Intra-Articular

500 mg daily, dissolved in up to 5 mL of water for injections, or 0.5% procaine hydrochloride.

Intrathecal Use

Not recommended.

Neonatal Dosage

The half-life of ampicillin sodium varies inversely with age in neonates. The recommended dosage is 25 mg/kg (50 mg/kg for meningitis) at the following intervals:

Infants < 2000 g and 0 to 7 days:	every 12 hr
Infants < 2000 g and > 7 days:	every 8 hr
Infants > 2000 g and 0 to 7 days:	every 8 hr
Infants > 2000 g and > 7 days:	every 6 hr

Impaired Renal Function

In renal impairment the excretion of the antibiotic will be delayed and depending on the degree of impairment, it may be necessary to reduce the total daily dosage. The following dosage schedule is recommended.

Glomerular Filtration Rate (mL/min)	Dose	Dosage Interval (Hours)
10 to 50	Normal	6 to 12
<10	Normal	12 to 16

Preparation Of Injections

Use a 21G [0.8mm] needle for reconstitution. It is recommended to slice the bung with the bevelled edge facing upwards and avoid a stabbing action when inserting the needle of the syringe into the vial, through the rubber stopper (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE – Identified precautions)

Ampicillin sodium is unstable in concentrated solutions and contains no anti-microbial preservative. When AUSTRAPEN is reconstituted with water for injections, it must be administered immediately to reduce microbiological hazard. Shake the vial immediately after adding the diluent.

Following reconstitution, AUSTRAPEN may be held in certain intravenous fluids as described in Table 2 (see Section 6.4 SPECIAL PRECAUTIONS FOR STORAGE). Each AUSTRAPEN vial should be used in one patient on one occasion only and any residue discarded.

Intramuscular Administration

a) When the entire contents of a vial are to be used, 1.5 mL of water for injections should be added to the 1 g vial.
b) When only part of a vial's contents are required, the amount of water for injections which should be added to provide a convenient final concentration is shown in Table 1. The remaining contents of the vial should be discarded.

Table 1 – Recommended amount of sterile water for injections

Label Strength	Final Concentration (mg/mL)	Recommended amount of sterile Water for Injections
1 g	500 mg/mL	1.3 mL
	250 mg/mL	3.3 mL
	100 mg/mL	9.3 mL

Direct Intravenous Administration

Reconstitute in 10 to 20 mL of water for injections and inject **SLOWLY** over 3 to 5 minutes.

Caution - more rapid administration may result in convulsive seizures.

Intravenous Infusion

Reconstitute as for intramuscular administration prior to diluting with intravenous solution. The ampicillin solution should be administered as a rapid infusion over 30 to 40 minutes.

4.3 CONTRAINDICATIONS

Ampicillin is a penicillin and should not be given to patients with a history of a hypersensitivity to betalactam antibiotics (e.g. penicillins, cephalosporins).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe cutaneous adverse reactions

Severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in patients taking beta-lactam antibiotics. When SCAR is suspected, AUSTRAPEN should be discontinued immediately and an alternative treatment should be considered.

Identified Precautions

Coring has been reported during reconstitution. It is strongly advised that a 21G [0.8mm] diameter size needle is used during reconstitution. It is important that the correct needle size is used to avoid coring.

As further precaution, avoid stabbing action when inserting the needle of the syringe into the vial, through the rubber stopper; it is recommended to slice the bung with the bevelled edge facing upwards. (see Section 4.2 DOSE AND METHOD OF ADMINISTRATION, Preparation of Injections).

Sodium content

The medication contains 62 mg (equivalent to 2.7 mmol) of sodium in each vial. If the product is diluted with normal saline solution prior to intravenous infusion, the additional amount of sodium from the diluent should also be considered for the total sodium content.

Hypersensitivity reactions

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 therapy. Before commencing therapy with any beta-lactam antibiotic, careful enquires should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If a hypersensitivity reaction occurs, appropriate therapy should be instituted and AUSTRAPEN therapy discontinued.

Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management including intubation, should also be administered as indicated.

Pseudomembranous colitis

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including ampicillin. A toxin produced by *Clostridium difficile* appears to be the primary cause. The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases, appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolyte and protein replacement should be provided when indicated. Drugs which delay peristalsis, e.g. opiates and diphenoxylate with atropine may prolong and/or worsen the condition and should not be used.

Allergic diathesis

Caution should be exercised in the treatment of patients with an allergic diathesis.

AUSTRAPEN is not the treatment of choice in patients presenting with sore throat or pharyngitis. This is because the underlying cause may be infectious mononucleosis, in the presence of which there is a high incidence of rash if ampicillin is used. Patients with lymphatic leukaemia also appear to have a higher incidence of skin rashes when treated with ampicillin.

Renal, hepatic and haematopoietic function

As with any potent drug, periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Enterobacter, Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.

Indwelling urethral catheters should be checked regularly as the high concentrations of ampicillin in the urine may cause it to precipitate out of solution at room temperature. The risk of crystalluria should be avoided by maintaining a high urinary output.

Use in the Elderly

See Section 4.2 DOSE AND METHOD OF ADMINISTRATION.

Paediatric Use

See Section 4.2 DOSE AND METHOD OF ADMINISTRATION.

Effects on Laboratory Tests

As administration of AUSTRAPEN will result in high ampicillin concentrations in the urine, false positive reactions may be elicited when testing the urine for glucose with Clinitest, Benedict's solution or Fehling's solution. Tests based on enzymatic glucose oxidase reactions such as Testape or Clinistix should be used instead.

Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone and estradiol has been noted.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Probenecid

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

Tetracyclines, erythromycin and chloramphenicol

Tetracyclines, erythromycin and chloramphenicol antagonise the action of ampicillin.

Gentamicin

Gentamicin should not be mixed with ampicillin when both drugs are given parenterally as inactivation occurs.

Allopurinol and ampicillin

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients.

Oral contraceptives

In common with other antibiotics, patients should be warned that AUSTRAPEN may reduce the effectiveness of oral contraceptives.

Methotrexate

Use of ampicillin with methotrexate should be carefully monitored. A serious case of severe to methotrexate toxicity has been reported in a patient treated concomitantly with furosemide and phenoxymethylpenicillin. Penicillins, including ampicillin, may inhibit the renal clearance of methotrexate, which may increase serum concentrations of methotrexate.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

No information is available.

Use in Pregnancy – Pregnancy Category A

Ampicillin diffuses across the placenta into the foetal circulation. Animal studies with ampicillin have shown no teratogenic effects. The product has been in clinical use for nearly 30 years and the limited number of reported cases of use in human pregnancy have shown no evidence of untoward effect. The use of AUSTRAPEN in pregnancy should be reserved for cases considered essential by the clinician.

Use in Labour and Delivery

Studies in guinea pigs have shown that intravenous administration of ampicillin decreases uterine tone and the frequency, strength and duration of contractions. However, it is not known whether the use of ampicillin in humans during labour or delivery has any immediate or delayed adverse effects, prolongs the duration of the labour or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Use in Lactation

Ampicillin is excreted in breast milk. An alternative feeding method is recommended to avoid any possible sensitisation of the newborn.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

As with all penicillins, the possibility of allergic reactions should always be considered. Reactions are more likely to occur in those with an allergic diathesis. Anaphylactic shock is most likely to occur with injected penicillins (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

The following adverse reactions have been reported as associated with the use of ampicillin:

Gastro-intestinal:

Glossitis, stomatitis, black hairy tongue, nausea, vomiting, enterocolitis, diarrhoea and loose stools. These reactions are usually associated with oral dosage forms. (See Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Hypersensitivity reactions:

The most common adverse reaction is rash.

An erythematous maculopapular rash has been reported fairly frequently. A macular rash, which is not believed to be a hypersensitivity reaction, occurs predominantly in patients with infectious mononucleosis 4 to 5 days after beginning therapy with ampicillin.

Urticaria and erythema multiforme have been reported occasionally. A few cases of exfoliative dermatitis have been reported. Anaphylaxis is the most serious reaction experienced (See Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

NOTE: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, ampicillin should be discontinued unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to ampicillin therapy.

Skin and other Subcutaneous Tissue Disorders

Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported in beta-lactam antibiotics.

Exanthema has been reported frequently. Increased frequency of exanthema has been observed in patients with leukemia or mononucleosis.

Infections and infestations

Pseudomembranous colitis has been reported. Fungal overgrowth in the oral cavity may occur.

Hepatic:

A moderate rise in aspartate aminotransferase (AST) has been noted, particularly in infants, but the significance of this finding is unknown. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

Haematological:

Anaemia, thrombocytopenia, haemolytic anaemia, thrombocytopenic purpura, eosinophilia, leucopenia and agranulocytosis have been reported during therapy with the penicillins. These reactions are usually reversible on discontinuation of therapy, and are believed to be sensitivity reactions.

Renal:

Nephropathy has been reported rarely.

CNS:

Encephalopathy can occur when the ampicillin blood level reaches 800 mg/L. As the blood brain barrier becomes more permeable in meningitis, toxic symptoms may be precipitated by lower levels of ampicillin in patients with meningitis. This can result in drowsiness, hyper-reflexia, myoclonic twitches, convulsions and coma.

Injection site:

Pain may be experienced at the site of intramuscular injection and phlebitis at the site of intravenous injection.

Other:

Vaginal or oral moniliasis may occur following the use of antibiotics.

Seventy two percent of all adverse events to ampicillin recorded in the Australian Adverse Drug Reaction System include rash as a symptom.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms

The injection of large doses has caused toxicity in patients with impaired kidney function or an impaired blood-brain barrier. Signs and symptoms of ampicillin toxicity may include nausea, vomiting, diarrhoea, electrolyte disturbances, decreased consciousness, muscle fasciculations, seizures, and coma.

Encephalopathy can occur when the ampicillin blood level reaches 800 mg/L. As the blood brain barrier becomes more permeable in meningitis, toxic symptoms may be precipitated by lower levels of ampicillin in patients with meningitis. This can result in drowsiness, hyper-reflexia, myoclonic twitches, convulsions and coma.

Treatment

There is no specific treatment for AUSTRAPEN overdosage. Ampicillin is removed by haemodialysis. Patients usually recover as the penicillin blood level decreases.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Microbiology

Ampicillin is bactericidal and is active against a wider range of organisms than benzylpenicillin. It is less active than benzylpenicillin against Gram-positive organisms but is active *in vitro* against *Streptococcus pyogenes* (Group A, β-haemolytic Streptococci) and many strains of *Streptococcus pneumoniae (D.*

pneumonia), Streptococcus viridans, non-penicillinase producing Staphylococci and *Enterococcus faecalis* (Group D Streptococci). There are strains of *Escherichia coli* that are sensitive to ampicillin, but isolates are becoming increasingly resistant *in vitro* due to the presence of penicillinase-producing strains. Some of the above organisms are sensitive to ampicillin only at concentrations achieved in the urine. Many strains of *Haemophilus influenzae*, *Neisseria meningitidis*, *Proteus mirabilis* and Salmonellae are sensitive to ampicillin, although the increasing incidence of beta-lactamase activity in *H. influenzae* and *E. coli* are reducing the capacity of ampicillin to treat diseases caused by these organisms.

Ampicillin is not effective against penicillinase producing bacteria, particularly resistant Staphylococci, which are now common. All strains of Pseudomonas, indole-positive Proteus, *Serratia marcescens*, Enterobacter, Klebsiella, Citrobacter and penicillinase producing *Neisseria gonorrhoeae* are resistant.

Like benzylpenicillin, ampicillin is bactericidal to sensitive organisms during the stage of active cell division. It is believed to act through the inhibition of cell wall synthesis.

Susceptibility tests

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (eg. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technique aspects of the laboratory procedures.

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small-uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections.

Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption and Distribution

Ampicillin sodium diffuses readily into most body tissues and fluids with the exception of brain and spinal fluid. Intramuscular injections of 500 mg and 1 g of ampicillin sodium result in peak plasma concentrations of around 7 and 10 mg/L respectively at one hour. Intravenous injection of 500 mg of ampicillin sodium yields a peak plasma concentration of 17 mg/L at 15 minutes. Some penetration occurs through inflamed meninges but maximum CSF levels are very much lower than peak serum levels. Ampicillin is excreted mainly via the urine where it exists at 0 to 6 hours at a concentration of 0.9 to 2.2 g/L following a 500 mg intramuscular dose and 0.1 to 0.6 g/L after 500 mg given intravenously.

Metabolism

Ampicillin is not highly protein-bound; 29 +12% is reported to be protein-bound in the serum.

The amount to be found in bile is variable. Approximately 0.1% is excreted unchanged in the bile.

The half-life of ampicillin is approximately 1 hour with normal renal function and up to 20 hours in the total absence of renal function. Renal clearance of ampicillin is slower than that of benzylpenicillin.

Excretion

Ampicillin is excreted in the urine both unchanged and as penicilloic acid. About 66% of a 500 mg intramuscular dose and 73% of a 500 mg intravenous dose is excreted in the urine in 6 hours in the presence of normal renal function.

Excretion of ampicillin can be delayed by concurrent administration of probenecid, thus prolonging its therapeutic effect.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No available information.

Carcinogenicity

No available information.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

AUSTRAPEN powder for injection contains no antiseptic or buffering agent nor are there any excipients.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

AUSTRAPEN should be stored below 25°C, protected from light.

Dry powder: If stored below 25°C, potency is maintained until the expiry date on the container label.

Solution: Ampicillin is unstable in concentrated solution and when prepared for injection or infusion, should be administered immediately.

Intravenous Fluids: To reduce microbiological hazard, use as soon as practicable after reconstitution/dilution. If required, AUSTRAPEN may be held at 2-8ºC in certain intravenous fluids following reconstitution.

Table 2: Storage of Intravenous Fluids at 2 - 8ºC

INTRAVENOUS FLUID	CONCENTRATION TESTED	POTENCY LOSS		
		1 HOUR	6 HOURS	24 HOURS
Physiological Saline*	15 g/500 mL	Not Tested	<5%	10%
M/6 Sodium Lactate+	15 g/500 mL	Not Tested	10%	-
Ringer's Solution*	4 g/500 mL	Not Tested	<5%	<10%
1.4% Sodium Bicarbonate+	4 g/500 mL	Not Tested	10%	Not Tested
Rheomacrodex 10% in Physiological in Saline+	4 g/500 mL	Not Tested	10%	25%

+ Reconstituted AUSTRAPEN Powder for Injection (as ampicillin sodium) should be used within 6 hours in M/6 Sodium Lactate, 1.4% sodium bicarbonate and 10% Rheomacrodex in physiological saline (Dextran 40 Injection BP in Sodium Chloride Injection) (see Section 4.2 DOSE AND METHOD OF ADMINISTRATION, PREPARATION OF INJECTIONS – Direct Intravenous Administration).

* It is stable in normal saline and Ringer's solution (Compound Sodium Chloride Injection BP 1959) for up to 24 hours.

Reconstituted AUSTRAPEN Powder for Injection should not be added to infusion bottles containing 10% Rheomacrodex in 5% glucose (Dextran 40 Injection BP in Glucose Injection), 5% glucose or glucose saline, but may be injected into the drip tubing of such an infusion (see Section 4.2 DOSE AND METHOD OF ADMINISTRATION, PREPARATION OF INJECTIONS – Direct Intravenous Administration).

6.5 NATURE AND CONTENTS OF CONTAINER

Container type: Glass Type 1 Clear vial with a dark grey bromobutyl rubber stopper and aluminium flip-off seal in boxes of 5 vials.

Australian Register of Therapeutic Goods (ARTG)

AUST R 29354 – AUSTRAPEN ampicillin 1g (as sodium) powder for injection vial

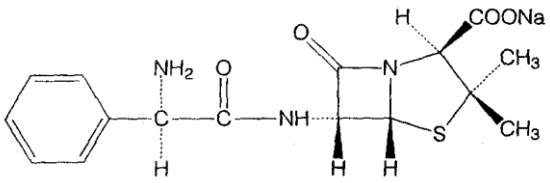
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Ampicillin (as sodium) is freely soluble in water, practically insoluble in acetone, in fatty oils & in liquid paraffin.

Chemical structure



CAS number

69-52-3

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

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Phone: 1800 274 276

9 DATE OF FIRST APPROVAL

04/11/1991

10 DATE OF REVISION

30/05/2024

Summary Table of Changes

Section Changed	Summary of New Information
All	Editorial updates
2	Moved sodium statement to section 4.4
4.4	Added information regarding sodium content
4.5	Added information regarding use with Methotrexate
4.8	Additional adverse side effects added: enterocolitis, loose stools, exanthema, pseudomembranous colitis, fungal overgrowth in the oral cavity
4.9	Additional potential overdose symptoms added

AUSTRAPEN_pi\May24/01 (CCDS 14 April 2023)