Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Amoxil 500 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

500 mg amoxicillin (as amoxicillin trihydrate) per capsule.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard
Maroon and gold capsules with ‘GS JVL' printed in white on the cap and body, containing a white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of infections due to organisms sensitive to amoxicillin and in the oral prophylaxis of endocarditis related to dental procedures, acute uncomplicated gonorrhoea and dental abscess (as an adjunct to surgical management).

4.2 Posology and method of administration

Route of administration: oral.

The absorption of ‘Amoxil’ is virtually unimpaired by the presence of food.

Standard adult dosage:
The usual daily dosage is 750mg in divided doses (i.e. 250mg three times daily by the oral route).

In cases of severe infection the dosage may be doubled or ‘Amoxil’ given by injection.

High dosage therapy: (maximum recommended oral dosage 6g daily in divided doses): A dosage of 3g twice daily is recommended in appropriate cases for the treatment of severe or recurrent purulent infection of the respiratory tract.

Short course therapy: *Simple acute urinary tract infection*: two 3g doses with 10-12 hours between the doses.

Gonorrhoea: 3g as a single dose.

Dental Abscess: two 3g doses with 8 hours between the doses.

Children up to ten years of age:

The usual total daily dosage is 375mg in divided doses (i.e. 125mg three times daily by the oral route). Dosage may be increased in cases of severe infection.
In severe or recurrent acute otitis media, especially where compliance may be a problem, 750mg twice a day for two days may be used as an alternative course of treatment in children aged three to ten years.

Prophylaxis of Endocarditis:
For the dental procedures where an oral dose is appropriate:

Adults: 3g dose followed by (6 hours later) a further 3g dose (or 1g IM dose if oral dose not tolerated), if considered necessary.

Children: Under 10: half the adult dose. (i.e., 1.5g given as 60ml dose of 'Amoxil' Syrup (125mg/5ml))
Under 5: quarter the adult dose.

Renal impairment: In patients with 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 doses.

Adults:

Glomerular filtration rate	Oral treatment
> 30ml/min	No adjustment necessary
10-30 ml/min	Max 500 mg b.i.d.
< 10ml/min	Max 500 mg/day

Children under 40 kg:

Glomerular filtration rate	Oral treatment
> 30ml/min	**No adjustment necessary**
10-30 ml/min	15 mg/kg given b.i.d. (Maximum 500mg/twice daily)
< 10ml/min	15 mg/kg given as a single day dose (Maximum 500mg)

Amoxicillin Paediatric Suspension is recommended for children under 6 months of age.

In patients receiving peritoneal dialysis:
Oral treatment: Max. 500mg/day.

Amoxicillin may be removed from the circulation by haemodialysis.

4.3 Contraindications

Use in patients with a history of hypersensitivity to beta-lactam antibiotics including penicillin or cephalosporins.

4.4 Special warnings and precautions for use

Before initiating therapy with Amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins. Cross-sensitivity between penicillins and cephalosporins is well documented. Serious and occasionally fatal hypersensitivity reactions (anaphalaxis) have been reported in patients receiving beta-lactam antibiotics. If an allergic reaction occurs, Amoxicillin should be discontinued and appropriate alternative therapy instituted.

Amoxicillin should be avoided if infections mononucleosis (glandular fever) is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of Amoxicillin.

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

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

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

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crytalluria

4.5 Interaction with other medicinal products and other forms of interaction

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

Concurrent administration of allopurinol during treatment with Amoxicillin can increase the likelihood of allergic skin reactions.

In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives

In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.

4.6 Fertility, pregnancy and lactation

Use in pregnancy:
Animal studies with 'Amoxil' have shown no teratogenic effects. The product has been in extensive clinical use since 1972 and its suitability in human pregnancy has been well documented in clinical studies. Amoxicillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Use in lactation:
Amoxicillin may be administered during the period of lactation. With the exception of the risk of sensitisation associated with the excretion of trace quantities of amoxicillin in breast milk, there are no known detrimental effects for the infant.

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

The following convention has been utilised for the classification of undesirable effects:-
Very common (more than 1/10), common (more than 1/100, less than 1/10), uncommon (more than 1/1000, less than 1/100), rare (more than 1/10,000, less than 1/1000), very rare (less than 1/10,000). The majority of the side-effects listed below are not unique to amoxicillin and may occur when using other penicillins.
Unless otherwise stated, the frequency of adverse events (AEs) has been derived from more than 30 years of post-marketing reports.

Blood and lymphatic system disorders

Very rare:	Reversible leucopenia (including severe neutropenia or agranulocytosis), reversible thrombocytopenia and haemolytic anaemia. Prolongation of bleeding time and prothrombin time.

Immune system disorders

Very rare:	As with other antibiotics, severe allergic reactions, including angioneurotic oedema, anaphylaxis (*see Warnings and Precautions*), serum sickness and hypersensitivity vasculitis.

If a hypersensitivity reaction is reported, the treatment must be discontinued. (*See also Skin and subcutaneous tissue disorders).*

Nervous system disorders

Very rare: Hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Infections and Infestations

Very rare: Mucocutaneous candidiasis

Gastrointestinal disorders

#Common: Diarrhoea and nausea.

#Uncommon: Vomiting.

Very rare: Antibiotic associated colitis (including pseudomembraneous colitis and haemorrhagic colitis).
Black hairy tongue
Superficial tooth discolouration has been reported in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing (***for suspension and chewable tablet formulations only)***

Hepato-biliary disorders

Very rare: Hepatitis and cholestatic jaundice. A moderate rise in AST and/or ALT.

The significance of a rise in AST and/or ALT is unclear.

Skin and subcutaneous tissue disorders

#Common: Skin rash.

#Uncommon: Urticaria and pruritus.

Very rare: Skin reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP).
(See also Immune system disorders).

Renal and Urinary tract disorders

Very rare: Interstitial nephritis, crystalluria (see Overdosage)

#The incidence of these AEs was derived from clinical studies involving a total of approximately 6,000 adult and paediatric patients taking amoxicillin.

4.9 Overdose

Gross overdosage will produce very high urinary concentrations, more so after parenteral administration. Symptoms of water/electrolyte imbalance should be treated symptomatically. Problems are unlikely to occur if adequate fluid intake and urinary output are maintained; however, amoxicillin crystalluria in some cases leading to renal failure has been observed (see Section 4.4, Special Warnings and Special Precautions for Use. More specific measures may be necessary in patients with impaired renal function: the antibiotic is removed by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification (Group + ATC code): Beta-Lactam Antibacterials Penicillins JO1CA-04.

`Amoxil` is a broad-spectrum antibiotic which possesses the safety profile of the penicillins and is rapidly bactericidal against a wide range of Gram-negative and Gram-positive organisms.

5.2 Pharmacokinetic properties

`Amoxil` is well absorbed by the oral and parenteral routes, peak levels are achieved one to two hours after administration. Oral administration produces high serum levels independent of the time at which the food is taken. `Amoxil` gives good penetration into the bronchial secretions and the high urinary concentrations of unchanged antibiotic. The average serum half life is 60 minutes. Elimination is mainly via the urine.

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 SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate (E572)
Erythrosine (E127)
Indigo carmine (E132)
Titanium dioxide (E171)
Yellow iron oxide (E172)
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Polypropylene containers with polyethylene lid containing 100 capsules.
PVC/aluminium foil blister packs containing 21 capsules.
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

GlaxoSmithKline (Ireland) Limited
Stonemasons Way
Rathfarnham
Dublin 16
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1077/33/2

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