An important consideration for the family doctor : Famicillin CAPS brand of ampicillin.

AN IMPORTANT CONSIDERATION FOR THE FAMILY DOCTOR

Reg. No. H/20.1.2/195, H/20.1.2/196 Capsules; J/20.1.2/448, J/20.1.2/449 Granules; J/20.1.2/451, J/20.1.2/450 Injection
Ampicillin FAMICILLIN capsules, granules and injection. P.P.

FAMICILLIN®

CAPS BRAND OF AMPICILLIN

The broad spectrum Antibiotic ideal for upper and lower respiratory infections

125 mg/5 ml Ampicillin Granules for 100 ml elixir

250 mg/5 ml Ampicillin Granules for 100 ml elixir

500 mg Ampicillin Capsules in 20's 100's & 500's

250 mg Ampicillin Capsules in 20's 100's & 500's

500 mg Ampicillin Injection 10 ml

250 mg Ampicillin Injection 5 ml

FAMICILLIN®

The complete economical range of Ampicillin presentations at ideal prices for the whole family

FAMICILLIN

Caps quality Ampicillin at a price that keeps temperature and inflation down

CAPS

A PHARMACEUTICAL HALLMARK FOR QUALITY, EFFICACY AND ECONOMY

Further information is available on request.

FAMICILLIN®

The broad spectrum Antibiotic ideal for upper and lower respiratory infections

Registration number: H/20.1.2/196 capsules 500 mg, H/20.1.2/195 capsules 250 mg, J/20.1.2/449 granules 250 mg and J/20.1.2/448 granules 125 mg.

Pharmacological classification: 20.1.2 penicillins

Scheduling category: PP

Approved name: ampicillin

Trade name

FAMICILLIN

Composition: *Capsules* – 250 mg and 500 mg ampicillin per capsule. *Granules* – 125 mg and 250 mg ampicillin per 5 ml elixir (preserved with 0,1% m/m nipasept).

Identification: *Capsules 250 mg* – white powder in lavender and white capsule overprinted. *500 mg* – white powder in lavender and white capsule, overprinted. *Granules* – pink granules in amber bottle.

Pharmacological action: Ampicillin is bactericidal with a broad spectrum of activity.

Indications: Infections of sensitive organisms including – gram-positive non-penicillinase producing staphylococci, haemolytic and non-haemolytic streptococci, diplococcus pneumoniae, clostridia sp. and streptococcus faecalis – gram-negative cocci (neisseri sp.), H. Influenzae, E. coli, proteus mirabilis, and many strains of brucellae, salmonellae and shigellae. *Note:* specific organisms are known to have developed a resistance to ampicillin.

Contra-indications: Hypersensitivity to penicillins, premature and very young infants, and pregnancy.

Dosage and directions for use: *Capsules and granules* – Adults: 250 mg–1,5 g every six hours between meals – Children 6–12 years: 250 mg every six hours between meals – Children under 6 years: 50–100 mg per bodymass per day in four to six equal doses.

Side-effects and special precautions: Side-effects similar to those found with other penicillins are usually infrequent and mild, but include transient diarrhoea, nausea, heartburn and pruritis ani, skin rashes of non-allergic origin especially in mono-nucleosis,

hypersensitivity reactions including urticaria, and more rarely exfoliative dermatitis eosinophilia, angioneurotic oedema, fever and swollen joints – *severe reactions which may be fatal can occur,*

erythema multiforme conditions have been known to occur up to two weeks after cessation of treatment,

reactions are more common after parenteral administration, but may occur with oral dosing of penicillin derivatives when hypersensitivity to pencillins has resulted from a previous course of treatment,

symptoms of reaction usually appear either within a few hours of treatment, or may be delayed some days, or even to the start of a subsequent course of penicillin therapy.

Note (i) If superinfection with non-susceptible organisms (aerobacter aerogenes, pseudomonas, candida, etc.) occurs, the drug should be withdrawn and specific or supporting therapy administered.

(ii) In treatment of enterococcemial endocarditis concomitant use of an aminoglycoside is indicated.

(iii) In impaired drug elimination, arising from such as inadequate renal or hepatic function, excessive serum concentration may indicate reduced dosage schedules or, if severe reaction occurs, withdrawal of treatment.

Known symptoms of overdosage and its treatment: Overdosing is virtually impossible. However, in patients with renal impairment, because serum levels increase, dosage may be reduced if required. Should a serious allergic reaction occur, the drug should be discontinued and the patient treated specifically (anti-histamines, pressor amines or corticosteroids).

Conditions of registration of the medicine: None.

Presentation: *Capsules* – containers of 20, 100 and 500 capsules. *Granules* – containers for the preparation of 100 ml elixir.

Storage directions: Keep well closed in a cool, dark, dry place *beyond the reach of children.*

Registration number: J/20.1.2/425 1 000 mg, J/20.1.2/451 500 mg and J/20.1.2/450 250 mg.

Pharmacological classification: 20.1.2 antibiotics-penicillin

Scheduling category: PP

Approved name: ampicillin sodium

Trade name:

FAMICILLIN

Composition: Vials containing 250 mg, 500 mg or 1 g ampicillin as ampicillin sodium.

Identification: A white powder in sealed vials.

Pharmacological action: Famicillin is bactericidal with a broad spectrum of activity.

Indications: Famicillin is effective in conditions caused by the gram-positive non-penicillinase producing staphylococci, haemolytic and non-haemolytic streptococci, diplococcus pneumoniae, clostridia sp. and streptococcus faecalis. Also the gram-negative cocci (neisseria sp.), H. influenzae, E. coli, proteus mirabilis and many strains of brucellae, salmonellae and shigellae.

Contra-indications: Should not be given to subjects known to be hypersensitive to penicillin, nor, in the neo-natal period, to babies born of hypersensitive mothers.

Dosage and directions for use: The usual dose for adults is 500 mg six-hourly. In severe infections, this dose may be given up to six times a day.

The recommended intravenous and intramuscular dosages for children are ¼ to ¾ of the adult dose, and are increased in relation to the age, from infants up to 15 years.

Intramuscular – 250 mg, 500 mg and 1 g – add 1,5–2,0 ml Water for Injections B.P.

Intravenous – dissolve the contents of the vial in the specified volume of Water for Injections B.P. 250 mg — 5,0 ml, 500 mg — 10,0 ml and 1 g — 20,0 — 30,0 ml. Administer by slow injection over a period of three to four minutes. Alternatively, if the fluids are being given by intravenous infusion, the solution may be injected slowly into the drip tubing – refer to the table under "stability".

Intrathecal – infants 0–2 years, 5–10 mg daily – dissolve in 0,5–ml. *Single injection daily. Children 2–12 years, 10–20 mg daily – dissolve in 0,5–1 ml. *Single injection daily. Adults up to 40 mg daily – dissolve in up to 2 ml. *Single injection daily.

*(Only sterile solutions should be used, i.e. Water for Injections B.P., sterile normal saline or C.S.F.)

Intraperitoneal – dialysis – 50 mg per litre of dialysate.

Therapeutic – dissolve 500 mg in 10 ml Water for Injections B.P.

Intrapleural – dissolve 500 mg in 5–10 ml Water for Injections B.P.

Intra-articular – 50–100 mg/ml of Water for Injections B.P. or 0,5% lignocaine hydrochloride B.P. to make up to volume of 2,5 ml.

Sub-conjunctival – dissolve 100 mg in 0,5 ml of Water for Injections B.P.

Topical – sprinkle 500 mg to 1 g dry powder extra peritoneally before closure and suturing.

Stability and compatibility – injectable solution – only freshly prepared solutions should be used.

Intravenous infusion – Famicillin is compatible with the following intravenous fluids, but solutions must be used within the periods shown below.

Table

Period of stability of Famicillin intravenous infusion solutions at room temperature.	N. saline	6–8 hours
	5% Dextrose	1 hour
	Dextrose saline	1 hour
	M/6 Sodium lactate	4 hours
	Ringer's solution	6–8 hours
	⅛% Sodium bicarbonate	4 hours

Famicillin should not be added to infusion bottles containing Dextran 40 Injection B.P., but may be injected into the drip tubing of such an infusion.

Blood and plasma – a dilute solution (i.e. 500 mg dissolved in 20 ml Water for Injections B.P.) should be injected slowly into the drip tubing rather than added to the infusion bottle.

Side-effects and special precautions: If symptoms due to overgrowth of non-susceptible organisms (aerobacter aerogenes, pseudomonas, candida, etc.) appear, the drug should be discontinued and specific or supportive therapy instituted.

Side-effects are usually mild, transitory and infrequent and are similar to those found with other penicillins. However, the administration of high doses to children may cause cerebral irritation and convulsions.

Transient diarrhoea, nausea, heartburn and pruritis ani may occur. When ampicillin is administered to a hypersensitive patient, allergic reactions may occur – urticaria and skin rashes are common – exfoliative dermatitis, eosinophilia, angio-neurotic oedema, fever and swollen joints are less frequent – *occasionally severe allergic reactions, which may be fatal, occur.*

These reactions are more common after parenteral use, but may occur after oral administration of any penicillin derivative in persons who have become hypersensitised after a previous course of treatment.

The onset of symptoms varies. It may occur within a few hours or days of the beginning of treatment or not until therapy with a penicillin derivative is resumed on a subsequent occasion.

Occasionally an erythema multiforme type of rash may occur up to 15 days after stopping administration.

Known symptoms of overdosage and particulars of its treatment: Overdosing is virtually impossible. However, in patients with renal impairment, because serum levels increase, dosage may be reduced if required.

Should a serious allergic reaction occur, the drug should be discontinued and the patient treated specifically (anti-histamines, adrenaline or corticosteroids).

Conditions of registration of the medicine: None.

Presentation: Vials of sterile powder containing 250 mg, 500 mg or 1 g ampicillin as ampicillin sodium.

Storage directions: Keep well closed in a cool, dark, dry place *beyond the reach of children.*

Further information is available on request.

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