For The Medical Profession Only

E-MOX®

EIPICO

Capsules – Dry Mix – Vials

Broad Spectrum Antibiotic

Composition:

Each dosage unit contains:	Capsule	Suspension (5 ml)	Vial
Amoxicillin	500 mg (as trihydrate)	125 mg or 250 mg (as trihydrate)	250 mg, 500 mg or1 g (as trihydrate)

Properties:

E-Mox (amoxicillin) is a semisynthetic, acid –stable, aminopenicillin and an analogue of ampicillin. It is a broad-spectrum bactericidal agent and is inactivated by penicillinase. It is active against a wide range of gram positive and gram negative bacteria including: Staphylococci (nonpenicillinase- producing strains), Streptococcus pneumonia, S. faecalis, S.viridans, Escherichia coli, Haemophilus influenza, Helicobacter pylori, Listeria monocytogenes, Moraxella cartarrhalis, Neisseria gonorrhoeae, N.meningitidis, Proteus mirabilis, and Salmonella species. **E-MOX®** acts by inhibiting mucoprotein synthesis in the cell wall of bacteria. It is more rapidly and more completely absorbed than ampicillin when given by mouth.

Pharmacokinetics:

Amoxicillin is rapidly and almost completely absorbed after oral administration. Peak plasma-concentrations have been observed after 1 – 2 hours. Doubling the dose can double the concentration. Food in the stomach does not diminish the absorption of the drug. Concentrations of amoxicillin after IM injection are similar to those achieved with oral administration. Amoxicillin is widely distributed at varying concentration in body tissues and fluids. It crosses the placenta; passes into the CSF when the meninges are inflamed; and small amounts are distributed into breast milk. Amoxicillin is about 20% bound to plasma proteins. It is metabolized in the liver giving penicilloic acid which is excreted in the urine. About 60% of an oral dose is excreted unchanged in the urine in 6 hours. High concentrations have been reported in bile; some may be excreted in faeces. Plasma half--lives of 1-1.5 hours have been reported. The half-life may be prolonged in neonates, the elderly, and renal impairment. In severe renal impairment, half-life is 7 – 20 hours.

Indications:

Treatment of infections caused by susceptible bacteria, including:

- Upper respiratory tract infections: otitis media, sinusitis, tonsillitis, pharyngitis, and laryngitis.
- Lower respiratory tract infections: acute and chronic bronchitis, and pneumonia.
- Gastrointestinal tract infections: typhoid and paratyphoid fevers, biliary tract infections, and gastroenteritis.
- Eradication of Helicobacter pylori.
- Genito-urinary tract infections.
- Skin and soft tissue infections.
- Prophylaxis of bacterial endocarditis.

Doses and Administration:

- Oral administration:

Adults: 500 mg every 8 hours.
Children up to 10 years: 125 – 250 mg every 8 hours;
Children under 40 kg body weight: 20 – 40 mg/kg daily in divided doses every 8 hours, or 25 – 45 mg/kg daily in divided doses every 12 hours.
Higher oral doses, either as a single dose or in short courses, may be used as follows:
For dental abscesses: 3 gm repeated once after 8 hours.
Uncomplicated acute urinary-tract infections: 3 gm repeated once after 10 – 12 hours.
Severe or recurrent infections of respiratory tract: 3 gm twice daily.
Children aged 3 – 10 years with otitis media: 750 mg twice daily for 2 days.
Uncomplicated gonorrhoea: A single dose of 3 gm amoxicillin, with 1 gm probenecid.
Prophylaxis of endocarditis: 2 – 3 gm is given about 1 hour before dental procedures.
Eradication of H.pylori: **E-MOX®** is given with either metronidazole or clarithromycin and gastric secretion inhibitor or ranitidine bismuth compound, in doses of 0.75 – 1.00 gm twice daily or 500 mg 3 times daily.
Reconstitution of **E-MOX® Dry Mix:**
To make up, first shake the bottle to loosen powder, then add water to the content of the bottle and shake well. Fill up to the line and allow to stand for 5 minutes to ensure full dispersion.
After reconstitution, **E-MOX® suspension** should be stored in a refrigerator and used only within 10 days. Shake well before use.

- Parenteral administration:

By IM or slow IV injection
Adults: 500 mg every 8 hours. In severe infections, 1 gm every 6 hours by slow IV injection over 3 – 4 minutes or by infusion over 30 – 60 minutes.
Children aged up to 10 years: 50 – 100 mg/kg daily in divided doses.
Doses may be reduced in renal impairment.

Drug Interactions:

- Tetracyclines may inhibit activity of amoxicillin.
- Probenecid prolongs the activity of amoxicillin.

Precautions:

- **E-MOX®** should be used with caution in:
- History of suspected allergy (such as eczema, hay fever, and asthma).
- Severely impaired renal function.
- History of cephalosporin allergy.
- Pregnancy or lactation.

Contraindications:

- Hypersensitivity to penicillins.
- Infectious mononucleosis.

Side Effects:

As with other penicillins, side effects may include hypersensitivity (rash, anaphylaxis), superinfection, diarrhoea, nausea, vomiting, pseudomembranous colitis (rare), hemolytic anemia, eosinophilia, agranulocytosis (rare); pruritus, and urticaria.

Packaging:

E-MOX® 500 mg Capsules: Blisters of 8 capsules each.
E-MOX® 125 mg Dry Mix: Bottle of 60 ml or 100 ml suspension after reconstitution.
E-MOX® 250 mg Dry Mix: Bottle of 60 ml or 100 ml suspension after reconstitution.
E-MOX® 250 mg Vials: Box of 1 vial.
E-MOX® 500 mg Vials: Box of 1 vial.
E-MOX® 1 g Vials: Box of 1 vial.

This is a Medicament.
•Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
•Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
•The doctor and the pharmacist are experts in medicine, its benefits and risks.
•Do not interrupt the period of treatment prescribed by yourself.
•Do not repeat the same prescription without consulting your doctor.
•Keep medicines out of the reach of children.

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