

JULPHAMOX

A Broad Spectrum Antibiotic

Capsules, Powder for Oral Suspension, Paediatric Drops for Oral Suspension

Composition

Capsules

Each capsule contains:

Active ingredient: Amoxicillin trihydrate equivalent to amoxicillin 250mg or 500mg.

Excipients: Magnesium stearate and gelatin.

Powder for Oral Suspension

Each teaspoonful (5mL) of the suspension contains:

Active ingredient: Amoxicillin trihydrate equivalent to amoxicillin 125mg or 250mg.

Excipients: Sodium citrate, xanthan gum, sucrose, aerosil, simethicone, and flavour.

Paediatric Drops for Oral Suspension

Each 1mL of the suspension contains:

Active ingredient: Amoxicillin trihydrate equivalent to amoxicillin 100mg.

Excipients: Sodium citrate, xanthan gum, sodium saccharin, D&C Yellow No.10, aerosil, and flavours (orange, vanilla, and banana).

Properties

Amoxicillin, the active ingredient of **JULPHAMOX**, is a synthetic broad-spectrum penicillin derivative (aminopenicillin) with proven safety. It is active against a wide range of Gram-positive and Gram-negative bacteria including *Streptococci*, *Staphylococci* (penicillin-sensitive), *Haemophilus influenzae*, *E. coli*, *Proteus mirabilis*, *Salmonellae*, and *Neisseriae*.

JULPHAMOX is well absorbed regardless of the presence of food in the stomach. It is excreted in the urine, over 60% being recovered within 6 hours. Concurrent administration of probenecid delays excretion.

Indications

• **JULPHAMOX** is indicated for the treatment of the following infections when caused by susceptible microorganisms:

- Ear, nose, and throat infections including otitis media and sinusitis.
- Dental infection and dental abscess (as an adjunct to surgical management).
- Respiratory tract infections including pharyngitis, acute and chronic bronchitis, and uncomplicated community acquired pneumonia.
- Gastroenteritis including *E.coli* enteritis and *Salmonella* enteritis.
- Typhoid and paratyphoid fever.
- Uncomplicated urinary tract infections.
- Uncomplicated endocervical and urethral gonorrhoea.
- Chlamydial infections in pregnant women.
- *Helicobacter pylori*-associated gastritis or peptic ulcer as an adjunctive treatment.

• **JULPHAMOX** is also used as a prophylaxis to prevent the development of bacterial endocarditis, in patients with heart-valve lesion, septal defect, patent ductus arteriosus, or prosthetic valve.

Dosage

• Usual dose:

Adults and children above 10 years: 250mg every 8 hours, to be increased in severe infections to 500mg every 8 hours.

Children 10 years of age and below: 125mg every 8 hours, to be increased in severe infections to 250mg every 8 hours.

• Severe or recurrent purulent respiratory infections: The recommended dose is 3g every 12 hours.

• Short - course **JULPHAMOX** therapy:

- Otitis media in children 3 - 10 years: 750mg twice daily for 2 days.

- Dental abscess: 3g repeated after 8 hours.

- Urinary tract infections: 3g repeated after 10 - 12 hours.

- Gonorrhoea: A single dose of 2-3g **JULPHAMOX** with probenecid 1g.

• Endocarditis prophylaxis:

For multistage dental procedures in patients who have not had endocarditis, a maximum of 2 single doses of a penicillin (amoxicillin) may be given in a mouth; alternative drugs should be used for further treatment and the penicillin can be used again after 3 - 4 months.

- Dental procedures *under local or no anaesthesia* (in patients who have not received more than a single dose of a penicillin in the previous month), the recommended dose of **JULPHAMOX** is:

Adults and children above 10 years: 3g 1 hour before procedure.

Children 5 - 10 years: 1.5g 1 hour before procedure.

Children under 5 years: 750mg 1 hour before procedure.

- Dental procedures *under general anaesthesia* (in patients who have not received more than a single dose of a penicillin in the previous month), the recommended dose is, *either* 3g **JULPHAMOX** in addition to oral probenecid 1g 4 hours before procedure.

Or the following regimen according to the age of the patient:

Adult and children above 10 years: 3g **JULPHAMOX** 4 hours before induction of anaesthesia then 3g as soon as possible after procedure.

Children 5 - 10 years: 1.5g **JULPHAMOX** 4 hours before induction of anaesthesia then 1.5mg as soon as possible after procedure.

Children under 5 years: 750mg **JULPHAMOX** 4 hours before induction of

anaesthesia then 750mg as soon as possible after procedure.

• Eradication of *Helicobacter pylori*:

One-week triple therapy regimens:

- **JULPHAMOX** 500mg and metronidazole 400mg, both given three times daily in addition to omeprazole 20mg twice daily (or 40mg once daily).

- **JULPHAMOX** 1g and clarithromycin 500mg, both given twice daily, in addition to omeprazole 20mg twice daily (or 40mg once daily).

- **JULPHAMOX** 1g, clarithromycin 250mg (or metronidazole 400mg), and lansoprazole 30mg all given twice daily.

Two-week triple therapy regimen:

JULPHAMOX 750mg and metronidazole 500mg, both given three times daily addition to ranitidine 300mg at night (or 150mg twice daily).

Two-week dual therapy regimen:

JULPHAMOX 500mg 4 times daily and ranitidine bismuth citrate 400mg twice daily.

Note: Triple therapy regimens have higher eradication rates than with the dual therapy regimen.

Direction for reconstitution

Suspension: Loosen powder, add 56mL of water in two portions and shake well after each addition or add water to 2/3 of the mark on the bottle. Shake well and make up to the mark. Shake well to disperse.

Paediatric Drops: Loosen powder, add 15mL or a measuring cup of water, close the bottle and shake well to disperse.

If you miss a dose

- Take the missed dose as soon as possible.

- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

Do not take two doses at one time.

Contraindications

Amoxicillin is contraindicated in patients with a previous history of penicillin hypersensitivity. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management should be implicated as necessary.

Precautions

Amoxicillin should be given with caution to patients having a previous history of allergy. It is usually advisable to reduce the dose of amoxicillin in patients having severe renal impairment.

The use of broad-spectrum penicillins (e.g. ampicillin, amoxicillin) should be avoided in patients with glandular fever (infectious mononucleosis) where there is a high risk to develop erythematous maculopapular skin rashes. Rashes are also reported in patients with severe renal impairment, chronic lymphatic leukaemia, and possibly in those infected with the human immunodeficiency virus (HIV).

Pregnancy and Lactation: Penicillins, in general, are not known to be harmful during pregnancy as well as during lactation as only trace amounts are reported to be excreted in breast milk.

Side Effects

As with other penicillins, adverse reactions are usually mild and transitory in nature. Nausea, diarrhoea, or an occasional rash is sometimes reported. Urticarial rashes suggesting penicillin hypersensitivity may be experienced, in which case it is advisable to discontinue the treatment.

Rarely, antibiotic - associated colitis has been reported.

Overdosage

Since there is no specific antidote for amoxicillin, treatment is essentially symptomatic and supportive. Haemodialysis may aid in the removal of the drug from the blood.

Drug Interactions

As with other penicillins, the excretion of amoxicillin is reduced upon simultaneous administration of probenecid.

Presentations

JULPHAMOX capsules: Pack of 20 capsules.

Hospital pack of 500 or 1000 capsules.

JULPHAMOX powder for oral suspension: Bottle of 60ml or 100mL.

JULPHAMOX paediatric drops: Bottle of 20mL with a dropper

* *Store at a temperature of 15 - 25°C in a dry place. Keep the capsules protected from light.*

After reconstitution of the suspension, when stored at a temperature of 15 - 25°C, discard unused portion after 7 days and if stored in refrigerator, discard unused portion after 14 days.

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