

MILOXY Granules for Oral Suspension 125mg/5ml

Amoxicillin 125mg/5ml

Not to be used in patients with known hypersensitivity to Penicillin

Product Description

MILOXY Granules for Oral Suspension 125mg/5ml:

Light pink coloured powder with pleasant flavour. After reconstitution: Pink coloured oral suspension having pleasant flavour.

Composition

MILOXY Granules for Oral Suspension 125mg/5ml:

Each 5ml contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 125 mg.

Pharmacodynamics

Amoxicillin is a beta-lactam antibiotic that inhibits synthesis of the bacterial cell wall. It is a broad-spectrum penicillin and active against both gram-positive and gram-negative microorganisms.

Clinically relevant gram-negative pathogens covered by amoxicillin are *Escherichia coli*, *Proteus mirabilis*, *Salmonella*, *Shigella*, *Haemophilus influenzae*, *Helicobacter pylori*, *Chlamydia* and others. Other microorganisms responding to amoxicillin include all those susceptible to penicillin G, e. g. Streptococcus groups A, B, C and G, H, L and M, *Streptococcus pneumoniae*, non-penicillinase-producing *Staphylococcus aureus* Neisseri, *Erysipelothrix rhusiopathiae*, *Corynebacterium*, *Bacillus anthracis*, *Actinomyces*, streptobacilli, spirillum minus, *Pasteurella multocida*, *Listeria* and *Spirochetal* organisms, as well as numerous aerobic organisms (among them *peptococci*, *Clostridia* and *Fuso*-bacteria).

Pharmacokinetic

Amoxicillin is rapidly absorbed from the gastrointestinal tract. The absorption of amoxicillin is unaffected by meals. Following oral administration, peak serum levels are reached within 1 – 2 hours. Amoxicillin readily distributes in body tissue and fluids including purulent and mucoid sputum. Elimination of amoxicillin is predominantly via renal. Approximately, 60 – 70% of amoxicillin is excreted unchanged in the urine in 6 hours after administration.

The elimination half-life of amoxicillin is similar for children aged around 3 months and above. For very young children (including preterm new-borns), the interval of administration should not exceed twice daily administration due to immaturity of the renal pathway of elimination. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Indications

Miloxi is useful in the treatment of infections caused by amoxicillin susceptible organisms:

Respiratory tract infection

- Upper airways and ENT infections
- Lower airways infections, e.g. acute and chronic bronchitis, pneumonia, lung abscesses, pertussis (incubation period and early stages).

Urogenital infections

- Acute and chronic pyelonephritis, pyelitis, prostatitis, epididymitis
- Cystitis, urethritis, asymptomatic bacteriuria during pregnancy
- Gonorrhoea

Gynaecologic infections (septic abortion, adnexitis, endometritis, etc.)

Gastrointestinal infections

- Typhoid fever, paratyphoid, particularly if complicated by septicaemia (in combination with an aminoglycoside antibiotic); control of salmonella carriers
- Shigellosis
- Infections of the biliary system (cholangitis, cholecystitis)

Skin and soft tissue infections

Leptospirosis

Acute and latent listeriosis

Unless parenteral treatment (e.g. with ampicillin) is required, Miloxy is also active in the conditions below:

- Short-term (24 to 48 hrs) prophylactic treatment of patients undergoing surgery (e.g. in the oral cavity)
- Endocarditis, e.g. enterococcal endocarditis (alone or in combination with an aminoglycoside antibiotic)
- Bacterial meningitis (pending the outcome of the susceptibility test; particularly in children)
- Septicaemias caused by amoxicillin-susceptible pathogens

Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G.

Recommended Dosage

The dosage of amoxicillin is dependent on age, bodyweight and renal function of the patient, on the seriousness and localisation of the infection and on the expected or proved causative agent.

Method of administration:

Shake bottle until all powder flows freely. Add small quantity of water with intermittent shaking then add remaining quantity of water up to the ring mark. Shake vigorously. This produces 100ml of suspension. Miloxy is stable in the presence of gastric acid and may be given before or after food. The preparation is administered orally with a measuring cup. The ready-for-use suspension should be taken with a glass of water.

Adult, children 20 kg of body weight and above:
250 – 500 mg every 8 hours.

Infants up to 6 kg of body weight:
25 – 50 mg every 8 hours.

Infants 6 – 8 kg of body weight:
50 – 100 mg every 8 hours

Infants and children 8 -20 kg of body weight:
6.7 – 13.3 mg/kg of body weight every 8 hours

Gonorrhea:

3 g as a single dose with 1 g of probenecid

Treatment should be continued for a minimum of 48 – 72 hours beyond the time that the patient become asymptomatic or evidence of bacterial eradication has been obtained.

Route of administration

Oral.

Contraindications

Amoxicillin is penicillin and should not be given to penicillin-hypersensitive patients. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics eg. Cephalosporins

Warnings and precautions

Serious and occasionally fatal hypersensitivity reaction (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Miloxy, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporin, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Miloxy must be discontinued immediately and appropriate alternative therapy instituted.

In patients with renal function impairment, the excretion of amoxicillin will be delayed and, depending on the degree of the impairment, it may be necessary to reduce the total daily dosage. Precaution should be taken in premature children and during neonatal period: renal, hepatic and haematological functions should be monitored.

The prolonged use of amoxicillin may occasionally result in an overgrowth of non-susceptible bacteria or yeasts. Patients should therefore carefully be watched for superinfections. The occurrence of anaphylactic shock and other severe allergic reactions is rare following the oral administration of amoxicillin. However, if such reactions occur, appropriate emergency treatment measures must be taken.

The presence of high urinary concentrations of amoxicillin can cause precipitation of the product in urinary catheters. Therefore, catheters should be visually inspected at intervals. At high doses, adequate fluid intake and urinary output must be maintained to minimise the possibility of amoxicillin crystalluria.

Amoxicillin should not be used for the treatment of bacterial infections in patients with viral infections, acute lymphatic leukaemia, or infectious mononucleosis as erythematous (morbilliform) rashes have been associated with glandular fever in patients receiving amoxicillin.

Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of any antibiotics. Should antibiotic-associated colitis occur, amoxicillin should immediately be discontinued, a physician be consulted and appropriate therapy is initiated. Anti-peristaltic medicinal products are contra-indicated in this situation.

As with other beta-lactams, the blood should be checked regularly during high-dose therapy. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy. High dose therapy with beta-lactams for patients with renal insufficiency or seizures history, treated epilepsy and meningeal affection, could exceptionally lead to seizures. The occurrence of generalized erythema with fever and pustules at the beginning of treatment should make suspect a generalized acute exanthematous pustulosis; this necessitates the interruption of therapy and contraindicated any further administration of amoxicillin.

Interaction with other medicaments

Concomitant use not recommended

Allopurinol

Concomitant administration of allopurinol may promote the occurrence of allergic cutaneous reactions and is therefore not advised.

Digoxin

An increase in the absorption of digoxin is possible on concurrent administration with amoxicillin. A dose adjustment of digoxin may be necessary.

Anticoagulants

Concomitant administration of amoxicillin and anticoagulants from the coumarin class, may prolong the bleeding time. A dose adjustment of anticoagulants may be necessary. A large number of cases showing an increase of oral anticoagulant activity has been reported in patients receiving antibiotics. The infectious and inflammatory context, age and the general status of the patient appear as risk factors. In these circumstances, it is difficult to know the part of the responsibility between the infectious disease and its treatment in the occurrence of INR disorders. However, some classes of antibiotics are more involved, notably fluoroquinolones, macrolides, cyclines, cotrimoxazole and some cephalosporins.

Methotrexate

Interaction between amoxicillin and methotrexate leading to methotrexate toxicity has been reported. Serum methotrexate levels should be closely monitored in patients who receive amoxicillin and methotrexate simultaneously. Amoxicillin decreases the renal clearance of methotrexate, probably by competition at the common tubular secretion system.

Caution is recommended when amoxicillin is given concomitantly with:

Oral hormonal contraceptives

Administration of amoxicillin can transiently decrease the plasma level of estrogens and progesterone, and may reduce the efficacy of oral contraceptives. It is therefore recommended to take supplemental non-hormonal contraceptive measures.

Other forms of interactions:

- Forced diuresis leads to a reduction in blood concentrations by increased elimination of amoxicillin.
- It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.
- Amoxicillin may decrease the amount of urinary estriol in pregnant women.
- At high concentrations, amoxicillin may diminish the results of serum glycemia levels.
- Amoxicillin may interfere with protein testing when colormetric methods are used.

Pregnancy and Lactation

There is no current evidence to suggest any embryotoxic, teratogenic or mutagenic effects of Miloxy during pregnancy. However, amoxicillin is excreted into the breast milk in small quantities with the possible risk of sensitisation. Amoxicillin may be used in pregnancy and during breast feeding when the potential benefits outweigh the potential risks associated with treatment.

Side effects

Blood and lymphatic system disorders: Very rare cases of reversible leucopenia, reversible thrombocytopenia, haemolytic anaemia and prolongation of bleeding time and prothrombin time.

Immune system disorders: Like all other penicillin, Miloxy may exceptionally cause severe allergic reactions (anaphylactic shock). Hypersensitivity reactions like urticarial rashes, fever, joint pain, erythema multiforme, exfoliative dermatitis and angioneurotic edema may occur. Patients treated for typhoid fever, leptospirosis or syphilis may develop Jarisch-Herxheimer's reaction secondary to bacterial lysis.

Nervous system disorders: Hyperkinesia, dizziness and convulsions may occur. As with all penicillin producing high plasma levels, patients with epilepsy or meningitis and impaired renal function will increase the risk of developing neurotoxic manifestation (seizures).

Gastrointestinal disorders: Common transient side effects like diarrhoea and nausea.

Hepatobiliary disorders: Very rare cases of hepatitis and cholestatic jaundice. Minor transient elevations of AST and/or ALT have occasionally been seen.

Skin and subcutaneous tissue disorders: Skin rash, urticaria, pruritus and very rare cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Renal and urinary tract disorders: Very rare cases of interstitial nephritis and crystalluria.

Symptoms and Treatment of Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed. Amoxicillin may be removed from the circulation by haemodialysis.

Effects on Ability to Drive and Use Machine

Adverse effects on the ability to drive or operate machinery have not been observed.

Storage Condition

Granules to be store below 30 °C up to shelf life of the product.

The reconstituted suspension can be store below 25 °C up to 7 days. Protect from light.

Dosage form and packaging available

MILOXY Granules for Oral Suspension 125/5ml- Box contains 1 glass bottle @ 100 ml.

Immediate container: Amber coloured glass bottle (USP Type III) having marking on its 100 ml position ring mark inner side/outer side. Cap: 25 mm silver coloured, aluminium ROPP cap having blue printed text matter. Capacity of the bottle: 100 ml. Secondary pack: Carton, with package insert and clear, transparent measuring cup inside the carton.

Shelf-life

24 months.

After reconstitution: Do not store suspension for more than 7 days.

Registration Number

MILOXY Granules for Oral Suspension 125mg/5ml- MAL19036009AZ

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