

# AMOXIDREX<sup>®</sup> / AMOXICILLIN

## Broad Spectrum Antibiotic

### Forms and Presentation

**Amoxidrex Capsules:** Boxes of 20

**Amoxidrex Suspension:** Powder for preparation, fruit flavored oral suspension: Bottle of 60 ml & 100 ml.

### Composition

**Amoxidrex Capsules :** Each capsule contains 500 mg Amoxicillin activity.

**Amoxidrex Suspension :** Each 5 ml reconstituted suspension contains 250 mg Amoxicillin activity.

### Properties

**Amoxidrex<sup>®</sup>**, brand of Amoxicillin trihydrate, is a broad spectrum possessing a bactericidal activity against a wide range of Gram + and Gram - microorganisms.

**Amoxidrex<sup>®</sup>** is a  $\beta$ -lactam antibiotic. It has a bactericidal effect & exerts its killing action on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis through binding to and un-activating trans-peptidases, penicillin - binding proteins on the inner surface of the bacterial cell membrane.

### Indications

**Amoxidrex<sup>®</sup>** is indicated in the treatment of infections due to a susceptible ( ONLY  $\beta$  -lactamase-negative) strains of the designated microorganisms in the conditions listed below:

- Infections of the ear, nose, and throat due to *Streptococcus* spp. ( $\alpha$ - and  $\beta$ -hemolytic strains only ), *Streptococcus pneumoniae*, *Staphylococcus* spp., or *H. influenzae*.
- Infections of the genitourinary tract ( e.g. cystitis, urethritis, pyelonephritis ) due to *E. coli*, *P. mirabilis* or *E. faecalis*;
- Infections of the skin and skin structure due to *Streptococcus* spp. ( $\alpha$ -and  $\beta$  - hemolytic strains only), *Staphylococcus* spp., or *E. coli*;
- Infections of the lower respiratory tract ( e.g. acute exacerbation of chronic bronchitis ) due to *Streptococcus* spp. (  $\alpha$ -and  $\beta$  - hemolytic strains only ), *Streptococcus pneumoniae*, *Staphylococcus* spp., or *H. influenzae*;
- Gonorrhoea, acute uncomplicated ( ano-genital and urethral infections ) due to *N. gonorrhoeae* ( males and females );
- *H. Pylori* eradications to reduce the risk of duodenal ulcer recurrence;
- Infections of the gastrointestinal tract ( e.g. typhoid and paratyphoid fever );
- Bone infections, Pelvic infections, Septicaemia, Endocarditis and Meningitis.

### Dosage and Administration

**Amoxidrex<sup>®</sup>** capsules and oral suspensions may be given without regard to meals.

**Amoxidrex Capsules :** Adults: 1 capsule three times daily .

#### Amoxidrex Suspension :

Children over 2 years : 250 mg, three times daily.

Children under 2 years : 125 mg, three times daily.

### Contraindications

**Amoxidrex<sup>®</sup>** should not be given to penicillin-hypersensitive patients. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotic ( e.g. cephalosporins).

### Precautions

Before initiating therapy with **Amoxidrex<sup>®</sup>**, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins or cephalosporins. Serious and occasionally fatal hypersensitivity ( anaphylactic ) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity to beta-lactam antibiotics. Erythematous ( morbilliform ) rashes have been associated with glandular fever in patients receiving amoxicillin.

Prolonged use of antibiotics may promote the overgrowth of non-susceptible organisms, including fungus. The possibility of superinfection with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, amoxicillin should be discontinued and appropriate therapy instituted. Dosage should be adjusted in patients with renal impairment.

**Nursing mothers:** Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is administered to a nursing woman.

### Drug Interactions.

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased and prolonged blood levels of amoxicillin. In common with other broad spectrum antibiotics, **Amoxidrex®** may reduce the efficacy of oral contraceptives and patients should be warned accordingly. Concurrent administration of allopurinol during treatment with amoxicillin can increase the like-hood of allergic skin reactions. Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. 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.

### Side Effects

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. The following adverse reactions have been reported as associated with the use of penicillins :

- **Gastrointestinal:** nausea, vomiting, diarrhea, and hemorrhagic / pseudomembranous colitis.
- **Hypersensitivity reactions:** skin rash, pruritis and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, and hypersensitivity vasculitis have been reported.
- **Liver** ; a moderate rise in AST ( SGOT ) and / or ALT ( SGPT ) has been noted but the significance of this finding is unknown. Hepatic dysfunction including cholestatic jaundice, hepatic cholestasis and acute cytolytic hepatitis have been reported.
- **Hemic and Lymphatic Systems** : Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported but these reactions are usually reversible on discontinuation of therapy.
- **Central Nervous System:** Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and / or dizziness have been reported rarely.
- **Miscellaneous:** Superficial tooth discoloration has been reported very rarely in children. It can usually be removed by brushing.

### Storage.

- Store in a cool and dry place, below 25 °C
- Keep out of the reach of children.
- Store away from heat and direct light.
- Once dispensed, **Amoxidrex®** suspension should be store below 25 °C and used within 14 days.

### THIS IS A MEDICINE

- Medicines are products which affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat the same prescription without consulting your doctor.

**KEEP MEDICINES OUT OF THE REACH OF CHILDREN.**

