

Patient information leaflet

MILOXY 250 - DT (Amoxicillin Tablets for Oral Suspension USP 250mg)

Read all of this leaflet carefully before you start taking this medicine.

- Read this leaflet carefully because it contains important information for you.
- Keep this leaflet; you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Miloxy 250 – DT are and what they are used for
2. Before you take Miloxy 250 – DT
3. How to take Miloxy 250 – DT
4. Possible side effects
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1. What Miloxy 250 – DT are and what they are used for

Amoxicillin Trihydrate, the active ingredient in Miloxy 250 – DT, is a medicine which is used in certain types of bacterial infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of amoxicillin tablets for oral suspension and other antibacterial drugs, amoxicillin tablets for oral suspension should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Amoxicillin is indicated in the treatment of infections due to susceptible (ONLY β -lactamase-negative) strains of the designated microorganisms in the conditions listed below:

Infections of the ear, nose, and throat due to *Streptococcus* spp. (α - and β -hemolytic strains only), *Streptococcus pneumoniae*, *Staphylococcus* spp., or *H. influenzae*

Infections of the genitourinary tract due to *E. coli*, *P. mirabilis*, or *E. faecalis*

Infections of the skin and skin structure due to *Streptococcus* spp. (α - and β -hemolytic strains only), *Staphylococcus* spp., or *E. coli*

Infections of the lower respiratory tract due to *Streptococcus* spp. (α - and β -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) Therapy may be instituted prior to obtaining results from bacteriological and susceptibility studies to determine the causative organisms and their susceptibility to amoxicillin.

Indicated surgical procedures should be performed.

2. Before you take Miloxy 250 - DT

Do not take Miloxy 250 – DT if:

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins.

Before initiating therapy with amoxicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, amoxicillin should be discontinued and appropriate therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including amoxicillin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of “antibiotic-associated colitis.”

After the diagnosis of pseudomembranous colitis has been established, appropriate therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

A Patient Information Sheet is provided with the drug product.

Labor and Delivery

Oral ampicillin-class antibiotics are poorly absorbed during labor. Studies in guinea pigs showed that intravenous administration of ampicillin slightly decreased the uterine tone and frequency of contractions but moderately increased the height and duration of contractions. However, it is not known whether use of amoxicillin in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

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.

Consult your doctor or pharmacist if:

You have any of these conditions:

- asthma
- kidney disease
- an unusual or allergic reaction to amoxicillin, other penicillins, cephalosporin antibiotics, other medicines, foods, dyes, or preservatives
- pregnant or trying to get pregnant
- breast-feeding

3. How to take Miloxy 250 - DT

Mix one tablet in a small amount of water [approximately 2 teaspoonfuls]. Drink the entire mixture. Rinse the container with an additional small amount of water and drink the contents to assure the whole dose is taken. Do not chew or swallow the tablets. The tablets will not rapidly dissolve in your mouth.

The tablet is not recommended to be mixed with any liquid other than water, as studies have only been conducted using water.

Method of administration

MILOXY 250 - DT should be taken orally in form of mixture. Do not chew or swallow the tablets. The tablets will not rapidly dissolve in your mouth.

4. Possible side effects

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins and in those with a history of allergy, asthma, hay fever, or urticaria. The following adverse reactions have been reported as associated with the use of penicillins:

Gastrointestinal:

Nausea, vomiting, diarrhea, and hemorrhagic/pseudomembranous colitis.

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

Hypersensitivity Reactions:

Serum sickness-like reactions, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, acute generalized exanthematus pustulosis, hypersensitivity vasculitis and urticaria have been reported.

NOTE: These hypersensitivity reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, amoxicillin should

be discontinued unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to amoxicillin therapy.

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.

Renal:

Crystalluria has also been reported

Hemic and Lymphatic Systems:

Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

Central Nervous System:

Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness have been reported rarely.

Miscellaneous:

Tooth discoloration (brown, yellow, or gray staining) has been rarely reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

If you have these or any other symptoms after taking this product, tell your doctor or pharmacist.

5. How to store MILOXY 250-DT Tablets

Do not store above 25°C. Protect from light.

Keep out of reach of children.

Do not use your tablets after the expiry date stated on the label or carton.

MILAN LABORATORIES (INDIA) PVT. LTD.
AMOXICILLIN TABLETS FOR ORAL SUSPENSION USP 250 mg



Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Each Tablet for oral suspension contains:

Amoxicillin Trihydrate Equivalent to Amoxicillin USP 250mg

Inactive Ingredients:- Microcrystalline Cellulose, Purified Talc, Magnesium Stearate, Aerosil (Colloidal Silicon Dioxide), Aspartame Powder, Sodium Starch Glycolate, Crospovidone, Maize starch, Lactose & Ess. Pineapple DM.

Miloxo 250 – DT is White, circular, flat uncoated dispersible tablets having break line on one side and plain on other side of each tablet.

Marketing Authorisation Holder

MILAN LABORATORIES (INDIA) Pvt. LTD.

Plot No.35, 36, 63, 64, 65, 67, 87,

J. C. I. E. Ltd., Kamothe, Panvel,

Navi Mumbai.

India.