

Claritrox Granules for Oral suspension 125mg/5ml

Claritrox Granules for Oral suspension 250mg/5ml

Each 5ml of Reconstituted suspension contains: clarithromycin 125mg and potassium sorbate 20mg as preservative.

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What is Claritrox Suspension used for

Clarithromycin is indicated in children 6 months to 12 years for treatment of infections due to susceptible organisms in the following conditions:

- Upper respiratory infections (e.g., streptococcal pharyngitis).
- Lower respiratory infections (e.g., bronchitis, pneumonia).
- Acute otitis media.
- Skin and skin structure infections (e.g., impetigo, folliculitis, cellulitis, abscesses).
- Disseminated or localized mycobacterial infections due to *Mycobacterium avium* or *Mycobacterium intracellulare*. Localized infections due to *Mycobacterium chelonae*, *Mycobacterium fortuitum*, or *Mycobacterium kansasii*.

How Claritrox Suspension works

Clarithromycin is an antibiotic from macrolide class. Clarithromycin works by destroying some types of bacteria that cause certain infections.

Before you use Claritrox Suspension

-When you must not take it

Do not take Claritrox Suspension if:

- You are hypersensitive to macrolides or any of the excipients

- You are receiving terfenadine, astemizole, cisapride, domperidone, pimozone therapy have pre-existing cardiac abnormalities such as abnormal heartbeat, heart disease (reduce blood supply to the heart), heart failure, etc. or electrolyte disturbances and torsades de pointes.
- Concomitant administration of clarithromycin and ergot alkaloids (e.g., ergotamine or dihydroergotamine) is contraindicated, as this may result in ergot toxicity.
- Concomitant administration of clarithromycin and oral midazolam is contraindicated.
- Clarithromycin should not be used concomitantly with statins.
- Clarithromycin should not be used concomitantly with colchicine, ticagrelor or ranolazine, lomitapide.
- You are having impaired kidney or liver function.

-Before you start take it

Tell your doctor if:

- You are allergic to any medicines, food and dyes.
- You are taking any other medicines (including those not prescribed by your doctor).

-Taking other medicine

You should tell your doctor or pharmacist if you are taking the following medicine as it may interact with your Claritrox Suspension:

- digoxin (for heart failure)
- intravenous or oromucosal midazolam (sedatives/sleeping pills)
- triazolam (sleeping pills)
- alprazolam (for anxiety)
- tolterodine (medicine to treat urinary incontinence)
- St. John's Wort (herbal product used for depression)
- theophylline (used in patients with breathing difficulties such as asthma)

- etravirine, efavirenz, ritonavir, zidovudine, nevirapine, atazanavir
- or saquinavir (anti-viral drugs used in the treatment of HIV)
- rifampicin, rifabutin or rifapentine (antibiotics used in the treatment of certain bacterial infections)
- fluconazole, itraconazole (antifungal medicine)
- oral anticoagulants such as warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (blood thinner). Your child's prothrombin time should be monitored frequently
- rosuvastatin (cholesterol-lowering drugs). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage). Signs of myopathy (muscle pain or muscle weakness) should be monitored.
- phenytoin, carbamazepine, valproate or phenobarbital (for epilepsy)
- insulin or other diabetes medicines, e.g. repaglinide, nateglinide (used to lower blood glucose levels)
- sildenafil, tadalafil and vardenafil (for impotence in adult males or for use in high blood pressure in the blood vessels of the lungs)
- hydroxychloroquine or chloroquine (medicines used to treat autoimmune diseases).
- cisapride, (used to treat heartburn in patients with gastroesophageal reflux disease (GERD))
- domperidone, (a medicine that increases the movements or contractions of the stomach and bowel)
- pimozone, (to control motor or verbal tics)
- astemizole (treatment of allergic conditions)

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- terfenafine (is an antihistamine. Antihistamines prevent sneezing, runny nose, itching and watering of the eyes, and other allergic symptoms.)
- ergot alkaloids (These drugs are used only to treat severe, throbbing headaches like migraine and cluster headaches)
- lomitapide (to lower bad cholesterol levels in the blood)
- antiarrhythmics (prevent and treat abnormal heartbeats (arrhythmias))
- CYP3A4-based Interactions (An HIV protease inhibitor used in combination with other antivirals in the treatment of HIV infection. A triazole compound used to treat fungal infections.)
- omeprazole (proton pump inhibitor (PPI). It works by decreasing the amount of acid produced by the stomach.)
- carbamazepine (to manage and treat epilepsy, trigeminal neuralgia, and acute manic and mixed episodes in bipolar I disorder.)
- colchicine (to prevent or treat attacks of gout)
- phenytoin (to control seizures (convulsions))
- valproate (to treat epilepsy and bipolar disorder)
- Calcium Channel Blockers (to treat conditions of the heart and blood vessels)

How to take Claritrox Suspension

-How much to take

Children:

children are 7.5 mg/kg b.i.d. up to a maximum dose of 500 mg b.i.d.

- The usual duration of treatment is for 5 to 10 days.
- The following table is a suggested guide for determining dosage based on the weight of the child and the concentration of the suspension:

DOSAGE GUIDELINES FOR PEDIATRIC PATIENTS Based on body weight		
Weight *		7.5mg/kg b.i.d dosage in ml given twice daily
Kg	Lbs.	125mg/5ml
8-11	18-25	2.5ml
12-19	26-43	5ml
20-29	44-64	7.5ml
30-40	65-88	10ml
* Children < 8 kg or < 18 lbs. should be dosed on a per kg or per lb. basis (approx. 7.5 mg/kg b.i.d. or 3.4 mg/lb b.i.d.)		

DOSAGE GUIDELINES FOR PEDIATRIC PATIENTS Based on body weight		
Weight *		7.5mg/kg b.i.d dosage in ml given twice daily
Kg	Lbs.	250mg/5ml
8-11	18-25	2.5ml
12-19	26-43	5ml
20-29	44-64	7.5ml
30-40	65-88	10ml
* Children < 8 kg or < 18 lbs. should be dosed on a per kg or per lb. basis (approx. 7.5 mg/kg b.i.d. or 3.4 mg/lb b.i.d.)		

- **Dosage in Patients with Mycobacterial Infections**

In children with disseminated or localized mycobacterial infections, the recommended dose is 7.5 to 15mg/g clarithromycin b.i.d, not exceeding a maximum dose of 500mg b.i.d.

- **Renal Impairment**

In children with creatinine clearance less than 30 ml/min/1.73m², the dosage of clarithromycin should be reduced by one-half, i.e., up to 250 mg once daily, or 250 mg twice daily in more severe infections. Dosage should not be continued beyond 14 days in these patients.

- The prepared suspension can be taken with or without meals, and can be taken with milk.

-When to take it

Follow doctors advice

-How long to take it

Follow doctors advice

-If you forget to take it

Take the missed dose as soon as possible as you remember it. However if it is almost for the next dose skip the missed dose and continue your regular doing schedule. Do not take a double dose to make up for a missed one

-If you take too much (overdose)

It is advisable for you to contact and inform your doctor if you did take Claritrox Suspension too much.

While you are using Claritrox Suspension

-Things you must do

Follow doctors advice

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-Things you must not do

Do not stop taking without consulting doctor first. Do not give you medicine to whom experiencing the same symptoms as you

-Things to be careful of

Avoid prolonged use with high dosage.

Side Effects

Like all medicines, Claritrox can cause side effects, although not everybody gets them. The following common side effects have been reported:

Very common (affects more than 1 user in 10):

- Injection site pain

Common (affects 1 to 10 users in 100)

- difficulty sleeping (insomnia)
- changes in sense of taste
- headache
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- abnormal liver function blood tests
- rash, excessive sweating, flushing
- pain or inflammation at the site of injection (Klacid IV)
- vasodilation

Uncommon (affects 1 to 10 users in 1000):

- infections of the skin or vagina, yeast infections (thrush)
- change in the level of white blood cells in the blood (which can make infections more likely)
- change in the levels of blood platelets in the blood (increased risk of bruising, bleeding or blood clots)
- allergic reaction
- anorexia, decreased appetite
- anxiety, nervousness

- fainting, dizziness, drowsiness, tremor, involuntary movements of the tongue, face, lips or limbs
- spinning sensation (vertigo), ringing in the ears, hearing loss
- fast, pounding heart (palpitations), changes in heart rhythm or heart stopping
- breathing problems (asthma), nosebleed
- blood clot in the lungs
- stomach problems such as bloating, constipation, wind (flatulence), belching, heartburn or anal pain,
- inflammation of the lining of the stomach or oesophagus (the tube connecting your mouth with your stomach)
- sore mouth, dry mouth, inflammation of the tongue
- liver problems such as hepatitis or cholestasis which may cause yellowing of the skin (jaundice), pale stools or dark urine
- increase in liver enzymes
- itching, hives, inflammation of the skin
- stiffness, aches or spasms in the muscles
- kidney problems such as raised levels of protein normally excreted by the kidneys or raised levels of kidney enzymes
- fever, chills, weakness, fatigue, chest pain or general feeling of discomfort
- abnormal blood test results

Not known (frequency cannot be estimated from available data):

- infection of the colon
- infection of the skin
- swelling of the skin around the face and the throat. This may

- cause difficulty in breathing (angioedema)
- psychotic disorder, confusion, change in sense of reality, depression, loss of bearings (disorientation), hallucinations (seeing things), abnormal dreams (nightmares), manic episodes.
- convulsions
- changes or loss in sense of taste and/or smell
- paraesthesia (tingling and burning sensation in the skin, numbness, 'pins and needles' sensation)
- deafness
- bleeding
- inflammation of the pancreas
- discoloration of the tongue, tooth discolouration
- liver failure, jaundice (yellowing of the skin)
- rare allergic skin reactions such as AGEP (which causes a red, scaly rash with bumps under the skin and blisters), Stevens-Johnson syndrome or toxic epidermal necrolysis (which cause severe illness with ulceration of the mouth, lips and skin), DRESS (which causes severe illness with rash, fever and inflammation of internal organs)
- acne
- muscle disease (myopathy), breakdown of muscle tissue (rhabdomyolysis)
- inflammation of the kidney (which can cause swollen ankles or high blood pressure) or kidney failure

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Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]”

Storage and Disposal of Claritrox

-Storage

Store below 30° C.

Storage condition for Reconstituted suspension: After Reconstitution store at room temperature not exceed 30° c and use within 14 days.

Do not refrigerate the reconstituted suspension.

-Disposal

Medicines should not be disposed of via waste water or household waste. These measures will help you to protect the environment.

Products Description

-How it looks like

For 250mg/5ml

White to off-white granular powder forming white to off-white suspension on reconstitution with water.

For 125mg/5ml

White to off-white granular powder forming white to off-white suspension on reconstitution with water.

-Ingredients:

Active material used is Clarithromycin
Non active material used are
Potassium sorbate ,Citric acid,Maltodextrin,Xathan Gum,Titanium dioxide,Aerosil 200 (Colliodal Silicon Dioxide),American ice cream soda and Caster sugar.

MAL No.:

For 250mg/5ml:

For 125mg/5ml:

Manufacturer and Product Registration

Holder:

SM PHARMACEUTICALS
SDN.BHD(218628-M)
Lot 88,Sungai Petani Industrial Estate
08000,Sungai Petani
Kedah Darul Aman,Malaysia

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