

**Metaxalone Cas No. : 1665-48-1**

This medication relaxes muscles. It is used along with rest and physical therapy to decrease muscle pain and spasms associated with strains, sprains or other muscle injuries.

Active Pharmaceuticals Ingredients Manufacturers



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**Taj Pharmaceuticals Ltd.****Metaxalone****CAS No. : 1665-48-1****Synonyms**

5-[(3,5-Dimethylphenoxy)methyl]oxazolidin-2-one

CAS number 1665-48-1

Formula C<sub>12</sub>H<sub>15</sub>NO<sub>3</sub>

Mol. mass 221.252 g/mol

DrugBank APRD00514

**Chemical data**

SMILES eMolecules &amp; PubChem

**Pharmacokinetic data**

Bioavailability Unknown

Metabolism Hepatic

Half life 9.2 (± 4.8) hours

Excretion Renal

**DOSAGE**

Metaxalone comes as a tablet to take by mouth. It usually is taken three or four times a day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take metaxalone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Take this medication by mouth usually 3 or 4 times a day, or as directed by your doctor. It may be taken with food or immediately after meals to prevent stomach upset. If you take this medication after a high-fat meal and experience side effects, it may be best to take this drug on an empty stomach or after a light meal. Dosage is based on your medical condition and response to therapy. Do not increase your dose or take it more often than prescribed because the risk of side effects may increase. This medication is intended for short-term use, usually no longer than 3 weeks, unless otherwise directed by your doctor. If your condition does not improve in 2-3 weeks, contact your doctor.

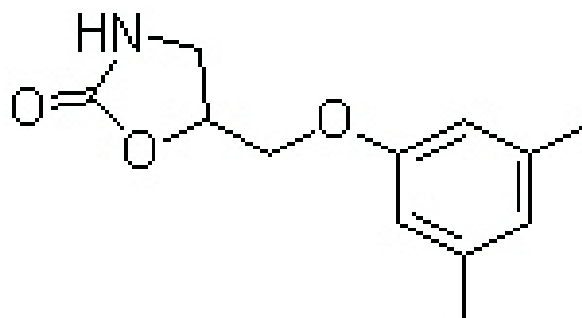
**SIDE EFFECTS**

Stomach upset, nausea, constipation, dry mouth, headache, blurred vision, lightheadedness, dizziness or drowsiness may occur during the first few days as your body adjusts to this medication. If these symptoms persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes, signs of infection (e.g., persistent sore throat, fever), yellowing eyes or skin, unusual tiredness, fast/pounding heartbeat, trouble urinating, worsening of seizures. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

Metaxalone may cause side effects

\* drowsiness

\* dizziness





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**Metaxalone**

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- \* upset stomach
- \* vomiting
- \* headache
- \* nervousness

If you experience any of the following symptoms, call your doctor immediately:

- \* severe skin rash
- \* difficulty breathing
- \* yellowing of the skin or eyes
- \* unusual bruising or bleeding
- \* unusual tiredness or weakness
- \* seizures

### PRECAUTIONS

Before taking metaxalone,

- \* tell your doctor and pharmacist if you are allergic to metaxalone or any other drugs.
- \* tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially medications for seizures, allergies, colds, or coughs; pain medications; sedatives; tranquilizers; and vitamins.
- \* tell your doctor if you have or have ever had kidney disease, liver disease, seizures, or a blood disorder.
- \* tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking metaxalone, call your doctor immediately.
- \* you should know that this drug may make you drowsy. Do not drive a car or operate machinery until you know how metaxalone affects you.
- \* remember that alcohol can add to the drowsiness caused by this drug.

Before taking metaxalone, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe liver disease, severe kidney disease, history of low blood cell counts (e.g., hemolytic anemia, other anemias) due to a drug reaction. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, seizures, severe difficulty urinating (urinary retention). This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Alcohol may enhance dizziness or drowsiness. Limit alcohol. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects, especially dizziness and drowsiness. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

### INTERACTION

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of drugs that cause drowsiness such as: certain antihistamines (e.g., diphenhydramine), anti-anxiety drugs (e.g., diazepam), anti-seizure drugs (e.g., carbamazepine), medicine for sleep (e.g., sedatives), narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., phenothiazines such as chlorpromazine, or tricyclic anti-depressants such as amitriptyline), tranquilizers. Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about the safe use of those products. This medication may cause false positive results with certain diabetic urine testing products (cupric sulfate-type). Make sure laboratory personnel and the doctors know you use this drug. Do not start or stop any medicine without doctor or pharmacist approval.



## DRUG DESCRIPTION

Metaxalone is a muscle relaxant used to relax muscles and relieve pain caused by strains, sprains, and other musculoskeletal conditions. Its exact mechanism of action is not known, but it may be due to general central nervous system depression. It is considered to be a moderately strong muscle relaxant, with relatively low incidence of side effects. Metaxalone exhibits increased bioavailability when taken with food. Specifically, in one study, compared to fasted conditions, the presence of food at the time of drug administration increased C(max) by 177.5% and increased AUC(last) by 123.5% and AUC(inf) by 115.4%.

Metaxalone is a white to almost white, odorless crystalline powder freely soluble in chloroform, soluble in methanol and in 96% ethanol, but practically insoluble in ether or water. Each tablet contains 800 mg metaxalone and the following inactive ingredients: alginic acid, ammonium calcium alginate, B-Rose Liquid, corn starch, and magnesium stearate.



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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

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or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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