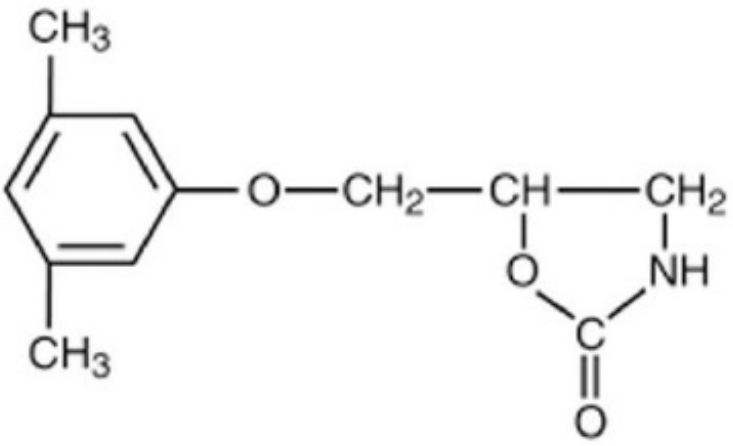
METAXALONE- metaxalone tablet
Highmark Pharma LLC

METAXALONE TABLETS, USP

DESCRIPTION

Metaxalone Tablets, USP are available as 400mg, 400mg tablets are round shaped, light pink tablets.

Chemically, metaxalone, USP is 5-[(3,5-dimethylphenoxy)methyl]-2-oxazolidinone. The empirical formula is $C_{12}H_{15}NO_3$, which corresponds to a molecular weight of 221.25. The structural formula is:



Metaxalone, USP is a white to almost white, crystalline powder freely soluble in dichloromethane, soluble in methanol, sparingly soluble in ethanol and ethyl acetate, slightly soluble in toluene and isopropanol, insoluble in water and *n*-hexane.

Each tablet contains 400 mg metaxalone, USP and the following inactive ingredients: alginic acid, corn starch, ferric oxide red, copovidone, magnesium stearate, povidone, pregelatinized starch, sodium alginate.

INDICATIONS AND USAGE

Metaxalone is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Metaxalone does not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS

Known hypersensitivity to any components of this product.

Known tendency to drug induced, hemolytic, or other anemias.

Significantly impaired renal or hepatic function.

WARNINGS

Serotonin Syndrome

Cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of serotonergic drugs with metaxalone used within the recommended dosage range (see PRECAUTIONS: Drug Interactions) and with metaxalone as a single agent taken at doses higher than the recommended dose (see OVERDOSAGE). Serotonergic drugs include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT3 receptor antagonists, opioids (particularly fentanyl, meperidine, and methadone), drugs that affect the serotonergic neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), and drugs that impair metabolism of serotonin (including monoamine oxidase (MAO) inhibitors, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue) (see PRECAUTIONS: Drug Interactions).

Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination, rigidity), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The onset of symptoms generally occurs within several hours to a few days, but may occur later than that. Discontinue metaxalone if serotonin syndrome is suspected.

Risks from Concomitant Use with Alcohol or other CNS Depressants

The sedative effects of metaxalone and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants (TCAs)) may be additive. Exercise caution with patients who take more than one of these CNS depressants simultaneously. Follow patients closely for signs and symptoms of respiratory depression and sedation (see PRECAUTIONS: Drug Interactions).

PRECAUTIONS

Metaxalone should be administered with great care to patients with pre-existing liver damage. Serial liver function studies should be performed in these patients.

False-positive Benedict’s tests, due to an unknown reducing substance, have been noted. A glucose-specific test will differentiate findings.

Taking metaxalone with food may enhance general CNS depression; elderly patients may be especially susceptible to this CNS effect. *(See* CLINICAL PHARMACOLOGY: Pharmacokinetics and PRECAUTIONS: Information for Patients).

Information for Patients

Driving or Operating Heavy Machinery:
Metaxalone may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle, especially when used with alcohol or other CNS depressants.

Serotonin Syndrome:

Inform patients that metaxalone could cause a rare but potentially life-threatening condition resulting from administration of doses higher than the recommended dose or from concomitant administration of serotonergic drugs with metaxalone used within the recommended dosage range. Warn patients of the symptoms of serotonin syndrome and to seek medical attention right away if symptoms develop. Instruct patients to inform their healthcare providers if they are taking, or plan to take, serotonergic medications (see WARNINGS, PRECAUTIONS: Drug Interactions, and OVERDOSAGE).

Drug Interactions

CNS Depressants:
The sedative effects of metaxalone and other CNS depressants (e.g., alcohol, benzodiazepines, opioids, tricyclic antidepressants (TCAs)) may be additive. Exercise caution with patients who take more than one of these CNS depressants simultaneously. Follow patients closely for signs and symptoms of respiratory depression and sedation (see WARNINGS).

Serotonergic Drugs:
Serotonin syndrome has resulted from concomitant use of serotonergic drugs with metaxalone used within the recommended dosage range (see WARNINGS). If concomitant use is warranted, carefully observe the patient, particularly during treatment initiation and dose adjustment. Discontinue metaxalone if serotonin syndrome is suspected.

Examples of serotonergic drugs include: selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT3 receptor antagonists, opioids (particularly fentanyl, meperidine, and methadone), drugs that affect the serotonin neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), monoamine oxidase (MAO) inhibitors (those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue).

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of metaxalone has not been determined.

Pregnancy
Reproduction studies in rats have not revealed evidence of impaired fertility or harm to the fetus due to metaxalone. Post marketing experience has not revealed evidence of fetal injury, but such experience cannot exclude the possibility of infrequent or subtle damage to the human fetus. Safe use of metaxalone has not been established with regard to possible adverse effects upon fetal development. Therefore, metaxalone tablets should not be used in women who are or may become pregnant and particularly during early pregnancy unless, in the judgement of the physician, the potential benefits outweigh the possible hazards.

Nursing Mothers
It is not known whether this drug is secreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Pediatric Use

Safety and effectiveness in children 12 years of age and below have not been established.

ADVERSE REACTIONS

The most frequent reactions to metaxalone include:

CNS: drowsiness, dizziness, headache, and nervousness or “irritability”;

Digestive: nausea, vomiting, gastrointestinal upset.

Other adverse reactions are:

Immune System: anaphylaxis, hypersensitivity reaction, rash with or without pruritus;

Hematologic: leukopenia; hemolytic anemia;

Hepatobiliary: jaundice.

CNS: cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of serotonergic drugs with metaxalone used within the recommended dosage range and with metaxalone as a single agent taken at doses higher than the recommended dose (see WARNINGS, PRECAUTIONS: Drug Interactions, and OVERDOSAGE).

To report SUSPECTED ADVERSE REACTIONS, contact SCIEGEN PHARMACEUTICALS, INC., at 1-855-724-3436 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch

OVERDOSAGE

Deaths by deliberate or accidental overdose have occurred with metaxalone, particularly in combination with antidepressants, and have been reported with this class of drug in combination with alcohol.

Serotonin syndrome has been reported when metaxalone was used at doses higher than the recommended dose (see WARNINGS and ADVERSE REACTIONS).

When determining the LD_{50} in rats and mice, progressive sedation, hypnosis and finally respiratory failure were noted as the dosage increased. In dogs, no LD_{50} could be determined as the higher doses produced an emetic action in 15 to 30 minutes.

Treatment - Gastric lavage and supportive therapy. Consultation with a regional poison control center is recommended.

DOSAGE AND ADMINISTRATION

The recommended dose for adults and children over 12 years of age is two 400 mg tablets (800 mg) three to four times a day.

HOW SUPPLIED

Metaxalone Tablets, USP 400 mg are available as light pink, round shaped tablet debossed with ‘SG 474’ on one side and plain on the other.

NDC 87450-101-10: Bottles of 100 Tablet

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Dispense in well-closed, light-resistant containers.

Rx Only

Manufactured for:

Highmark Pharma

Dallas TX 75228

PRINCIPAL DISPLAY PANEL

pdp

METAXALONE

metaxalone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:87450-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METAXALONE (UNII: 1NMA9J598Y) (METAXALONE - UNII:1NMA9J598Y)	METAXALONE	400 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALGINIC ACID (UNII: 8C3Z4148WZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	

Product Characteristics			
Color	pink (light pink)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	SG;474
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:87450-101-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207466	11/01/2021	

Labeler - Highmark Pharma LLC (144951288)