METAXALONE- metaxalone tablet
Northwind Pharmaceuticals

NDC: 51655-0162-10

MFG: 65162-553-10

Metaxalone, USP

800mg

10 tablets

Rx Only

Dosage: See Package insert

Store below 77 degrees F. (25 degrees C)

Store in a tight, light resistant container (See USP).

Keep out of the reach of children.

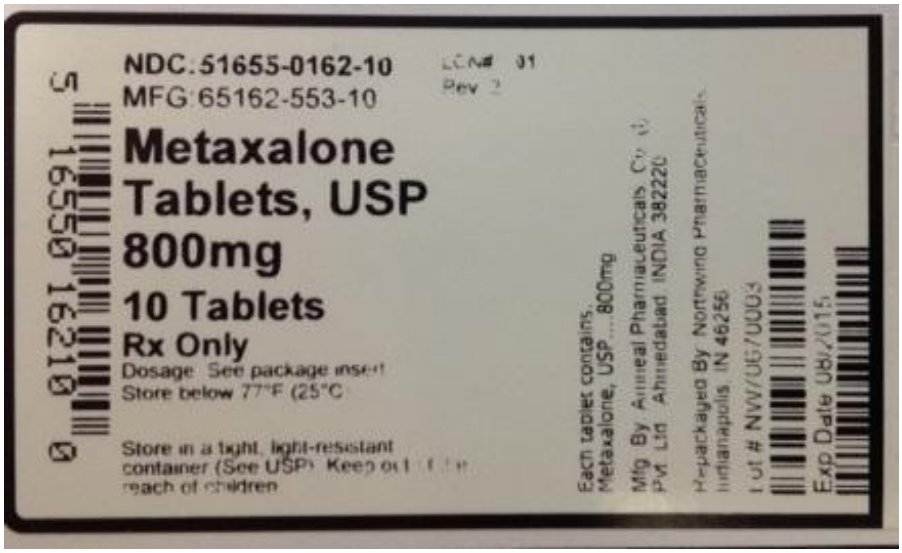
Each tablet contains Metaxalone, USP...800mg

Mfg. By Amneal Pharmaceuticals Co. Pvt. Ltd Ahmedabad, India 38220

Repackaged by Northwind Pharmaceuticals, Indianapolis, IN 46256

Lot#:

Exp. Date:



NDC: 51655-162-20

MFG: 65162-553-10

Metaxalone Tablets, USP

800 mg

20 Tablets

Rx only

Dosage: See package insert

Store below 77 degrees F.

Store in a tight, light resistant container (See USP) Keep out of the reach of children.

Mfg by: Amneal Pharmaceuticals Co. Pvt. Ltd. Ahmedabad, India 38220

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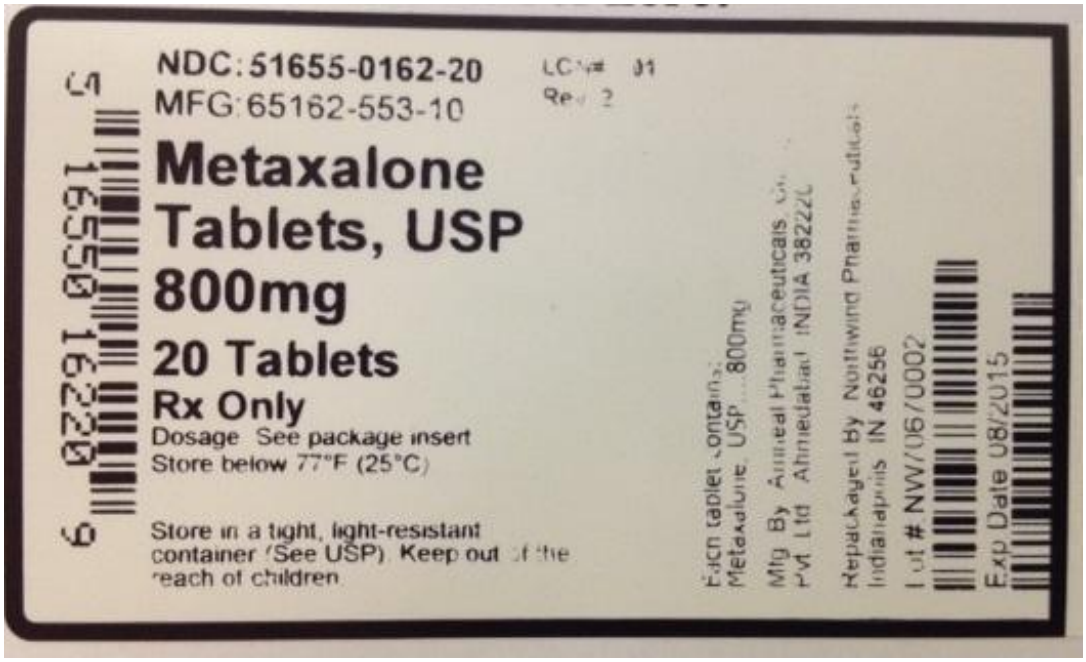

Warnings

WARNINGS

Metaxalone may enhance the effects of alcohol and other CNS depressants.

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 section).

Information for Patients

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.

Drug Interactions

The sedative effects of metaxalone and other CNS depressants (e.g., alcohol, alcohol, benzodiazepines, opioids, tricyclic antidepressants) may be additive. Therefore, caution should be exercised with patients who take more than one of these CNS depressants simultaneously.

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

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: hypersensitivity reaction, rash with or without pruritus;

Hematologic: leukopenia; hemolytic anemia;

Hepatobiliary: jaundice.

Though rare, anaphylactoid reactions have been reported with metaxalone.

Dosage and Administration

DOSAGE AND ADMINISTRATION

The recommended dose for adults and children over 12 years of age is one 800 mg tablet three to four times a day.

Online drug information link

For more information regarding this drug please see the manufacturer's information online at:

Permanent Link:

http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=3aa9dba9-29b0-4520-a0f7-66d19d52c6bc

METAXALONE

metaxalone tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51655-162(NDC:65162-553)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METAXALONE (UNII: 1NMA9J598Y) (METAXALONE - UNII:1NMA9J598Y)	METAXALONE	800 mg

Product Characteristics

Color	pink	**Score**	no score
Shape	capsule	**Size**	19mm
Flavor		**Imprint Code**	AN;553
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-162-10	10 in 1 BOTTLE, DISPENSING		
2	NDC:51655-162-20	20 in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203399	02/12/2014	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-162)

Revised: 6/2014 Northwind Pharmaceuticals