FLAVOXATE HYDROCHLORIDE- flavoxate hydrochloride tablet, film coated
Padagis US LLC

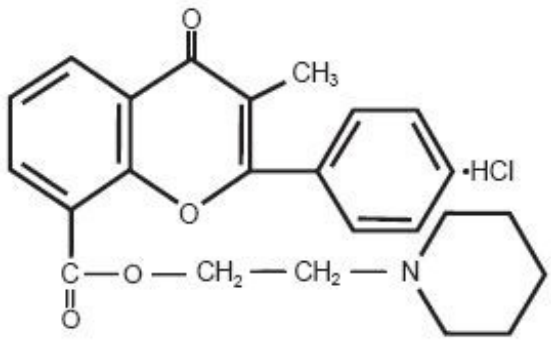
Flavoxate HCl Tablets
100 mg

PRESCRIBING INFORMATION

DESCRIPTION

Flavoxate HCl tablets contain flavoxate hydrochloride, a synthetic urinary tract spasmolytic.

Chemically, flavoxate hydrochloride is 2-piperidinoethyl 3-methyl-4-oxo-2-phenyl-4H-1-benzopyran-8-carboxylate hydrochloride. The empirical formula of flavoxate hydrochloride is $C_{24}H_{25}NO_4 \cdot HCl$. The molecular weight is 427.94. The structural formula appears below:



Flavoxate HCl is supplied in tablets for oral administration. Each round, white, film-coated Flavoxate HCl tablet is debossed "PAD" and "0115" on one side and plain on the other side and contains flavoxate hydrochloride, 100 mg. Inactive ingredients consist of colloidal silicon dioxide, ethyl acrylate, hypromellose, lactose monohydrate, magnesium stearate, methyl methacrylate, microcrystalline cellulose, nonoxynol 100 and sodium starch glycolate. Film coating is composed of hypromellose 2910 6cP and polyethylene glycol.

CLINICAL PHARMACOLOGY

Flavoxate hydrochloride counteracts smooth muscle spasm of the urinary tract and exerts its effect directly on the muscle.

In a single study of 11 normal male subjects, the time to onset of action was 55 minutes. The peak effect was observed at 112 minutes. 57% of the flavoxate HCl was excreted in the urine within 24 hours.

INDICATIONS AND USAGE

Flavoxate HCl tablets are indicated for symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis/urethrotrigonitis. Flavoxate HCl tablets are not indicated for definitive treatment, but are compatible with drugs used for the treatment of urinary tract infections.

CONTRAINDICATIONS

Flavoxate HCl tablets are contraindicated in patients who have any of the following obstructive conditions: pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal hemorrhage and obstructive uropathies of the lower urinary tract.

WARNINGS

Flavoxate HCl should be given cautiously in patients with suspected glaucoma.

PRECAUTIONS

Information for Patients:

Patients should be informed that if drowsiness and blurred vision occur, they should not operate a motor vehicle or machinery or participate in activities where alertness is required.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of flavoxate HCl have not been performed.

Pregnancy:

Teratogenic Effects-Pregnancy Category B.

Reproduction studies have been performed in rats and rabbits at doses up to 34 times the human dose and revealed no evidence of impaired fertility or harm to the fetus due to flavoxate HCl. There are, however, no well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when flavoxate HCl is administered to a nursing woman.

Pediatric Use:

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

ADVERSE REACTIONS

The following adverse reactions have been observed, but there are not enough data to support an estimate of their frequency.

Gastrointestinal: Nausea, vomiting, dry mouth.

CNS: Vertigo, headache, mental confusion, especially in the elderly, drowsiness, nervousness.

Hematologic: Leukopenia (one case which was reversible upon discontinuation of the drug).

Cardiovascular: Tachycardia and palpitation.

Allergic: Urticaria and other dermatoses, eosinophilia and hyperpyrexia.

Ophthalmic: Increased ocular tension, blurred vision, disturbance in eye accommodation.

Renal: Dysuria.

OVERDOSAGE

The oral LD_{50} for flavoxate HCl in rats is 4273 mg/kg. The oral LD_{50} for flavoxate HCl in mice is 1837 mg/kg.

It is not known whether flavoxate HCl is dialyzable.

DOSAGE AND ADMINISTRATION

Adults and children over 12 years of age:

One or two 100 mg tablets 3 or 4 times a day. With improvement of symptoms, the dose may be reduced. This drug cannot be recommended for infants and children under 12 years of age because safety and efficacy have not been demonstrated in this age group.

HOW SUPPLIED

Flavoxate HCl Tablets, 100 mg, are supplied as round, white, film-coated tablets debossed "PAD" and "0115" on one side and plain on the other side, in bottles of 100.

100 mg 100's:
NDC 0574-**0115**-01

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]

Manufactured For
Perrigo®
Minneapolis, MN 55427

Manufactured by:
Mikart, INC.
Atlanta, GA 30318

Code 917A00

7H700 RC J2

Rev 10-16 B

PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle

Rx Only

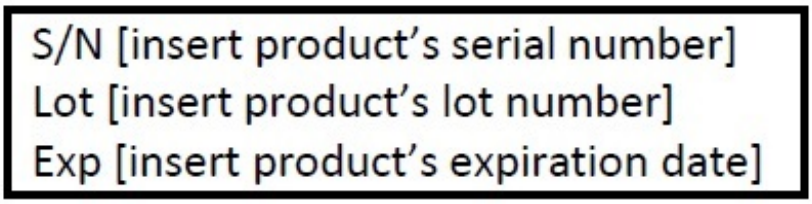
NDC 0574-**0115**-01

Flavoxate HCl Tablets

100 mg

100 Tablets

The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.



FLAVOXATE HYDROCHLORIDE

flavoxate hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0574-0115
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLAVOXATE HYDROCHLORIDE (UNII: 9C05J6089W) (FLAVOXATE - UNII:3E74Y80MEY)	FLAVOXATE HYDROCHLORIDE	100 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYL ACRYLATE (UNII: 71E6178C9T)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL METHACRYLATE (UNII: 196OC77688)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
NONOXYNOL-100 (UNII: A906T4D368)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	PAD;0115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-0115-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/22/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076831	12/22/2004	

Labeler - Padagis US LLC (967694121)