**FLAVOXATE HYDROCHLORIDE- flavoxate hydrochloride tablet**
**Epic Pharma, LLC**

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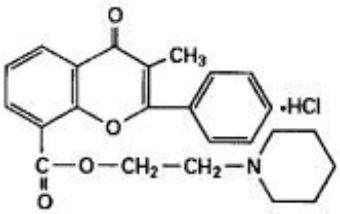
**Flavoxate Hydrochloride Tablets 100 mg, Film-Coated**

**Rx only**

## DESCRIPTION

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

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




Each tablet for oral administration contains 100 mg flavoxate hydrochloride. In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, corn starch, dibasic calcium phosphate dihydrate, magnesium stearate, hypromellose, polydextrose, polyethylene glycol, titanium dioxide and triacetin.

## 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 hydrochloride was excreted in the urine within 24 hours.

## INDICATIONS AND USAGE

Flavoxate hydrochloride 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 hydrochloride tablets are not indicated for definitive treatment, but are compatible with drugs used for the treatment of urinary tract infections.

## CONTRAINDICATIONS

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

It is not known whether flavoxate hydrochloride 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 hydrochloride 100 mg tablets are available as white, round biconvex, film-coated tablets, debossed " **Є58**" on one side and plain on the other side, and are available as follows:

NDC 42806-058-01 Bottles of 100

NDC 42806-058-10 Bottles of 1000

Store at 20° - 25°C (68° - 77°F) [see USP Controlled Room Temperature]. Dispense contents in a tight, light-resistant container.

Distributed by

Epic Pharma, LLC

Laurelton, NY 11413

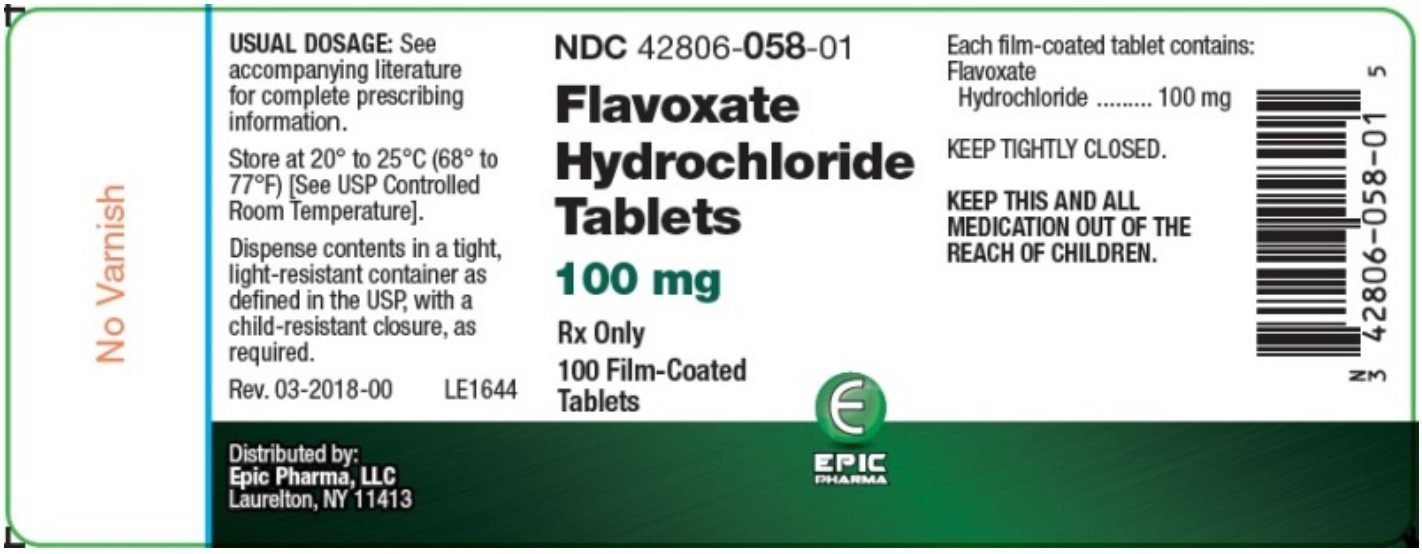
Rev. 05-2018-00

MF058REV05/18

OE1140

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 100 mg 100ct

Flavoxate Hydrochloride Tablets, 100 mg 100ct




## FLAVOXATE HYDROCHLORIDE

flavoxate hydrochloride tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:42806-058 |
| **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) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **HYPROMELLOSE 2910 (50 MPA.S)** (UNII: 1IVH67816N) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | ROUND | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | E58 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:42806-058-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 02/21/2011 | |
| **2** | NDC:42806-058-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 02/21/2011 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA076835 | 02/21/2011 | |

## Labeler - Epic Pharma, LLC (827915443)

## Registrant - Epic Pharma, LLC (827915443)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Epic Pharma, LLC | | 827915443 | manufacture(42806-058) |