

LOTRONEX™(alosetron hydrochloride) Tablets

of 60 tablets (NDC 0173-0690-00) and 120 tablets (NDC 0173-0690-03) with child-resistant closures and Unit Dose Pack of 60 (NDC 0173-0690-04).

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

APPENDIX

Diagnostic Criteria: Irritable Bowel Syndrome (IBS)*
At least three months continuous or recurrent symptoms of:
1. abdominal pain or discomfort which is:
(a) relieved with defecation,
(b) and/or associated with a change in frequency of stool,
(c) and/or associated with a change in consistency of stool;
and
1. two or more of the following, at least a quarter of occasions or days;
(a) altered stool frequency,
(b) altered stool form (lumpy/hard or loose/watery stool),
(c) altered stool passage (straining, urgency, or feeling of incomplete evacuation),
(d) passage of mucus,
(e) bloating or feeling of abdominal distention

*Thompson WG, Creed F, Drossman DA, et al. Functional bowel disease and functional abdominal pain, *Gastroenterol Int* 1992; 5: 75-91.

GlaxoWellcome

Glaxo Wellcome Inc.

Research Triangle Park, NC 27709

US Patent No. 5,360,800

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Date of Issue: February 2000

RL-XXX

PHARMACIST--DETACH HERE AND GIVE LEAFLET TO PATIENT.

Information for the Patient

LOTRONEX™(alosecron hydrochloride) Tablets

Read this information carefully before you start taking LOTRONEX (pronounced LOW-trah-nex) Tablets. Read the information included with LOTRONEX each time you refill your prescription, in case something has changed. This information does not take the place of discussions with your doctor.

What is LOTRONEX?

LOTRONEX is a prescription medicine used to treat irritable bowel syndrome (IBS) in women who have diarrhea as their main symptom. Lotronex has not been shown to work in men with IBS. IBS has been called by many names including irritable colon, and spastic colon. IBS is a medical condition causing cramping abdominal pain, abdominal discomfort, urgency (a sudden need to have a bowel movement), and irregular bowel habits such as diarrhea or constipation.

It is not clear why some people develop IBS. It may be caused by your body's overreaction to a body chemical called serotonin. This overreaction may cause your intestinal system to be overactive. LOTRONEX works by blocking the action of serotonin on the intestinal system. This reduces the cramping abdominal pain, abdominal discomfort, urgency, and diarrhea caused by IBS.

LOTRONEX may not work for every patient who takes it. For women who are helped by LOTRONEX, the medicine works faster in some and slower in others. Some women taking LOTRONEX will have relief from their IBS pain and discomfort within the first week of

LOTRONEX™ (alosetron hydrochloride) Tablets

use. Other women have relief of abdominal pain and discomfort within four weeks of starting LOTRONEX. Within one week, urgency and diarrhea occur less often for some patients. When you stop taking LOTRONEX, IBS symptoms will likely return within one week.

A. Who should not take LOTRONEX?

You should not start taking LOTRONEX when you are constipated or constipated most of the time.

Do not take LOTRONEX if you are allergic to LOTRONEX or any of its ingredients. The active ingredient in LOTRONEX is alosetron hydrochloride. The inactive ingredients are listed at the end of this leaflet.

Lotronex may not be right for you. Tell your doctor if you are:

- constipated most of the time.
- pregnant or plan to become pregnant.
- breast feeding.
- taking or planning to take any other medicines, including those you can get without a prescription.

B. How should LOTRONEX be taken?

Take LOTRONEX exactly as your doctor prescribes it. You can take Lotronex with or without food. If you miss a dose of LOTRONEX, do not double the next dose. Instead, simply go to the next regularly scheduled dosing time and take your normal prescribed dose of LOTRONEX.

What are the possible side effects of LOTRONEX?

LOTRONEX™(alosetron hydrochloride) Tablets

If you have a sudden worsening of abdominal pain or if you see blood in your stool (bowel movement), call your doctor right away. These symptoms may be a sign of a serious medical condition.

Constipation is a common side effect of treatment with LOTRONEX. If you become constipated while taking LOTRONEX, call your doctor. Your doctor may tell you to stop taking LOTRONEX or suggest other ways to manage your constipation.

This description of side effects is not complete. Your doctor or pharmacist can give you a more complete list of side effects with LOTRONEX. Talk to your doctor right away about any side effects you have.

Medicines are sometimes prescribed for purposes not listed in patient information leaflets. Do not use Lotronex for a condition for which it was not prescribed. Do not share Lotronex with other people. As with any medicine, LOTRONEX may be harmful without appropriate medical supervision.

If you have questions about Lotronex, ask your doctor or pharmacist. They can show you detailed information about Lotronex that was written for health professionals.

Inactive Ingredients: Lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The blue film-coat contains hydroxypropyl methylcellulose, titanium dioxide, triacetin, and indigo carmine.

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LOTRONEX™(alosetron hydrochloride) Tablets

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Labeling

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Free offer
PEEL here

MDC 0173-0690-00 60 Tablets



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LOTRONEX™

(alosetron hydrochloride) Tablets

Each film-coated tablet contains alosetron hydrochloride equivalent to 1 mg alosetron.

Rx only
See package insert for Dosage and Administration.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) (see USP Controlled Room Temperature).

Dispense in a light-resistant container as defined in the USP.

US Patent No. 5,360,800

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For a FREE patient booklet on Irritable Bowel Syndrome and treatment options, please call
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Free offer
PEEL here

NDC 0173-0690-03 120 Tablets Disperse in a tight, light-resistant container as defined in the USP.

Rx only

LOTRONEX™
(alosetron hydrochloride) Tablets

Each film-coated tablet contains alosetron hydrochloride equivalent to 1 mg alosetron.

US Patent No. 5,360,800

See package insert for Dosage and Administration.

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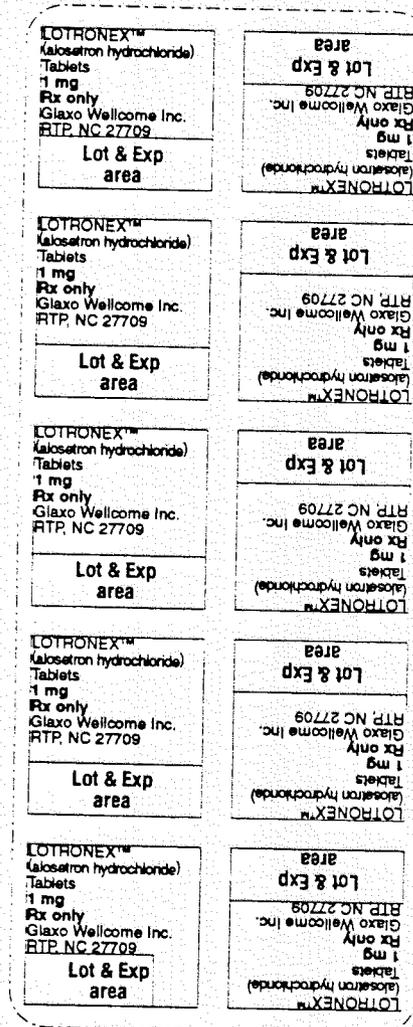
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NDC 0173-0690-04

LOTRONEX™ (alosetron hydrochloride) Tablets

Each film-coated tablet contains alosetron hydrochloride equivalent to 1 mg alosetron.

Rx only

60 Tablets

(6 blisterpacks each containing 10 tablets)

UNIT DOSE PACK

LOTRONEX™
(alosetron hydrochloride) Tablets

UNIT DOSE PACK

LOTRONEX™ (alosetron hydrochloride) Tablets

See package insert for Dosage and Administration.
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UNIT DOSE PACK

NDC 0173-0690-04

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Rx only

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(6 blisterpacks each containing 10 tablets)

UNIT DOSE PACK



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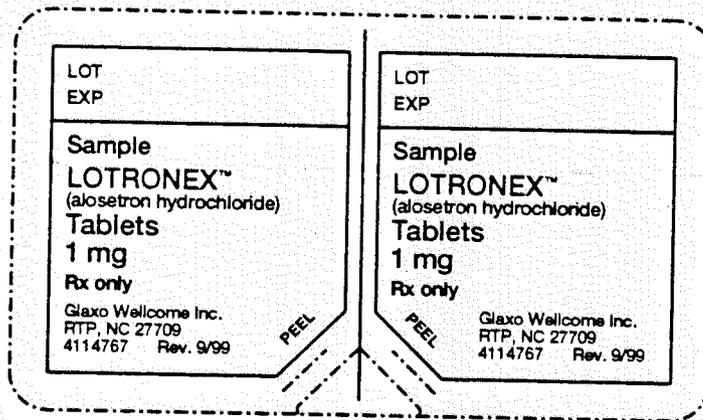
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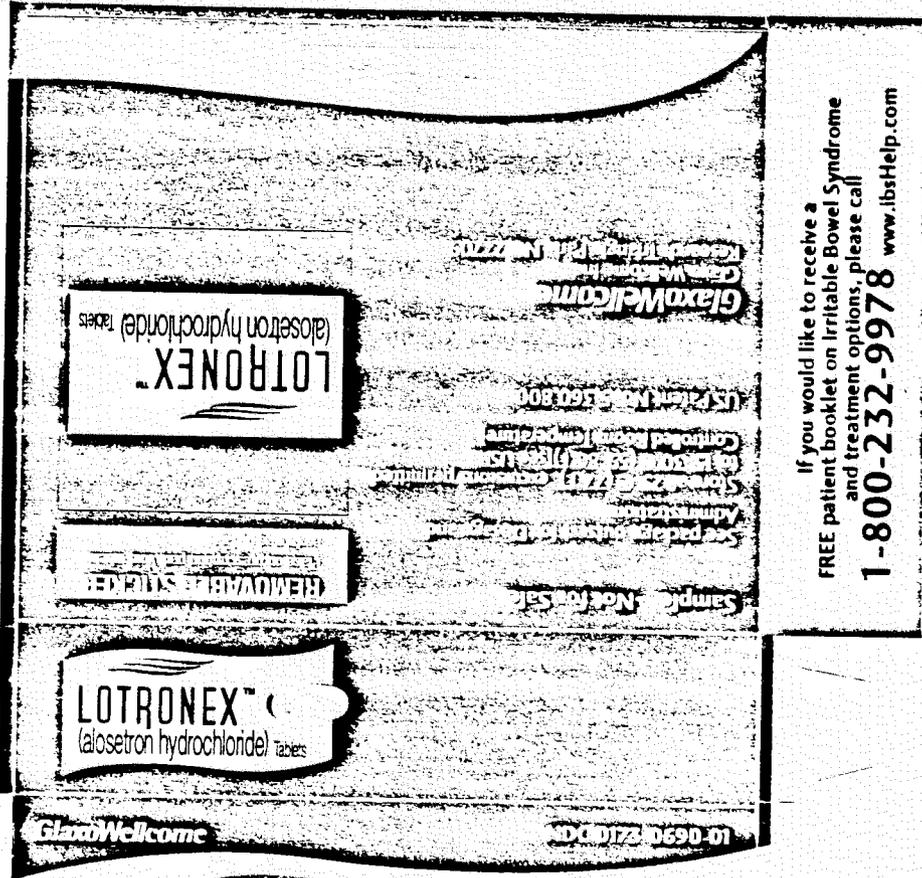
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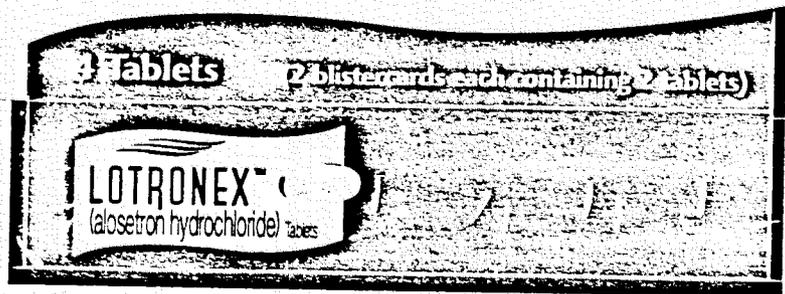
Sample—Not for Sale

LOTROXEX™

(alosetron hydrochloride) Tablets

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Rx only



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