Medication Guide
Alosetron (a-LO-ze-tron) Hydrochloride Tablets

Before using alosetron hydrochloride tablets for the first time, you should:
• Understand that alosetron hydrochloride tablets have serious risks for some people.
• Read and follow the directions in this Medication Guide.

Carefully read the Medication Guide you get with each refill for alosetron hydrochloride tablets. There may be new information. This Medication Guide does not take the place of talking with your doctor.

1. What is the most important information I should know about alosetron hydrochloride tablets?

A. Alosetron hydrochloride tablets are a medicine only for some women with severe chronic irritable bowel syndrome (IBS) whose:
• main problem is diarrhea and
• IBS symptoms have not been helped enough by other treatments.

B. Some patients have developed serious bowel side effects while taking alosetron hydrochloride tablets. Serious bowel (intestine) side effects can happen suddenly, including the following:

1. Serious complications of constipation: About 1 out of every 1,000 women who take alosetron hydrochloride tablets may get serious complications of constipation. These complications may lead to a hospital stay and, in rare cases, blood transfusions, surgery and death. People who are older, who are weak from illness, or who take other constipating medicines may be more likely to have serious complications of constipation with alosetron hydrochloride tablets.

To lower your chances of getting serious complications of constipation, do the following:
• If you are constipated, do not start taking alosetron hydrochloride tablets.
• If you get constipated while taking alosetron hydrochloride tablets, stop taking it right away and call your doctor.
• If your constipation does not get better after stopping alosetron hydrochloride tablets, call your doctor again.
• If you stopped taking alosetron hydrochloride tablets, do not start taking alosetron hydrochloride tablets again unless your doctor tells you to do so.

2. Ischemic colitis (reduced blood flow to the bowel): About 3 out of every 1,000 women who take alosetron hydrochloride tablets over a 6-month period may get a serious problem where blood flow to parts of the large bowel is reduced. This is called ischemic colitis. The chance of getting ischemic colitis when you take alosetron hydrochloride tablets for more than 6 months is not known. Ischemic colitis may lead to a hospital stay and, in rare cases, blood transfusions, surgery and death.

To lower your chances of getting serious complications of ischemic colitis, stop taking alosetron hydrochloride tablets and call your doctor right away if you get:
• new or worse pain in your stomach area (abdomen) or
• blood in your bowel movements.

C. Are alosetron hydrochloride tablets right for you?
Alosetron hydrochloride tablets may be right for you if all of these things are true about you:
• Your doctor has told you that your symptoms are due to IBS.
• Your IBS bowel problem is diarrhea.
• Your IBS has lasted for 6 months or longer.
• You tried other IBS treatments and they did not give you the relief you need.
• Your IBS is severe.

You can tell if your IBS is severe if at least 1 of the following is true for you:
• You have lots of painful stomach cramps or bloating.
• You often cannot control the need to have a bowel movement, or you have “accidents” where your underwear gets dirty from diarrhea or bowel movements.
• You cannot lead a normal home or work life because you need to be near a bathroom.

Enough testing has not been done to confirm if alosetron hydrochloride tablets works in men or children under age 18.

2. What are alosetron hydrochloride tablets?
Alosetron hydrochloride tablets are a medicine only for some women with severe chronic IBS whose:
• main problem is diarrhea and
• IBS symptoms have not been helped enough by other treatments.

Alosetron hydrochloride tablets do not cure IBS and it may not help every person who takes it. For those who are helped, alosetron hydrochloride tablets reduces lower stomach area (abdominal) pain and discomfort, the sudden need to have a bowel movement (bowel urgency) and diarrhea from IBS. If you stop taking alosetron hydrochloride tablets, your IBS symptoms may return within 1 or 2 weeks to what they were before you started taking alosetron hydrochloride tablets.

Alosetron hydrochloride tablets are not recommended for children.

3. Who should not take alosetron hydrochloride tablets?
Alosetron hydrochloride tablets are not right for everyone. Do not take alosetron hydrochloride tablets if any of the following apply to you:
• Your main IBS problem is constipation or you are constipated most of the time.
• You have had a serious problem from constipation. If you are constipated now, do not start taking alosetron hydrochloride tablets.
• You have had serious bowel blockages.
• You have had blood flow problems to your bowels, such as ischemic colitis.
• You have had blood clots.
• You have had Crohn’s disease, ulcerative colitis, diverticulitis, or severe liver disease.
• You do not understand this Medication Guide or you are not willing to follow it.
• You are taking fluvoxamine (LUVOX®).
4. What should I talk about with my doctor before taking alosetron hydrochloride tablets?

Talk with your doctor:
- about the possible benefits and risks of alosetron hydrochloride tablets.
- about how much of a problem IBS is in your life and what treatments you have tried.
- about any other illnesses you have and medicines you take or plan to take. These include prescription and non-prescription medicines, supplements and herbal remedies. Certain illnesses and medicines can increase your chance of getting serious side effects while taking alosetron hydrochloride tablets. Other medicines may interact with how the body handles alosetron hydrochloride tablets.
- about any allergies that you have. See the end of the Medication Guide for a complete list of ingredients in alosetron hydrochloride tablets.
- if you are pregnant, planning to get pregnant, or breastfeeding.

5. How should I take alosetron hydrochloride tablets?

- Take alosetron hydrochloride tablets exactly as your doctor prescribes it. You can take alosetron hydrochloride tablets with or without food.
- Begin with 0.5 mg two times a day for 4 weeks to see how alosetron hydrochloride tablets affects you. You and your doctor may decide that you should keep taking this dose if you are doing well.
- Check with your doctor 4 weeks after starting alosetron hydrochloride tablets:
  - If you try 0.5 mg two times a day for 4 weeks, it may not control your symptoms. If you do not get constipation or other side effects from alosetron hydrochloride tablets, your doctor may increase your dose up to 1 mg two times a day.
  - If 1 mg two times a day does not work after 4 weeks, alosetron hydrochloride tablets is not likely to help you. You should stop taking it and call your doctor.
- If you miss a dose of alosetron hydrochloride tablets, just skip that dose. Do not take 2 doses the next time. Wait until the next time you are supposed to take it and then take your normal dose.
- Follow the important instructions in the section “What is the most important information I should know about alosetron hydrochloride tablets?” about when you must stop taking the medicine and when you should call your doctor.
- If you see other doctors about your IBS or side effects from alosetron hydrochloride tablets, tell the doctor who prescribed alosetron hydrochloride tablets.

6. What are the possible side effects of alosetron hydrochloride tablets?

Constipation is the most common side effect among women with IBS who take alosetron hydrochloride tablets. Some patients have developed serious bowel side effects while taking alosetron hydrochloride tablets. Read the section “What is the most important information I should know about alosetron hydrochloride tablets?” at the beginning of this Medication Guide for information about the serious side effects you may get with alosetron hydrochloride tablets.

This Medication Guide does not tell you about all the possible side effects of alosetron hydrochloride tablets. Your doctor or pharmacist can give you a more complete list.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

7. How should I store alosetron hydrochloride tablets?

- Store alosetron hydrochloride tablets between 59°F to 86°F (15°C to 30°C).
- Protect alosetron hydrochloride tablets from light and getting wet (moisture).

Keep alosetron hydrochloride tablets and all medicines out of the reach of children.

8. General information about the safe and effective use of alosetron hydrochloride tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any questions or concerns about alosetron hydrochloride tablets, ask your doctor. Do not use alosetron hydrochloride tablets for a condition for which it was not prescribed. Do not share your medicine with other people. It may harm them.

Your doctor or pharmacist can give you more information about alosetron hydrochloride tablets that was written for healthcare professionals. You can also contact the company that makes alosetron hydrochloride tablets (toll free) at 1-877-835-5472 or at www.amneal.com.

9. What are the ingredients of alosetron hydrochloride tablets?

Active Ingredient: alosetron hydrochloride.

Inactive Ingredients: lactose anhydrous, magnesium stearate, microcrystalline cellulose and pregelatinized starch (maize). The white film-coat for the 0.5 mg tablet contains hypromellose, polyethylene glycol, polysorbate 80 and titanium dioxide. The light blue film-coat for the 1 mg tablet contains FD&C blue #2, hypromellose, macrogol, polysorbate 80 and titanium dioxide.

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Amneal Pharmaceuticals
Bridgewater, NJ 08807

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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