

MEDICATION GUIDE Alosetron (a-LOE-se-tron) Tablets, USP
Read the Medication Guide you get with each refill for alosetron tablets. There may be new information. This Medication Guide does not take the place of talking with your doctor.
What is the most important information I should know about alosetron tablets? Alosetron tablets is 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. Some people have developed serious bowel side effects while taking alosetron tablets. Serious bowel (intestine) side effects can happen suddenly, including the following: 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 tablets. To lower your chances of getting serious complications of constipation, do the following: If you are constipated, do not start taking alosetron tablets. If you get constipated while taking alosetron tablets, stop taking it right away and call your doctor. If your constipation does not get better after stopping alosetron tablets, call your doctor again. If you stopped taking alosetron tablets, do not start taking alosetron tablets again unless your doctor tells you to do so. Inflammation and injury of the intestines caused by reduced blood flow (ischemic colitis: Ischemic colitis is caused by reduced blood flow to parts of the large bowel. The chance of getting ischemic colitis when you take alosetron 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. Stop taking alosetron tablets and call your doctor or get medical help if you have symptoms of ischemic colitis such as new or worsening stomach-area (abdominal) pain, bloody diarrhea or blood in the stool.
What are alosetron tablets? Alosetron tablets are prescription medicine used 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 tablets do not cure IBS, and it may not help every person who takes it. For those who are helped alosetron 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 tablets, your IBS symptoms may return within 1 or 2 weeks to what they were before you started taking alosetron tablets. It is not known if alosetron tablets are safe and effective in men with IBS. It is not known if alosetron tablets are safe and effective in children.
Who should not take alosetron tablets? Do not take alosetron tablets if you: - have constipation or you are constipated most of the time. - have had a serious problem from constipation. If you are constipated now, do not start taking alosetron tablets. - have had serious bowel blockages. - have had blood flow problems to your bowels, such as ischemic colitis. - have had blood clots. - have had Crohn's disease, ulcerative colitis, diverticulitis, or severe liver disease. - are taking fluvoxamine (LUVOX).
What should I talk about with my doctor before taking alosetron tablets? Talk with your doctor: - about the possible benefits and risks of alosetron 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 tablets. Other medicines may interact with how the body handles alosetron tablets. - any allergies that you have. See the end of the Medication Guide for a complete list of ingredients in alosetron tablets. - if you have liver problems. - if you are pregnant or planning to become pregnant. It is not known if alosetron tablets can harm your unborn baby. - if you are breastfeeding or plan to breastfeed. It is not known if alosetron tablets can harm your baby. Talk to your doctor about the best way to feed your baby if you take alosetron tablets. How should I take alosetron tablets? - Take alosetron tablets exactly as your doctor prescribes it. You can take alosetron tablets with or without food. - Begin with 0.5 mg two times a day for 4 weeks to see how alosetron 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 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 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, is not likely to help you. You should stop taking it and call your doctor. - Follow the instructions in the section “What is the most important information I should know about alosetron tablets?” about when you must stop taking the medicine and when you should call your doctor.
What are the possible side effects of alosetron tablets? Alosetron tablets may cause serious side effects, including: See “What is the most important information I should know about alosetron tablets?” The most common side effects of Alosetron tablets include: - constipation - stomach (abdominal) discomfort and pain - nausea - intestinal discomfort and pain These are not all the possible side effects of alosetron tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
How should I store alosetron tablets? - Store alosetron tablets at room temperature between 68°F to 77°F (20°C to 25°C). - Protect alosetron tablets from light and moisture. Keep alosetron tablets and all medicines out of the reach of children. Alosetron tablets comes in a child resistant package
General information about the safe and effective use of alosetron tablets Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use alosetron tablets for a condition for which it was not prescribed. Do not give alosetron tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about alosetron tablets that is written for healthcare professionals. For more information, call Lifestar Pharma LLC at 1-888-995-4337.
What are the ingredients of alosetron tablets? Active Ingredient: alosetron hydrochloride, USP Inactive Ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (maize). The white film-coat for the 0.5 mg tablet contains hypromellose, polyethylene glycol and titanium dioxide. The blue film-coat for the 1 mg tablet contains hypromellose, polyethylene glycol, titanium dioxide, FD&C Blue No. #2 - Aluminum Lake and Iron Oxide Yellow. All brand names listed are the registered trademarks of their respective owners and are not trademarks of Lifestar Pharma LLC Manufactured for: Lifestar Pharma LLC 1200 MacArthur Blvd. Mahwah, NJ 07430 USA Made in India <i>This Medication Guide has been approved by the U.S. Food and Drug Administration.</i> Rev. September 2025, V-04