

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 08/2020

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Iribow OD Tablets 5mcg

Active ingredient: Ramosetron hydrochloride

Dosage form: light yellowish red orally-disintegrating tablet, diameter: approx. 8.5 mm, thickness: approx. 3.8 mm

Print on wrapping: (Face) イリボーOD 5 μ g, イリボーOD, 5 μ g, 口腔内崩壊錠, アステラス製薬, (Back) IribowOD 5 μ g, イリボーOD, 5, 下痢型過敏性腸症候群治療剤, house-mark, house-mark+157



Effects of this medicine

This medicine improves diarrhea by exerting an opposing effect on serotonin 5-HT₃ receptors on the efferent nerves. It also improves abdominal pain by exerting an opposing effect on serotonin 5-HT₃ receptors on the afferent nerves. It is usually used for the treatment of diarrhea-predominant irritable bowel syndrome.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- If you have a history of abdominal operations.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
 - For male: In general, for male adults, take 1 tablet (5 μ g of the active ingredient) at a time, once a day. The dosage may be adjusted according to the symptoms. However, the maximum daily dose is 2 tablets (10 μ g).
 - For female: In general, for female adults, take 2.5 μ g at a time, once a day. The dosage may be increased if the effect is insufficient. However, the maximum daily dose is 1 tablet (5 μ g).
- This preparation contains 5 μ g of the active ingredient in a tablet. This preparation should be used when you are instructed to take 5 μ g or 10 μ g (male) at a time according to the dosage regimen specified above. In any case, strictly follow the instructions.
- Take the tablet with water or lukewarm water in the same way as you usually take tablets. Since the tablet promptly dissolves in saliva, you may place it on your tongue, moisten with saliva, crush it with your tongue and swallow it together with saliva.
 - Do not take the tablets without water while you are lying down.
 - If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
 - If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
 - Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include constipation and hardened stool. If any of these symptoms occur, consult with your doctor or pharmacist. If there is no bowel movement for three consecutive days or longer, stop taking the medicine temporarily and consult with your doctor or pharmacist about the subsequent use of the medicine. Please note that female tend to experience constipation or hardened stool more often than male.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- facial pallor, cold sweat, dizziness on standing up [shock, anaphylaxis]
- sudden abdominal pain, bloody stool, fever [ischemic colitis]
- failure of passing stool, constipation [serious constipation]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Ingredients of the tablets may be visible as white or red spots on the surface of the tablets.
- The tablet surface may look white due to rubbing.
- Keep out of reach of children. Store away from light, heat and moisture.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution how to

discard.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.