

PATIENT INFORMATION LEAFLET

Itopride Hydrochloride Sustained Release Tablets
(150 mg)

ITOMINE SR

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What ITOMINE SR is and what it is used for
2. What you need to know before you take ITOMINE SR
3. How to take ITOMINE SR
4. Possible side effects
5. How to store ITOMINE SR
6. Contents of the pack and other information

1. What ITOMINE SR is and what it is used for

ITOMINE SR belongs to a group of drugs called prokinetic agents. Prokinetic agents are drugs which normalise or enhance and accelerate bowel movement (motility). ITOMINE SR is indicated for the treatment of symptoms resulting from the slow gastric emptying, such as feeling of gastric fullness up to upper abdominal pain, lack of appetite, heartburn, nausea and vomiting, which are not caused by ulcer disease or organic disease affecting the rate of passage of digested food through the gastrointestinal tract.

2. What you need to know before you take ITOMINE SR

Do not take ITOMINE SR –

- ❖ If you are allergic to itopride or any of the other ingredients of this medicine (listed in section 6),
- ❖ If accelerated gastric emptying can be harmful for you, e. g. if you suffer from gastrointestinal bleeding, obstruction or perforation.

If any of the above applies to you, do not take ITOMINE SR and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before or when taking ITOMINE SR:

Itopride hydrochloride enhances the action of acetylcholine and caution should be exercised when administering ITOMINE SR. In case side effects occur in elderly patients, doctor takes appropriate measures such as reduction of dosage or discontinuation of the medicine.

Other medicines and ITOMINE SR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. No interactions have been seen with

coadministration of warfarin, diazepam, diclofenac, ticlopidine, nifedipine, and nicardipine.

Since ITOMINE SR has gastrokinetic effects it could influence the absorption of concomitantly orally administered drugs.

Anticholinergic agents (used for treatment of asthma, chronic obstructive pulmonary disease, diarrhoea, support of anesthesia, Parkinson's disease and for decrease of spasms of smooth muscles – e. g. urine bladder, gastrointestinal tract) may decrease effect of itopride.

Antiulcer agents (used to prevent and treat ulcers in the digestive tract) such as cimetidine, ranitidine, teprone and cetraxate do not affect the effect of ITOMINE SR on gastrointestinal motility.

Itopride can influence absorption of other medicines due to its effect on digestive tract, in particular medicines with narrow therapeutic range, sustained released medicines and medicines released in intestine.

If any of the above applies to you, tell your doctor or pharmacist before you take ITOMINE SR.

ITOMINE SR with food and drink

ITOMINE SR should be taken before meals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. In pregnant women or women in that pregnancy cannot be excluded ITOMINE SR can be used only on recommendation from doctor if therapeutic benefits outweigh possible risks considerably. Because of the potential risk of side effects in nursing infants, a decision should be made by the doctor whether to discontinue nursing or to discontinue the treatment.

Driving and using machines

Although no influence of ITOMINE SR on the ability to drive and use machines has been observed, impaired alertness cannot be excluded. Very rarely, dizziness can occur. In these cases you should not drive or use machines until these symptoms disappear.

3. How to take ITOMINE SR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended daily dose for adults is 1 tablet three times a day before the meal. This dose can be reduced by your doctor according to your age and the symptoms of the disease. Duration of the treatment will be determined by your doctor. ITOMINE SR should not be used longer than 8 weeks.

Use in children and adolescents

ITOMINE SR should not be given to children and adolescents under 16 years of age. If you take more ITOMINE SR than you should If you take more tablets of ITOMINE SR than you should, or in case of accidental ingestion by children, consult a doctor. Swallow the tablets with a

glass of water. You can take ITOMINE SR with or without food. Splitting or crushing of the tablets is not recommended.

If you take more ITOMINE SR than you should

If you have accidentally taken too many ITOMINE SR tablets, or if someone else has taken your tablets, contact your doctor immediately. If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible and lie down.

If you forget to take ITOMINE SR

It is advisable to take your medicine at the same time each day. However, if you forget to take a dose, you should simply take the next one at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking ITOMINE SR

Stopping your treatment with ITOMINE SR may cause your condition to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be serious.

If you experience swelling of your hands, legs, swelling of face, lips or throat that can cause you swallowing or breathing difficulties. Rash or pruritus can also appear. This can indicate that you have an allergic reaction. Other possible side effects:

If any of the side effects listed below becomes severe, tell your doctor or pharmacist.

Uncommon (may affect up to 1 in 10 people)

- ❖ Diarrhoea.
- ❖ Constipation.
- ❖ Abdominal pain.
- ❖ Excessive saliva production.
- ❖ Headache. - Dizziness.
- ❖ Increased levels of hormone prolactin.
- ❖ Change in laboratory blood values (low white cell count, low platelet count).

Rare (may affect up to 1 in 1000 people)

- ❖ Rash formation, redness and itching of the skin.

Not known (frequency cannot be estimated from the available data)

- ❖ Increased laboratory blood values (AST, ALT, gamma-GTP, alkaline phosphatase, bilirubin).

- ❖ Decreased amount of platelets (it can manifest with contusions and increased bleeding).
- ❖ Tremor.
- ❖ Nausea.
- ❖ Jaundice.
- ❖ Enlarged breasts in men. If galactorrhea (production and secretion of breast milk not associated with breast-feeding) or gynecomastia (enlarged breasts in men) occurs, the treatment must be interrupted or stopped.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ITOMINE SR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information

What ITOMINE SR contains

The active substances are Itopride Hydrochloride

ITOMINE SR

Each film-coated sustained release tablet contains:

Itopride Hydrochloride 150 mg

Colours: Titanium Dioxide

What ITOMINE SR looks like and contents of the pack

ITOMINE SR 50 tablets are White, Round, Biconvex and Film-coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.



Manufactured by :
Quest Pharmaceuticals Pvt. Ltd.
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