Package leaflet: Information for the user

REFLAD 50 mg film-coated tablets
itopride hydrochloride

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. See section 4.

What is in this leaflet

1. What REFLAD is and what it is used for

REFLAD belongs to a group of drugs called prokinetic agents. Prokinetic agents are drugs which normalise or enhance and accelerate bowel movement (motility).
REFLAD 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.

REFLAD is intended for adults.

2. What you need to know before you take REFLAD

Do not take REFLAD
- 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine.

Itopride hydrochloride enhances the action of acetylcholine and caution should be exercised when administering REFLAD.

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 REFLAD
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 REFLAD 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, teprenone and cetrexate do not affect the effect of REFLAD 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.

REFLAD with food and drink
REFLAD 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 REFLAD 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 REFLAD 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 REFLAD

Always take this medicine exactly as your doctor 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. REFLAD should not be used longer than 8 weeks.

Use in children and adolescents
REFLAD should not be given to children and adolescents under 16 years of age.

If you take more REFLAD than you should
If you take more tablets of REFLAD than you should, or in case of accidental ingestion by children, consult a doctor.

If you forget to take REFLAD
If you forget to take REFLAD, continue at your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking REFLAD
If you stop taking REFLAD early your symptoms may worsen. Consult your doctor before stopping the treatment.

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.

Stop taking REFLAD and inform your doctor
- 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.

Following side effects can occur during the treatment with REFLAD:
Uncommon (may affect up to 1 in 100 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 1,000 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store REFLAD

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

This medicine does not require any special storage conditions.

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.

Do not throw away any medicines via wastewater or household waste. 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 REFLAD contains

- The active substance is itopride hydrochloride. Each film-coated tablet contains 50 mg of itopride hydrochloride.
- The other ingredients are mannitol, povidone 25, crospovidone, silica colloidal anhydrous, magnesium stearate, tablet coating Opadry TF White 269F280005 (polyvinyl alcohol partly hydrolysed, calcium carbonate, macrogol 3350, talc).

What REFLAD looks like and contents of the pack

REFLAD are white to almost white, round, biconvex, film-coated tablets with score line, 7 mm in diameter.
The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

REFLAD is supplied in blister packs of 15, 20, 40, 90, 100 or 120 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PRO.MED.CS Praha a.s., Telčská 377/1, Michle, 140 00 Prague 4, Czech Republic

This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic	Itopride PMCS
Austria	Itomed 50mg Filmtabletten
Belgium	Itoprom 50 mg comprimés pelliculés
Ireland	REFLAD 50 mg film-coated tablets
Luxembourg	Itoprom 50 mg comprimés pelliculés
Lithuania	PROGIT 50 mg plėvele dengtos tabletės
Croatia	Itonorm 50 mg filmom obložene tablete
Greece	Progit 50 mg επικαλυμμένα με λεπτό υμένιο δισκία

This leaflet was last revised in