PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

GANATON film-coated tablets

Itopride hydrochloride

Contains sugar (35 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking GANATON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- GANATON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same of yours.

What is in this leaflet

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

1. What GANATON is and what it is used for

GANATON contains the active substance itopride hydrochloride which improves motility in the digestive tract.

GANATON is used to treat symptoms caused by delayed gastric emptying, such as gastric fullness, painful pressure in the upper abdomen, loss of appetite, heartburn, nausea (feeling sick) and vomiting (being sick) affecting the movement of food through the digestive tract.

2. What you need to know before you take GANATON

Do not take GANATON:

- If you are hypersensitive (allergic) to itopride hydrochloride or any of the other ingredients of GANATON (see **What GANATON contains**).
- If you have a problem or condition in which an increase in gastric emptying can be dangerous, such as gastrointestinal bleeding, mechanical obstruction or perforation.

Warnings and precautions

Talk to your doctor or health care provider before taking GANATON.

Do not use GANATON for long periods of time if there is no improvement in your symptoms.

Children and adolescents

GANATON should not be used in children and adolescents under the age of 16 years, as safety and efficacy have not been established.

Liver or kidney impairment

Inform your doctor or pharmacist if you have kidney or liver problems.

Other medicines and GANATON

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor or pharmacist if you are currently using:

- Anticholinergic medicines (used to treat asthma, long-term lung disease, diarrhoea, Parkinson's disease and medicines used to release small intestine spasms) as these medicines can decrease the effect of GANATON.
- GANATON can affect the absorption of other medicines because of its effect on the motility of the digestive tract, mainly medicines with a narrow therapeutic index, with prolonged release and gastro-resistant medicines. Ask your doctor if any of this relates to you.

GANATON with food, drink and alcohol

GANATON should be taken before meals.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking GANATON.

Safety and efficacy of GANATON during pregnancy and lactation have not been established. Do not GANATON if you are pregnant or breastfeeding.

Driving and using machines

GANATON may cause dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how GANATON affects you.

GANATON contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking GANATON.

3. How to take GANATON

Do not share medicines prescribed for you with any other person. Always take GANATON exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet three times a day before meals.

Your doctor can reduce your dose based on your age and symptoms.

Your doctor will tell you how long your treatment with GANATON will last. If you have the impression that the effect of GANATON is too strong or too weak, tell your doctor or pharmacist.

If you take more GANATON than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and the remaining GANATON with you so the doctor will know what you have taken.

If you forget to take GANATON

If you have forgotten a dose, take the next dose at the scheduled time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

GANATON can have side effects.

Not all side effects reported for GANATON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GANATON, please consult your health care provider for advice.

If any of the following happens, stop taking GANATON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to GANATON. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers,
- bleeding or bruising more easily than normal,
- yellowing of your skin and eyes, also called jaundice or hepatitis.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- dizziness, headache,
- stomach pain, diarrhoea,
- increased salivation,
- rash,
- decreased level of white blood cells.

Side effects occurring with an unknown frequency:

- increased blood prolactin levels (which can cause milk lactation or enlargement of the mammary gland),
- tremors (involuntary trembling or shaking of hands and feet),
- constipation, nausea (feeling sick),
- itching, redness of skin,
- breast enlargement in men,
- increased level of certain enzymes in the blood, such as aspartate aminotransferase, alanine aminotransferase, gamma-glutamyltransferase, blood alkaline phosphatase and blood bilirubin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GANATON. Abbott Laboratories South Africa Pharmacovigilance: pv.south-africa@abbott.com.

5. How to store GANATON

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GANATON contains

The active substance is itopride hydrochloride. Each tablet contains 50 mg itopride hydrochloride.

The other ingredients are lactose monohydrate, maize starch, carmellose, colloidal silica anhydrous, magnesium stearate, hypromellose, macrogol 8 000, titanium oxide (E171) and

carbauba wax.

What GANATON looks like and contents of the pack

White, round film-coated tablets with a score on one side and embossed with “HC 803” on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/PVDC/Aluminium foil blister strips, placed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

Abbott Laboratories S.A. (Pty) Ltd

Abbott place, 219 Glof Club Terrace

Constantia Kloof 1709

South Africa

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