Patient Package Insert
in Accordance with the
Pharmacists' Regulations
(Preparations)-1986

This medicine can be sold with a physician's prescription only.

SETRON 1 mg
Tablets

Each tablet contains granisetron 1 mg (as hydrochloride)

Inactive ingredients and allergens in the medicine - see section 2 "**Important information about some of the ingredients of this medicine**" and section 6 in the leaflet.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

For the prevention of nausea and vomiting arising from cytostatic-anti-cancer treatments (chemotherapy or radiation).

Therapeutic group: 5-HT_3 (serotonin) receptor antagonists - anti-sickness and anti-emetic.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (granisetron), or to any of the other ingredients this medicine contains (see section 6). If you are not sure, refer to the physician, nurse, or pharmacist before taking the medicine.

Special warnings regarding the use of the medicine

○ **Before the treatment with Setron 1 mg, tell the physician if:**

- you have a blockage in the intestines causing symptoms such as stomach ache, wind, nausea or vomiting, or constipation.
- you have heart problems, you are taking a medicine for the treatment of cancer that is known to damage the heart or you have problems with levels of salt in the body such as: potassium, sodium or calcium (electrolyte level abnormalities).
- you are taking other medicines from the '5-HT_3 (serotonin) receptor antagonist' group. These medicines include for example the medicines ondansetron and dolasetron and are used, like Setron, in the prevention of nausea and vomiting.
- The use of buprenorphine together with Setron can cause serotonin syndrome, a potentially life threatening condition (see "**Drug interactions**").

Serotonin syndrome is a rare but potentially life threatening reaction, that may occur when taking setron (see section 4 "**Side effects**"). This syndrome may cause serious changes in the functioning of your brain, muscles and digestive system. The reaction can occur if you take Setron alone but is more likely to occur when using Setron together with certain other medicines (in particular fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine). Tell the physician, nurse or pharmacist about all the medicines you are taking.

Children and adolescents:
The medicine is not intended for use in children.

Drug interactions
If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. This is because Setron can affect the way other medicines work. Also other medicines can affect the way Setron tablets work. Especially if you are taking:

- Medicines used to treat an irregular heartbeat, other medicines of the "5-HT_3 (serotonin) receptor antagonist" type such as: ondansetron and dolasetron (see "**Special warnings regarding the use of the medicine**").
- SSRIs (selective serotonin reuptake inhibitors) that are used for the treatment of depression and/or anxiety such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- SNRIs (serotonin and noradrenaline reuptake inhibitors) used to treat depression and/or anxiety such as venlafaxine and duloxetine.
- Buprenorphine/opioids. These medicines may interact with Setron and cause symptoms such as: rhythmic, involuntary contractions of muscles, including the muscles that control movement of the eye, overexcitement, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, increase in body temperature above 38°C. Refer to your physician if these symptoms appear.

Pregnancy, breastfeeding and fertility
Do not take the tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your physician insructs you to take them.
If you are pregnant, breastfeeding, think you may be pregnant or are trying to become pregnant, consult the physician, nurse or pharmacist before taking this medicine.

Driving and using machines
Setron is unlikely to affect the ability to drive or operate machinery.

Important information about some of the ingredients of this medicine
The medicine contains lactose (a type of sugar). If your physician has told you that you have an intolerance for certain sugars, refer to the physician before beginning to use the medicine.
Each tablet contains less than 23 mg of sodium, and therefore the medicine is considered sodium-free.

3. How to use the medicine

Always use this medicine according to the physician's instructions. Check with the physician or pharmacist if you are not sure about the dosage and the treatment regimen with the medicine. The dosage and treatment regimen will be determined by the physician only. The recommended dosage varies from patient to patient. The dosage depends on the patient's age and weight.
One tablet twice a day or 2 tablets once a day are taken for up to a week after chemotherapy or radiation treatment, with the first dose being taken approximately one hour before the treatment.
Use this medicine at set times as determined by the attending physician.
Do not exceed the recommended dose.

How to take
Swallow the tablets whole with water. Crushing/halving/chewing: Do not chew/crush/halve the tablet as it is coated.

If you have accidentally taken a higher dosage or if a child or anyone else has accidentally swallowed the medicine, proceed **immediately** to a physician or to the nearest hospital emergency room. Bring the package of the medicine and the remaining tablets with you. The symptoms of an overdose include mild head aches. You will be treated according to your symptoms.

If you forgot to take this medicine at the designated time, consult the physician or nurse. Do not take a double dose to make up for a forgotten dose.

If you stop taking the medicine
Do not stop taking the medicine before the treatment is finished. If you do stop taking it, your symptoms may return. Speak to your physician first if you wish to stop taking the medicine.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of this medicine, consult the physician or pharmacist.

4. Side effects

Like any medicine, the use of Setron may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

- **Refer to the physician immediately** if you suffer from allergic reactions (anaphylactic shock). The symptoms may include: swelling of the throat, face, lips and mouth, difficulty in breathing or swallowing.

Other side effects:
Very common side effects (effects that appear in more than one out of 10 users):

- Headache
- Constipation. Your physician will monitor your condition.

Common side effects (effects that appear in 1-10 out of 100 users):

- insomnia
- Changes in liver function shown by blood tests
- Diarrhea.

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):

- Skin rashes or an allergic skin reaction or "hives" (urticaria). The signs may include red and itchy bumps on the skin.
- Changes in heartbeat (rhythm) and changes seen on ECG tests (recordings of the heart's electrical activity).
- Abnormal involuntary movements such as shaking, muscle rigidity and muscle contractions.
- Serotonin syndrome. The symptoms may include diarrhea, nausea, vomiting, high temperature and blood pressure, excessive sweating and rapid heartbeat, agitation, confusion, hallucinations, shivering, muscle shakes, sudden muscle contractions, jerks or stiffness, loss of coordination, and restlessness.

If a side effect appears, if one of the side effects gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the physician.

Reporting of side effects:
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: https://sideeffects.health.gov.il
Additionally, side effects can be reported to Perrigo via the following address: www.perrigo-pharma.co.il

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C.

6. Additional information

- In addition to the active ingredient, this medicine also contains:
  microcrystalline cellulose, lactose monohydrate, sodium starch, opadry (consists of: hydroxypropylmethylcellulose, titanium dioxide, macrogol 400, polysorbate 80), hypromellose, magnesium stearate.
- What does the medicine look like and what is the contents of the package:
  The package contains 10 round white to off-white tablets with "GS" debossed on one side and blank on the other side.
- Manufacturer and registration holder: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Revised in March 2021 according to MOH guidelines.
- Registration number of the medicine at the National Drug Registry of the Ministry of Health:10857.29244

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