**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only.

# SETRON® 1 mg

## Film coated tablets

**Each film coated tablet contains 1 mg Granisetron (as hydrochloride)**

Inactive and allergenic ingredients in the medicine – see section 2 **"Important information about some of the ingredients of the medicine"** and section 6 **"Further information"** in the leaflet.

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

For the prevention of nausea and vomiting induced by cytostatic treatments.

**Therapeutic group:** 5-HT3 (serotonin) receptor antagonists – antiemetics.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient granisetron or to any of the additional ingredients contained in the medicine (see section 6 "Further information").

**Special warnings regarding use of the medicine**

- **Before treatment with Setron 1 mg, tell the doctor if:**
  - You have an intestinal blockage that causes symptoms such as abdominal pain, flatulence, nausea or vomiting, or constipation.
  - You have heart problems, you are treating cancer with a medicine that is known to damage the heart or you have problems with salt levels in your body, such as: potassium, sodium or calcium (abnormal electrolyte levels).
  - You are taking other medicines from the "5-HT3 receptor antagonist" group. These medicines include, for example, ondansetron and dolasetron, and are used, like Setron, for the prevention of nausea and vomiting.
  - Use of buprenorphine with Setron can cause serotonin syndrome, a condition that can be life-threatening (see **"Drug interactions"** section).

Serotonin syndrome is an uncommon but possibly life-threatening reaction, that can occur when taking Setron (see section 4 "Side effects"). This syndrome may cause serious changes in your brain, muscle and digestive system activity. The reaction can occur if you take Setron alone, but is more likely to occur if you take Setron with certain other medicines (especially fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine). Tell the doctor, nurse or pharmacist about all the medicines you are taking.

**Children and adolescents:**

This 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 doctor or pharmacist**, since Setron can affect the way other medicines work. Similarly, other medicines can affect the way Setron works. Especially if you are taking:

- Medicines used to treat an irregular heartbeat, other medicines from the "5-HT3 receptor antagonists" group, such as: ondansetron or dolasetron (see section **"Special warnings regarding use of the medicine"**).
- SSRIs (selective serotonin reuptake inhibitors) used to treat 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/ opiates. These medicines can react with Setron and you may experience the following symptoms: rhythmic involuntary muscle spasms, including muscles that control eye movement, agitation, hallucinations, coma, excessive sweating, tremor, exaggerated reflex reactions, increased muscle tone, an increase in body temperature to above 38°C. Refer to your doctor if these symptoms occur.

**Pregnancy and breastfeeding**

Do not take Setron tablets if you are pregnant, trying to get pregnant or are breastfeeding, unless the doctor has instructed you to take them.

If you are pregnant or breastfeeding, think you may be pregnant or are trying to get pregnant, consult with the doctor, nurse or pharmacist before taking this medicine.

**Driving and operating machinery**

Setron should not affect the ability to drive or to operate machinery.

**Important information about some of the ingredients of the medicine**

The medicine contains lactose (a type of sugar). If you have been told by the doctor that you have an intolerance to certain sugars, such as lactose, refer to the doctor before starting to use this medicine.

Each tablet contains less than 23 mg sodium, and therefore, the medicine is considered sodium-free.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage varies from one patient to another. The dosage depends on the age and weight of the patient.

One tablet is taken twice a day or 2 tablets once a day, for up to one week after chemotherapy or radiotherapy, with the first dose taken about one hour before treatment.

This medicine is to be taken at specific time intervals as determined by the attending doctor.

**Do not exceed the recommended dose.**

**Mode of administration**

Swallow the tablets whole with water.

Crushing/halving/chewing: Do not chew/crush/halve the tablet as it is coated.

**If you accidentally take a higher dosage**

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. The symptoms of an overdose include mild headaches. You will be treated in accordance with your symptoms.

**If you forgot to take the medicine at the required time,** consult a doctor or nurse. Do not take a double dose to compensate for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

**If you stop taking the medicine**

Do not stop taking the medicine before the end of the treatment. If you stop taking it, the symptoms may recur. If you want to stop taking the medicine, first talk to your doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, 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 a doctor immediately if** you suffer from allergic reactions (anaphylactic shock). The symptoms can include: swelling of the throat, face, lips and mouth, difficulty in breathing or swallowing.

**Other side effects:**

**Very common side effects (effects that occur in more than 1 user in 10):**

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

**Common side effects (effects that occur in 1-10 in 100 users):**

- Insomnia.
- Changes in liver functions that can be seen in blood tests.
- Diarrhea.

**Uncommon side effects (effects that occur in 1-10 in 1,000 users):**

- Skin rashes or an allergic skin reaction or urticaria. The signs may include red and itchy bumps on the skin surface.
- Changes in the heart rate and changes seen on ECG tests (electrical recordings of the heart).
- Abnormal involuntary movements, such as: tremor, muscle rigidity and muscle contractions.
- Serotonin syndrome. The symptoms may include: diarrhea, nausea, vomiting, high fever and high blood pressure, excessive sweating and rapid heart rate, agitation, confusion, hallucinations, tremor, muscle tremors, sudden muscle spasms, twitches or rigidity of muscles, loss of coordination, and restlessness.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

**Reporting of side effects:**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

In addition, you can report to Padagis via the following address: Padagis.co.il

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe 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 doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and tray (blister). The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C.

## 6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:

  Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate (type A), opadry (consists of: hydroxypropylmethylcellulose, titanium dioxide, macrogol 400, polysorbate 80), hydroxypropylmethylcellulose, magnesium stearate.
- What the medicine looks like and the contents of the package:

  The package contains 10 round, white to off-white film coated tablets with 'GS' imprinted on one side and smooth on the other side.
- Registration holder and importer: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Revised in November 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 108-57-29244



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