

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

The medicine is dispensed with a doctor's prescription only

# Ondansetron Inovamed 4 mg film-coated tablets

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Each Ondansetron Inovamed 4 mg film-coated tablet contains:

Ondansetron (as hydrochloride dihydrate) 4 mg

Each Ondansetron Inovamed 8 mg film-coated tablet contains:

Ondansetron (as hydrochloride dihydrate) 8 mg

Inactive and allergenic ingredients in the preparation – see section 6 “Further Information” and section 2 “Important information about some of the ingredients of the medicine”.

**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.

- Keep the leaflet; you may need it again
- 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?

Ondansetron Inovamed tablets are intended for:

Adults:

- Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy
- Prevention and treatment of post operative nausea and vomiting (PONV)

Pediatric population:

- Management of nausea and vomiting induced by cytotoxic chemotherapy

## Therapeutic group

Ondansetron Inovamed tablets contain an active ingredient called ondansetron. Ondansetron Inovamed belongs to a group of medicines called anti-emetics.

Serotonin receptor antagonist (5HT3)

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- You take apomorphine (used to treat Parkinson's disease).
- You are sensitive (allergic) to ondansetron or to any of the additional ingredients contained in the medicine (as detailed in section 6 “Further Information” and in section 2 “Important information about some of the ingredients of the medicine”).

If you are not sure, talk to your doctor or pharmacist before taking Ondansetron Inovamed tablets.

## Special warnings regarding use of the medicine

**Before treatment with Ondansetron Inovamed, tell the doctor if:**

- You have ever had heart problems (e.g., heart failure that causes shortness of breath and swollen ankles)
- You have an irregular heart rate (arrhythmias)
- You have congenital QT prolongation syndrome on ECG. The medicine should be administered with caution to patients who may develop QT prolongation, in particular patients with abnormal electrolyte levels, heart failure, slow heartbeat or patients taking other medical supplements that may lead to QT prolongation or electrolyte abnormalities
- You are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- You have liver problems
- You have a blockage in your gut
- You are going to undergo surgery of enlarged tonsils, as the medicine may mask occult bleeding
- You have problems with the levels of salts in your blood, such as potassium, sodium and magnesium

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Ondansetron Inovamed tablets.

## Drug interactions:

**If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines and nutritional supplements, tell the doctor or pharmacist. This is because Ondansetron Inovamed could affect the way some of the medicines work. Also, some of the other medicines could affect the way Ondansetron Inovamed works. In particular, inform the doctor or pharmacist if you are taking:**

- Carbamazepine or phenytoin used to treat epilepsy
- Rifampicin used to treat infections such as tuberculosis
- Antibiotics such as erythromycin
- Antifungal medicines such as ketoconazole
- Anti-arrhythmic medicines used to treat irregular heart rhythm
- Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- Tramadol and fentanyl, painkillers
- Medicines that affect the heart (such as haloperidol or methadone)
- Cancer medicines (especially anthracyclines and trastuzumab)
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety, including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram. There have been reports of the development of serotonin syndrome when these medicines were combined with Ondansetron Inovamed
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety, including venlafaxine, duloxetine. There have been reports of the development of serotonin syndrome when these medicines were combined with Ondansetron Inovamed
- Other medicines that can cause serotonin syndrome such as mirtazapine for the treatment of depression, monoamine oxidase inhibitor drugs for the treatment of Parkinson's, lithium for the treatment of psychiatric disorders or injectable methylene blue

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Ondansetron Inovamed tablets.

Tell your doctor or pharmacist immediately if you experience any of these symptoms during and after the treatment with Ondansetron Inovamed:

- If you experience sudden chest pain or chest tightness (myocardial ischemia).

## Pregnancy, breastfeeding and fertility

- If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking Ondansetron Inovamed, since Ondansetron Inovamed may slightly increase the risk that your baby will be born with a cleft palate (partial or complete palate closure defect).
- Do not breastfeed if you are taking Ondansetron Inovamed. This is because small amounts pass into breast milk. Ask your doctor for advice.

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

The tablets contain lactose anhydrous, which is a type of sugar. If you have been told by the doctor that you have an intolerance to lactose or cannot digest certain sugars, consult with the doctor before taking this medicine.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only. The dose you have been prescribed depends on the treatment you are receiving.

### To treat nausea and vomiting from chemotherapy or radiotherapy (adults only)

On the day of chemotherapy or radiotherapy

- The usual dose for adults is 8 mg taken one to two hours before treatment and another 8 mg taken twelve hours after the first dose.

On the following days

- The usual dose for adults is 8 mg twice a day
- The treatment may be given for up to 5 days.

Children:

### To treat nausea and vomiting from chemotherapy

The doctor will decide the dose depending on the child's size (body surface area).

### To prevent and treat nausea and vomiting after an operation (adults only)

The usual dose for adults is 16 mg before your operation.

### Patients with moderate or severe liver problems (adults only)

The total daily dose should not be more than 8 mg.

Ondansetron Inovamed tablets will start working within one or two hours of taking a dose.

### Do not exceed the recommended dose

**If you vomit within one hour of taking a dose**

- Take the same dose again
- Otherwise, do not take more Ondansetron Inovamed tablets than the doctor ordered. If you continue to experience nausea, tell your doctor.

### Crushing/halving/chewing:

The tablets are film-coated and should not be crushed, halved or chewed.

### 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.

### If you forget to take the medicine

If you forgot a dose **and you** experience nausea or vomiting:

- Take your Ondansetron Inovamed tablets as soon as possible, then take your next tablet at the usual time.

- Do not take a double dose to make up for a forgotten dose.

If you forgot a dose but are not experiencing nausea:

- Take the next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the 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 Ondansetron Inovamed 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.

Some side effects could be serious.

Stop taking Ondansetron Inovamed and seek medical help immediately if you or your child experience any of the following:

### Allergic reactions

- Wheezing and pain or pressure in the chest that occur suddenly
- Swelling of the eyelids, face, lips, mouth or tongue
- Skin rash – red spots or lumps under your skin (hives) anywhere on your body
- Collapse

### Myocardial ischemia

- Sudden chest pain or
- Chest tightness

### Other side effects

**Very common side effects – effects that occur in more than one user in ten:**

- Headache

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

- A feeling of warmth or flushing
- Constipation
- Changes to liver function test results (if you take Ondansetron Inovamed tablets with a medicine called cisplatin, otherwise this side effect is uncommon)

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

- Hiccups
- Low blood pressure, which can make you feel faint or dizzy
- Irregular heart rhythm
- Chest pain
- Convulsions (fits)
- Unusual body movements or shaking

**Rare side effects – effects that occur in 1-10 in 10,000 users:**

- Feeling dizzy or lightheaded
- Blurred vision
- Disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

**Very rare side effects – effects that occur in less than one user in 10,000:**

- Impaired vision or temporary vision loss, which usually returns within 20 minutes

**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.**

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](http://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>

## 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order 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. The expiry date refers to the last day of that month.

### Storage conditions:

Store below 25°C.

Do not dispose of medicines in the wastewater or household waste bin. Consult the pharmacist about where to dispose of medicines that are not in use. These measures will help protect the environment.

## 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Lactose (anhydrous), cellulose microcrystalline (PH-102), magnesium stearate, starch pre-gelatinised (maize starch), hypromellose 6cps (E464), titanium dioxide (E171), triacetin.

Ondansetron Inovamed 8 mg tablet also contains: Iron oxide yellow (E172).

### What does the medicine look like and what is the content of the package:

Ondansetron Inovamed 4 mg tablets: White to off-white, oval shaped, film-coated tablets debossed with 'E' on one side and '01' on the other side.

Ondansetron Inovamed 8 mg tablets: Yellow colored, oval shaped, film-coated tablets debossed with 'E' on one side and '02' on the other side.

The tablets are packaged in plastic trays (blisters), which are packaged in carton packages.

### Package sizes:

Carton packages containing blister packs with 3, 4, 6, 7, 10, 14, 15, 20, 28, 30, 40, 49, 50, 60, 90, 100, 200, 300, 500 tablets. The number of blister packs in each package may vary depending on the package size.

The number of tablets in each carton package appears on the carton package.

Not all package sizes may be marketed.

**Registration holder and its address:** Inovamed Ltd., 55 Beer Ganim St., P.O.B. 62 Even Yehuda, 40500, Israel.

**Name of Manufacturer and its address:** Aurobindo Pharma Ltd., Plot #2, Maitrivihar, Ameerpet, Hyderabad, India.

Revised in May 2022 according to MOH's guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Ondansetron Inovamed 4 mg: 152-95-34231.

Ondansetron Inovamed 8 mg: 152-96-34210.