

**Package Leaflet: Information for the User**  
**Onzetran OD 8 mg**  
Ondansetron

**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.

**What is in this leaflet**

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

**1. What Onzetran OD is and what it is used for**

Onzetran OD contains a medicine called ondansetron. This belongs to a group of medicines called antiemetics. Onzetran OD is a special type of Onzetran tablet that dissolves very quickly when put on top of the tongue.

Onzetran OD is used for preventing:

- nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- nausea and vomiting after surgery (adults only).

Ask your doctor or pharmacist if you would like any further explanation about these uses.

**2. What you need to know before you take Onzetran OD**

**Do not take Onzetran OD**

- If you are taking apomorphine (used to treat Parkinson's disease)
- If you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Onzetran OD (listed in Section 6).

If you are not sure, talk to your doctor or pharmacist before taking Onzetran OD.

**Warnings and precautions**

Check with your doctor or pharmacist before taking Onzetran OD:

- If you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- If you have an uneven heart beat (arrhythmias)
- If you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- If you have liver problems
- If you have a blockage in your gut
- If 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 apply to you, talk to your doctor or pharmacist before taking Onzetran OD.

### **Other medicines and Onzetran OD**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Onzetran OD can affect the way some medicines work. Also some other medicines can affect the way Onzetran OD works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- carbamazepine or phenytoin used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer
- 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
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

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

### **Pregnancy and breast-feeding**

Only use during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. This is because Onzetran OD can slightly increase the risk of a baby being born with cleft lip and/or cleft palate

(openings or splits in the upper lip and/or the roof of the mouth). If you are already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron OD. If you are a woman of childbearing potential you may be advised to use effective contraception.

Do not breast-feed if you are taking Ondansetron OD. This is because small amounts pass into the mother's milk. Ask your doctor for advice.

### **3. How to take Ondansetron OD**

Always take Ondansetron OD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

#### **To prevent nausea and vomiting from chemotherapy or radiotherapy**

On the day of chemotherapy or radiotherapy

- the usual adult dose is 8 mg taken one or two hours before treatment and another 8 mg twelve hours after.

On the following days

- the usual adult dose is 8 mg twice a day
- this may be given for up to 5 days.

Children aged over 6 months and adolescents:

The doctor will decide the dose depending on the child's size (body surface area) or weight. Look at the label for more information.

- the usual dose for a child is up to 4 mg twice a day
- this can be given for up to 5 days.

#### **To prevent nausea and vomiting after an operation**

The usual adult dose is 16 mg before your operation.

Children aged over 1 month and adolescents

It is recommended that Ondansetron is given as an injection.

#### **Patients with moderate or severe liver problems**

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

#### **If you are sick (vomiting) within one hour of taking a dose**

- take the same dose again
- otherwise, do not take more Ondansetron OD than the label says.

If you continue to feel sick, tell your doctor.

**If you take more Onzetran OD than you should**

If you or your child take more Onzetran OD than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

**If you forget to take Onzetran OD**

If you miss a dose and feel sick or vomit:

- take Onzetran OD 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 miss a dose but do not feel sick

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Onzetran OD can cause side effects, although not everybody gets them.

**Allergic reactions**

If you have an allergic reaction, stop taking it and see a doctor straight away. The signs may include:

- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- collapse

**Other side effects include:**

*Very common (may affect more than 1 in 10 people)*

- Headache

*Common (may affect up to 1 in 10 people)*

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

*Uncommon (may affect up to 1 in 100 people)*

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat

- chest pain
- fits
- Unusual body movements or shaking.

*Rare (may affect up to 1 in 1,000 people)*

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

*Very rare (may affect up to 1 in 10,000 people)*

- Poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

### **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. By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store Onzetran OD**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Onzetran OD contains**

- The active ingredient is ondansetron. Each Onzetran OD contains ondansetron 8 mg.
- The other ingredients are microcrystalline cellulose, mannitol, Croscarmellose sodium, sucralose, magnesium stearate, strawberry flavor.

#### **What Onzetran OD looks like and contents of the pack**

Onzetran OD is a white round plain tablet.

Onzetran OD is available in boxes containing 10 orodispersible tablets.

#### **Marketing Authorisation Holder and Manufacturer**

Pharmaline s.a.l. – Lebanon

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Contact us: [pharmaline@maliagroup.com](mailto:pharmaline@maliagroup.com)

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Reg. No. for Onzetran OD in Lebanon:

**This is a medicament:**

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists

**The leaflet was last revised in July 2022.**