

**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.

## **OMETIC film coated tablets 4 mg** **OMETIC film coated tablets 8 mg**

*ondansetron*

### **What is in this leaflet**

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

### **1. What OMETIC is and what it is used for**

**OMETIC** contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. **OMETIC** tablets are used for:

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

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

### **2. What you need to know before you take OMETIC**

#### **Do not take OMETIC if:**

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in **OMETIC** (listed in section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before taking **OMETIC**.

### **Warnings and precautions**

Check with your doctor, nurse or pharmacist before taking **OMETIC** if:

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- 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 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, nurse or pharmacist before taking **OMETIC**.

### **Other medicines and OMETIC**

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take other medicines. This includes medicines that you buy without a prescription and herbal medicines.

This is because **OMETIC** can affect the way some medicines work. Also some other medicines can affect the way **OMETIC** works.

In particular, tell your doctor, nurse 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 an thiacyclines 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, nurse or pharmacist before taking **OMETIC**.

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

It is not known if **OMETIC** is safe during pregnancy. If you are pregnant, think you are pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **OMETIC**. Do not breast-feed if you are taking **OMETIC**. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

### **Important information about some of the ingredients of OMETIC tablets**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking this medicine.

### **3. How to take OMETIC tablets**

Always take **OMETIC** tablets exactly as your doctor has told you. You should check with your doctor, nurse 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 to 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.

#### Patients with moderate or severe liver problems

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

**OMETIC** should start to work within one or two hours of taking a dose.

If you are sick (vomit) within one hour of taking a dose

- take the same dose again
- otherwise, do not take more **OMETIC** tablets than the label says.

If you continue to feel sick, tell your doctor or nurse.

### **If you take more OMETIC than you should**

If you or your child take more **OMETIC** 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 OMETIC**

If you miss a dose and feel sick or vomit:

- take **OMETIC** as soon as possible, then
- take your next tablet at the usual time (as shown on the label)
- 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 as shown on the label

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

### Possible side effects

Like all medicines, **OMETIC** 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 **OMETIC** tablets 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, pharmacist or nurse. 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 OMETIC

**Do not store above 25°C. Store in the original pack.**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What OMETIC film coated tablet contains?

#### OMETIC 4mg

Each film coated tablet contains 4 mg of the active ingredient ondansetron, as ondansetron hydrochloride dihydrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, magnesium stearate.

Film: Opadry II yellow, purified water.

#### OMETIC 8mg

Each film coated tablet contains 8 mg of the active ingredient ondansetron, as ondansetron hydrochloride dihydrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, magnesium stearate.

Film: Opadry II yellow, purified water.

### What OMETIC looks like and contents of the pack

Ometic tablets are yellow, oval, film coated tablets and come in two strengths, 4 mg and 8 mg.

Carton box of 10 ( 1 x 10 ) tablets of 4mg ondansetron in

PVC / PVDC Aluminium blister packs.  
Carton box of 10 ( 1 x 10 ) tablets of 8mg ondansetron in  
PVC / PVDC Aluminium blister packs.

### Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.

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75300 Lukavac, Bosnia and Herzegovina.

### Data of first authorisation / renewal of the authorisation in BIH:

#### OMETIC 4 mg film coated tablets

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#### OMETIC 8 mg film coated tablets

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