

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZYTRON

Zytron 4mg and 8mg Film-coated Tablets

ONDANSETRON

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 Ondansetron is and what it is used for
2. What you need to know before you take Ondansetron
3. How to take Ondansetron
4. Possible side effects
5. How to store Ondansetron

1. WHAT ONDANSETRON IS AND WHAT IT IS USED FOR

Ondansetron belongs to a group of drugs called anti-emetics. Ondansetron inhibits the effect of the neurotransmitter serotonin in the brain. Serotonin causes nausea and vomiting.

Ondansetron is used for:

Preventing and treating nausea and vomiting induced by cytotoxic chemotherapy (CINV) and radiotherapy (adults and children aged ≥ 6 months).

Preventing and treating nausea and vomiting in patients following an operation (PONV) (in adults and children aged ≥ 1 month).

Your doctor may have prescribed Ondansetron for another use. Always follow your doctor's advice.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ONDANSETRON

Do not take Ondansetron:

- if you are allergic to Ondansetron or any of the other ingredients of this medicine
- if you have previously experienced allergy to other drugs belonging to the group of serotonin antagonists (e.g. granisetron, dolasetron). If this is the case, it is possible that you are also allergic to Ondansetron
- if you are taking apomorphine (used to treat Parkinson's disease).

Warnings and precautions

Talk to your doctor or pharmacist before taking Ondansetron:

- if you have a blockage of your intestines or constipation, as you will need to be closely monitored by your doctor
- if you are going to have or recently have had your tonsils removed, because treatment with Ondansetron may hide symptoms of internal bleeding
- if you have problems with the levels of salts in your blood such as potassium and magnesium
- if you have heart problems, such as irregular heartbeat (with arrhythmias or conduction disorders) and are being treated with other medication such as anaesthetics, anti-arrhythmics or beta-blockers at the same time, because of the limited experience hereby
- if it is for children below the age of 6 months or with a body surface of less than 0.6 m²
- if you have liver problems
- if children or adolescents receive ondansetron together with drugs, that may have a harmful effect on the liver. Careful monitoring of the liver function is recommended
- if you take other serotonergic drugs (medicines of the type SSRI or SNRI, used in the treatment of depressions).

Tell your doctor if any of the above warnings apply to you.

Please tell your doctor or nurse if you need to have blood or urine tests, that you are being treated with Ondansetron.

Other medicines and Ondansetron

Ondansetron may have an effect on other drugs or other drugs may have an effect on Ondansetron.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

You must tell your doctor that you are taking Ondansetron, if he/she starts treating you with the following medicine:

- Drugs for epilepsy (phenytoin, carbamazepine), which may reduce the effect of ondansetron
- Antibiotics and antifungal medicines (e.g. rifampicin, erythromycin or ketoconazole)
- Pain relieving medicine (tramadol)
- Apomorphine (used to treat Parkinson's disease)
- Medicines inducing heart damage (e.g. anthracyclines or trastuzumab)
- Serotonergic drugs (medicines of the type SSRI or SNRI, used in the treatment of depressions)
- Anti-arrhythmic medicines used to treat an uneven heart beat (e.g. amiodarone)
- Drugs which may result in QT prolongation (heart rhythm disorder)
- Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines (e.g. atenolol or timolol).

Talk with your doctor or the healthcare staff if you are taking any of these types of medicines.

It may be necessary to adjust the dose.

Taking Ondansetron with food and drink

You may take Ondansetron with food and drinks. The tablets should be taken with a glass of water.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

Use in pregnancy has not been established and is not recommended.

If it is absolutely necessary that ondansetron be given, caution should be exercised when prescribing to pregnant women especially in the first trimester. Your doctor should evaluate the risk/benefit balance.

Breast-feeding:

Do not take Ondansetron if you are breast-feeding, because it is excreted into the milk.

Driving and using machines

Ondansetron does not affect the ability to use any tools or machines or the ability to drive safely in traffic.

Ondansetron contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ONDANSETRON

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Treatment and prevention of nausea and vomiting in connection with chemotherapy or radiotherapy

Adults:

The recommended oral dose is 8 mg 1-2 hours before chemotherapy or radiotherapy, followed by 8 mg every 12 hours for up to 5 days. Your doctor may decide to give the first dose as an injection.

Elderly:

The same dose as for adults.

Paediatric population (children aged ≥ 6 months and adolescents):

Ondansetron should be given immediately before chemotherapy as a single dose given into a vein. Oral dosing can commence twelve hours later and may be continued for up to 5 days. The total daily dose must not exceed 32 mg.

Treatment and prevention of post-operative nausea and vomiting

Adults:

The recommended oral dose is 16 mg one hour prior to anaesthesia or alternatively, 8 mg taken one hour prior to anaesthesia followed by an additional 8 mg after 8 and 16 hours. Your doctor may choose to give you the medicine as injections.

Elderly:

There is limited experience with the use of ondansetron in elderly patients.

Ondansetron is however tolerated well by patients above 65 years in chemotherapy (please refer to sections above).

Paediatric population (children aged ≥ 1 month and adolescents):

For prevention of PONV in paediatric patients having surgery performed under general anaesthesia, a single dose of ondansetron may be given by slow injection into a vein.

For the treatment of PONV after surgery in paediatric patients having surgery performed under general anaesthesia, a single dose of ondansetron may be given by slow injection into a vein. There are no data on the use of ondansetron in the treatment of PONV in children below 2 years of age.

Insufficient function of the liver:

The daily dose should not exceed 8 mg if you have moderately to severely reduced function of the liver.

The tablets should be taken with a glass of water.

Always follow your doctor's prescription. There are differences in what the individual patients need. Changes in or discontinuation of treatment should only occur in consultation with your doctor.

If you take more Ondansetron than you should

If you or your child take more Ondansetron than you should, talk to a doctor or go to a hospital straight away.

Take the medicine pack with you.

The symptoms of overdose are disturbances of vision, severe constipation, low blood pressure and disturbances in heart beat rhythm.

If you forget to take Ondansetron

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

4. POSSIBLE SIDE EFFECTS

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

Very common side effects (may affect more than 1 in 10 people):

- headache.

Common side effects (may affect up to 1 in 10 people):

- a sensation of reddening and warmth
- constipation
- local injection site reactions (if you use Ondansetron injection).

Uncommon side effects (may affect up to 1 in 100 people):

- seizures
- hiccups
- low blood pressure
- irregular heartbeats
- heart pain and slow pulse
- involuntary movements
- sometimes changes in liver function have been observed.

Rare side effects (may affect up to 1 in 1000 people):

- sudden skin rash, difficulty breathing, and fainting (within minutes to hours) due to hypersensitivity (anaphylactic shock)
- dizziness (usually during rapid injection of Ondansetron)
- transient visual disturbances such as blurred vision (usually during rapid injection of Ondansetron)
- Prolongation of QT-time in ECG, including abnormally rapid heart rhythm called “Torsade des pointes”.

If any of these symptoms occur, immediately seek medical attention.

Very rare side effects (may affect up to 1 in 10, 000 people):

- temporary blindness usually during injection of Ondansetron. Most of these blindness cases were resolved 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 ONDANSETRON

Keep out of the sight and reach of children

Store in the original package

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

This leaflet was last revised in January 2016