Package leaflet: Information for the user

Ondran 4 mg film-coated tablets
Ondran 8 mg film-coated tablets
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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ondran is and what it is used for

Ondran belongs to a group of medicines called anti-emetics. Ondran inhibits the effect of the neuro-transmitter serotonin in the brain. Serotonin causes nausea and vomiting.

Ondran 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 Ondran for another use. Always follow your doctor's advice.

2. What you need to know before you take Ondran

Do not take Ondran:
- if you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).
- if you have previously experienced allergy to other medicines 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, pharmacist or nurse before taking Ondran:
- 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 m^2
— if you have liver problems.
— if children or adolescents receive ondansetron together with medicines, that may have a harmful effect on the liver. Careful monitoring of the liver function is recommended.
— if you take other serotonergic medicines (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 Ondran
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Ondran may have an effect on other medicines or other medicines may have an effect on Ondran.

You must tell your doctor that you are taking Ondran, if he/she starts treating you with the following medicine:
- Medicines 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 including heart damage (e.g. anthracyclines and trastuzumab)
- Serotonergic medicines (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)
- Medicines 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.

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

Pregnancy and breast-feeding

Pregnancy:
You should not use Ondran during the first trimester of pregnancy. This is because Ondran 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 Ondran. If you are a woman of childbearing potential you may be advised to use effective contraception.

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

Driving and using machines
Ondran does not affect the ability to use any tools or machines or the ability to drive safely in traffic.

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

3. How to take Ondran
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 alternative1y, 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 Ondran than you should
Your doctor or nurse will give you or your child Ondran so it is unlikely that you or your child will receive too much. If you think you or your child have been given too much or have missed a dose, tell your doctor or nurse. The symptoms of overdose are disturbances of vision, severe constipation, low blood pressure and disturbances in heart beat rhythm.

If you forget to take Ondran
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, pharmacist or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Myocardial ischemia
Signs include:

- sudden chest pain or
- chest tightness

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

- headache.

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

- 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 1,000 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. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ondran

- 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 on the carton after "EXP". The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 protect the environment.

6. Contents of the pack and other information

What Ondran contains

- The active substance is ondansetron.
  Each film-coated tablet contains 4 mg or 8 mg ondansetron (as hydrochloride dihydrate).

- The other ingredients are:
  Tablet core: cellulose, microcrystalline; lactose monohydrate; starch, pregelatinised (maize); magnesium stearate
  Film-coated: hypromellose; hydroxypropylcellulose; propylene glycol (E1520); sorbitan oleate; sorbic acid (E200); vanillin; titanium dioxide (E17l) and quinoline yellow (E104).

What Ondran looks like and contents of the pack

Ondran 4 mg are yellow, round, biconvex, film-coated tablets with a diameter of 7.2 mm and marked with "41" on one side.
Ondran 8 mg are yellow, round, biconvex, film-coated tablets with a diameter of 9.2 mm and marked with "42" on one side.

4 mg blister: 6, 10, 30, 50 and 100 film-coated tablets.
8 mg blister: 6, 10, 15, 30, 50 and 100 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer

Pharmathen S.A., 6 Dervenakion str., 15351 Pallini Attikis, Greece

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