PATIENT INFORMATION LEAFLET
Ondansetron 4 mg & 8 mg Film-Coated Tablets
Ondansetron Hydrochloride Dihydrate

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, nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See section 4).

What is in this leaflet:

1 What Ondansetron Tablets are and what they are used for
2 What you need to know before you take Ondansetron Tablets
3 How to take Ondansetron Tablets
4 Possible side effects
5 How to store Ondansetron Tablets
6 Contents of the pack and other information

1. WHAT ONDANSETRON TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in your tablets is Ondansetron. This belongs to a group of medicines known as anti-emetics.

Ondansetron 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 ONDANSETRON TABLETS

Do not take Ondansetron Tablets if you:

- are allergic to Ondansetron, or to any of the other ingredients or to medicines (listed in section 6).
- are taking apomorphine (used to treat Parkinson's disease)

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Ondansetron Tablets if:

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath & swollen ankles).
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to Ondansetron, such as granisetron (known as 'Kytril') 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 Ondansetron Tablets

Children and Adolescents
The liver function for persons under 18 years of age taking Ondansetron Tablets should be regularly checked.

Other medicines and Ondansetron Tablets
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Ondansetron can affect the way some medicines work. Also some other medicines can affect the way Ondansetron works.

There are known interactions between the following medications and Ondansetron therefore their use with Ondansetron Tablets is not recommended.
- carbamazepine or phenytoin used to treat epilepsy, as it lowers the concentration of Ondansetron,
- rifampicin used to treat infections such as tuberculosis (TB), it lowers the concentration of Ondansetron,
- antibiotics such as erythromycin and antifungals such as ketoconazole
- anti-arrhythmic medicines used to treat an uneven heartbeat, as Ondansetron prevents this medication from working,
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines as beta-blocker may not work properly,
- tramadol, a pain killer, as tramadol may not work properly
- 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, nurse or pharmacist before having Ondansetron Tablets.

Ondansetron Tablets with food, drink and alcohol
You can take your Ondansetron Tablets with or without food.
There are no interactions with alcohol.

Pregnancy, breast-feeding and fertility
Pregnancy:
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 Ondansetron Tablets 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 Tablets. If you are a woman of childbearing potential you may be advised to use effective contraception.

Breastfeeding:
The Ondansetron in these tablets may pass into breast milk. Mothers taking Ondansetron Tablets should **not** therefore breast-feed. Ask your doctor or midwife for advice.

Fertility:
No data available.

Driving and using machines
Ondansetron can cause visual disturbances and dizziness. If you are affected do not drive or operate machinery.

Ondansetron Tablets contain 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 ONDANSETRON TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, nurse or pharmacist if you are not sure.
Ondansetron Tablets are an oral medicine and the recommended dose you are prescribed by your doctor will be dependent on your treatment.

To prevent Chemotherapy and radiotherapy induced nausea and vomiting
On the day of chemotherapy or radiotherapy:
• the usual adult dose is 8mg one or two hours before treatment, followed by another 8mg twelve hours later.
On following days:
• the usual adult dose is 8mg twice a day.
• this may be given for up to 5 days.

Children aged 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 4mg twice daily.
• This may be given for up to 5 days.

To prevent nausea and vomiting after an operation
The usual adult dose is 16mg before an operation or:
• 8mg before the operation, then
• 8mg after the operation, then
• 8mg after a further eight hours.

Children aged over 1 month and adolescents:
It is recommended that Ondansetron be given as an injection.

Patients with moderate to severe liver problems:
The total daily dose should not be more than 8 mg.
Ondansetron Tablets 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 Ondansetron Tablets than the label says.
If you continue to feel sick, tell your doctor or nurse.

If you forget to take Ondansetron Tablet
If you miss a dose **and** feel sick or vomit:
• Take Ondansetron Tablets 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.

If you take too many Ondansetron Tablets:
It is important to take these tablets as directed – taking more than prescribed can make you ill. If you do take more than you should, tell your doctor or go to the nearest hospital casualty department straight away. If you go to the hospital/doctor remember to take this leaflet and any remaining tablets with you so the doctor knows what you have taken.

If you stop taking Ondansetron Tablets:
This medication has been prescribed by your doctor; you should not stop taking Ondansetron Tablets without discussing this with your doctor first.

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

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

Allergic reactions:
If you have an allergic reaction, stop taking Ondansetron Tablets and see your doctor straight away. The signs of an allergic reaction may include:
- swelling of the face, eyelids, lips, mouth or tongue
- sudden wheezing, difficulty in breathing, chest tightness or chest pain,
- skin rash – red spots or lumps under the skin (hives) anywhere on your body
- collapse.

Other side effects include:

Very common (affects more than 1 in 10 people)
- headache
- changes to liver function test results (if you are taking with a medicine called cisplatin, otherwise its effect is uncommon)

Common (affects less than 1 in 10 people)
- sensation of warmth or flushing
- constipation

Uncommon (affects less than 1 in 100 people)
- hiccups,
- low blood pressure, which can make you feel dizzy or faint,
- uneven heart beat,
- chest pain,
- fits,
- unusual body movements or shaking.

Rare (affects less than 1 in 1,000 people)
- feeling dizzy or light headed,
- blurred vision,
- disturbances in heart rhythm (sometimes causing a sudden loss of consciousness).

Very rare (affects less than 1 in 10,000 people)
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

Unknown frequency (cannot be estimated from the available data):
- Myocardial Ischemia. Signs include sudden chest pain or chest tightness.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of medicines.

5. HOW TO STORE ONDANSETRON TABLETS

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 carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any damage/ discoloration to the tablets.

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

Store the tablets in the original package. Keep the blister in the outer carton.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ondansetron tablets contain:
The active substance is Ondansetron (as Ondansetron Hydrochloride Dihydrate).
The other ingredients include: lactose monohydrate, microcrystalline cellulose, maize starch, magnesium stearate, hypromellose, titanium dioxide (E171) and macrogol.

What Ondansetron Tablets look like and contents of the pack:
Ondansetron 4 mg Tablets are white, circular, biconvex, film-coated tablets plain on both sides.

Ondansetron 8 mg Tablets are white, circular, biconvex, film-coated tablets with a breakline on one side and plain on the other.

The tablets are available in pack sizes of 10, 30 or 100 tablets (not all packs may be marketed)

Marketing Authorisation Holder:
Cadila Pharmaceuticals (UK) Limited,
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Manufacturer responsible for batch release:

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Ennogen Healthcare International Limited, Unit G3, Riverside Industrial Estate Riverside Way, Dartford, DA1 5BS, United Kingdom

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