

## ONSETRON® ODT

contains the active ingredient ondansetron

### Consumer Medicine Information

#### What is in this leaflet

Please read this leaflet carefully before you start taking ONSETRON ODT.

This leaflet answers some common questions about ONSETRON ODT. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ONSETRON ODT against the benefits this medicine is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What ONSETRON ODT are used for

ONSETRON ODT belongs to a group of medicines called antiemetics.

ONSETRON ODT works by helping to stop the nausea (sick feeling) and vomiting which can occur after certain treatments. ODT used in the product name stands for Oral Dispersible Tablet. This type of tablet is placed on the tongue where it is rapidly dispersed and can then be swallowed with or without water. It is easier to swallow than ordinary tablets. ONSETRON ODT should only be used to treat the nausea and vomiting for which it has been prescribed.

Your doctor may have prescribed ONSETRON ODT for another reason.

Ask your doctor if you have any questions about why ONSETRON ODT has been prescribed for you.

ONSETRON ODT is not addictive.

#### Before you take ONSETRON ODT

##### *When you must not take them*

**Do not take ONSETRON ODT if you are taking apomorphine (used to treat Parkinson's disease).**

**Do not take ONSETRON ODT if you have ever had an allergic reaction to ondansetron or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

**Do not take ONSETRON ODT if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using ONSETRON ODT if you are pregnant or breastfeeding.

**Do not take ONSETRON ODT after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

**Do not take ONSETRON ODT if the packaging is torn or shows signs of tampering.**

**If you're not sure whether you should be taking ONSETRON ODT, talk to your doctor.**

#### *Before you start to take them*

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines**
- **you have, or used to have, liver problems**
- **you suffer from severe constipation or have a blockage in your gut**
- **you have phenylketonuria, as ONSETRON ODT contains aspartame.**

#### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by ONSETRON ODT, or may affect how well it works. These include:

- medicines to treat epilepsy
- tramadol, a pain reliever

Your doctor or pharmacist will be able to tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ONSETRON ODT.

#### *Use in children*

There is limited experience in children. ONSETRON ODT can be taken by children over 4 years of age.

#### How to take ONSETRON ODT

**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the packaging, ask your doctor or pharmacist for help.

##### *How much to take*

Do not take more tablets than your doctor or pharmacist tells you.

Do not take the tablets more often than your doctor or pharmacist tells you.

If you vomit within one hour of taking your first ONSETRON ODT of each course prescribed for you, you should take the same dose again. If you continue to vomit, tell your doctor.

##### *How to take them*

Place the ONSETRON ODT on top of your tongue. It will disperse very quickly, then swallow as normal.

##### *When to take them*

Your doctor or pharmacist will be able to tell you when you should take your ONSETRON ODT.

##### *How long to take them*

Your doctor or pharmacist will be able to tell you how long you should take your ONSETRON ODT.

##### *If you forget to take them*

If you miss your dose and you do not feel sick take your next dose when you are meant to.

If you miss your dose, and you feel sick, take the missed dose as soon as possible, then go back to taking your ONSETRON ODT as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

##### *If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ONSETRON ODT. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

#### While you are taking ONSETRON ODT

##### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking ONSETRON ODT.**

**Tell your doctor if you become pregnant or are trying to become pregnant.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

##### *Things you must not do*

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not use ONSETRON ODT to treat any other complaints unless your doctor says to.**

#### Side-Effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ONSETRON ODT.**

Like other medicines, ONSETRON ODT can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- headache
- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth
- hiccups
- dizziness or light-headed feeling

**Tell your doctor or pharmacist immediately if you notice any of the following:**

- chest pain or tightness of chest
- changes in the way your heart beats e.g. if you notice it beating faster or slower than normal, or if it beats irregularly or if it 'throbs'
- low blood pressure
- abnormal muscular body movements or shaking involuntary upward movement of the eyes
- unusual muscle tone causing distortion of the body
- fits or convulsions

**These are serious side-effects. You may need urgent medical attention. Serious side-effects are rare.**

**If you think you are having an allergic reaction to ONSETRON ODT, tell your doctor immediately or go to the casualty department of your nearest hospital.**

Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

**Other side-effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feeling unwell, even if it is not on this list.**

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

**If your nausea or vomiting does not go away, ask your doctor what to do.**

In certain illnesses and treatments where ONSETRON ODT has been used, blood vessel blockage has occurred. However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when ONSETRON ODT has not been used. Discuss this with your doctor if you have any concerns.

**Ask your doctor or pharmacist if you don't understand anything in this list.**

- Lactose
- Hydroxypropylcellulose
- Crospovidone
- Calcium silicate
- Aspartame
- Peppermint NAEFCO P0551 957685 (ARTG 2890) flavour
- Colloidal anhydrous silica
- Magnesium stearate.

ONSETRON ODT tablets do not contain gluten.

#### *Sponsor*

##### **Medis Pharma Pty Ltd**

Level 3, 5 Essex St  
The Rocks NSW 2000  
Australia

#### *Distributor*

##### **Actavis Pty Ltd**

Level 5, 117 Harrington St  
The Rocks NSW 2000  
Australia

Phone: 1800 554 414

#### *Australian Registration Numbers*

- ONSETRON ODT 4 mg:  
AUST R 176761
- ONSETRON ODT 8 mg:  
AUST R 176762

#### **Date of preparation:**

3 April 2014

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## After taking ONSETRON ODT

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### *Storage*

**Keep this medicine where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep ONSETRON ODT in a cool, dry place where it stays below 25°C.**

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**  
Heat and dampness can destroy some medicines.

**Keep your ONSETRON ODT in their pack until it is time to take them.**

If taken out of their pack, they may not keep well.

### *Disposal*

**If your doctor tells you to stop taking ONSETRON ODT, or they have passed their expiry date, ask your pharmacist what to do with any left over.**

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## Product Description

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### *What it looks like*

ONSETRON ODT is a special type of tablet called an Oral Dispersible Tablet.

- ONSETRON ODT 4 mg tablet is a white, round, flat-faced, bevel-edged tablet. It is available in blister packs of 4 or 10 tablets.
- ONSETRON ODT 8 mg tablet is a white, round, flat-faced, bevel-edged tablet. It is available in blister packs of 4 or 10 tablets.

### *Ingredients*

Each ONSETRON ODT contains 4 mg or 8 mg of the active ingredient ondansetron.

The inactive ingredients are: