#### **Consumer Medicine Information**

#### What is in this leaflet

Please read this leaflet carefully before you use Ondansetron AN ODT.

This leaflet answers some common questions about Ondansetron AN 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 benefits and risks. Your doctor has weighed the risks of you taking Ondansetron AN ODT against the benefits they expect it will have for you.

# If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

# What Ondansetron AN ODT is used for

ONDANSETRON AN contains a medicine called ondansetron. This belongs to a group of medicines called antiemetics.

ONDANSETRON AN ODT works by helping to stop the nausea (sick feeling) and vomiting which can occur after medical treatments.

ONDANSETRON AN ODT should only be used to treat the nausea and vomiting for which they have been prescribed.

Your doctor may have prescribed Ondansetron AN ODT for another reason.

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

Ondansetron AN ODT is not addictive.

# Before You Take Ondansetron AN ODT

When you must not take Ondansetron AN ODT

Do not take Ondansetron AN if:

- You are taking apomorphine (used to treat Parkinsons disease)
- You have ever had an allergic reaction to ondansetron or any of the ingredients listed towards the end of this leaflet (see 'ingredients')
   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.
- You are pregnant, trying to become pregnant or breastfeeding, unless your doctor says it is safe

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

 The expiry date printed n the pack has passed

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

 The packaging is torn or shows signs of tampering

If you are not sure whether you should be taking Ondansetron AN ODT, talk to your doctor.

Before you start to take them

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 had to stop taking another medicine for your nausea or vomiting.
- you are taking any other medicines, including medicines you buy without a prescription.
- You are breastfeeding, pregnant or trying to become pregnant.
- You have phenylketonuria, as Ondansetron AN 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 affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Ondansetron AN ODT with other medicines.

#### Use in children

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

#### How to take Ondansetron AN ODT

The Pharmacist's label on the pack will tell you how to take Ondansetron AN ODT. If there is something you do not understand, ask your doctor or pharmacist.

#### How much to take

DO NOT take more Ondansetron AN ODT than your doctor or pharmacist tells you.

DO NOT take Ondansetron AN ODT MORE OFTEN than your doctor or pharmacist tells you.

If you vomit within one hour of taking your first Ondansetron AN 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 it

PEEL BACK the foil top of the blister strip and GENTLY remove the Ondansetron AN ODT

(DO NOT try to push it through the foil top as the tablet is fragile and will break up inside the foil). Place the Ondansetron AN 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 Ondansetron AN ODT.

#### How long to take them

Your doctor or pharmacist will be able to tell you how long you should take your Ondansetron AN 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 Ondansetron AN 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) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Ondansetron AN ODT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers of these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

# While you are taking Ondansetron AN ODT

#### Things you must do

Tell your doctor or pharmacist that you are taking Ondansetron AN ODT if you are about to be started on any new medicines.

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 stop taking Ondansetron AN ODT, or change the dose without first checking with your doctor.

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

Do not use Ondansetron AN ODT to treat any other complaints unless your doctor says to.

#### Side Effects

Tell your doctor as soon as possible if you have any problems while taking Ondansetron AN ODT, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Ondansetron AN 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.

The most commonly reported side- effects are:

- headache
- a sensation of warmth or flushing
- mild stomach cramps
- constipation or diarrhoea
- dry mouth

- · hiccups
- · dizziness or light headed feeling

Ask your doctor or pharmacist to answer any questions you may have if you experience any side effects.

# Tell your doctor immediately if you notice any of the following:

- · 'wheezy' symptoms
- · Chest pain or tightness of the 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
  '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

If you think you are having an allergic reaction to Ondansetron AN ODT, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at 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

This is not a complete list of all possible side effects. Other may occur in some people and there may be some side effects not yet known

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

#### If your nausea (feeling of sickness) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where Ondansetron AN 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 Ondansetron AN ODT has NOT been used. Discuss this with your doctor if you have any concerns.

If you feel unwell or have any symptoms, including anything that is not in this list, you should tell your doctor immediately.

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

#### After taking Ondansetron AN

#### Storage

### Keep Ondansetron AN where 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 your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store this medicine or any other medicine in the bathroom or near a sink.

#### Do not leave in the car or on window sills.

Heat and dampness can destroy some medicines

#### Disposal

If your doctor tells you to stop taking Ondansetron AN ODT, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

#### Product description

#### What it looks like

### Ondansetron AN ODT 4 mg (AUST R 196807)

Contains 4 mg Ondansetron White to off white, round tablets debossed with '5' on one side and 'E' on one side with an embossed circular edge.

Available in blister packs of 4, 11, or 20 tablets.

### Ondansetron AN ODT 8 mg (AUST R

Contains 8 mg Ondansetron White to offwhite round tablets, debossed with '7' on one side and 'E' on the other side with an embossed circular edge.

Available in blister packs of 4, 10, or 20 tablets.

#### Ingredients

#### **Active Ingredient:**

Ondansetron

#### Other Ingredients:

- · mannitol
- crospovidone
- · lactose monohydrate
- · microcrystalline cellulose
- aspartame
- colloidal anhydrous silica
- · magnesium stearate
- strawberry guarana 586997 AP0551

Please read this leaflet carefully before you start taking Ondansetron AN. ODT You may wish to keep it to read again.

#### Name and Address of the Sponsor

Amneal Pharma Pty Ltd 12 River Street South Yarra, VIC – 3141 Australia

#### **Date of Preparation**

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