#### **ONDANSETRON TABLETS VIATRIS**

Ondansetron hydrochloride dihydrate

#### **Consumer Medicine Information**

#### What is in this leaflet

Please read this leaflet carefully before you use ONDANSETRON TABLETS VIATRIS.

This leaflet answers some common questions about ONDANSETRON TABLETS VIATRIS. 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 expected benefits of you taking ONDANSETRON TABLETS VIATRIS against the risks this medicine could 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 are ONDANSETRON

### TABLETS VIATRIS used for

ONDANSETRON TABLETS VIATRIS contain a medicine called ondansetron. This belongs to a group of medicines called serotonin receptor-3 antagonists.

ONDANSETRON TABLETS VIATRIS are used to help stop the nausea (sick feeling) and vomiting which can occur after medical treatments.

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

Your doctor may have prescribed ONDANSETRON TABLETS VIATRIS for another reason. If you want more information, ask your doctor.

ONDANSETRON TABLETS VIATRIS are not addictive.

#### Before you take ONDANSETRON TABLETS VIATRIS

#### Do not take if

## Do not take ONDANSETRON TABLETS VIATRIS if:

- you are taking apomorphine (used to treat Parkinson's disease)
- you have ever had an allergic reaction to ondansetron or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- you are pregnant, trying to become pregnant or breast feeding, unless your doctor says it is safe.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering

#### Tell your doctor if

#### You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- 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 have or used to have liver problems.

• you are breastfeeding, pregnant or trying to become pregnant.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking ONDANSETRON TABLETS VIATRIS with other medicines.

#### How do I take ONDANSETRON TABLETS VIATRIS

#### How much to take

Take ONDANSETRON TABLETS VIATRIS as directed by your doctor or pharmacist.

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, taking your first ONDANSETRON TABLETS VIATRIS tablet of each course prescribed to you, you should take the same dose again. If you continue to vomit, tell your doctor.

#### How to take them

Swallow each tablet with a drink of water. Do not crush the tablet. If you have trouble swallowing your tablet, please tell your doctor.

#### How long to take them for

#### Do not stop taking ONDANSETRON TABLETS VIATRIS, or change the dose without first checking with your doctor. 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 TABLETS VIATRIS 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 Poisons Information Centre (telephone 13 11 26) for advice, if you think you or anyone else may have taken too much ONDANSETRON TABLETS VIATRIS, even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

#### While you are using ONDANSETRON TABLETS VIATRIS

Things you must do

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

Otherwise, your doctor may think that it was not working as it should 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 ONDANSETRON TABLETS VIATRIS to treat any other complaints unless your doctor says to.

#### Side effects

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking ONDANSETRON TABLETS VIATRIS, even if the problem is not listed below. Like other medicines, ONDANSETRON TABLETS VIATRIS 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

These are all mild side effects. There is no immediate reason to stop taking your tablets unless you are concerned.

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 if it 'throbs'
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)
- patients may experience "serotonin syndrome" (confusion, sweating, unsteadiness, shaking, diarrhoea) when ONDANSETRON TABLETS VIATRIS is taken in combination with other serotonergic drugs. Serotonergic drugs can include certain types of antidepressants, opioid pain medicines such as tramadol and fentanyl, and lithium. Please note, this is not an exhaustive list. Please discuss with your pharmacist or doctor if you have any concerns.
- Severe skin reaction where the top layer of the skin detaches from the lower layers.
- low blood pressure
- fits or convulsions
- swelling of the eyelids, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- skin rash, skin lumps or hives

#### These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects.

Others 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 of them.

#### 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 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 TABLETS VIATRIS have NOT been used. Discuss this with your doctor if you have any concerns.

If you feel unwell or have any symptoms that you do not understand, you should tell your doctor immediately.

#### How do I store ONDANSETRON TABLETS VIATRIS

Keep this medicine where children cannot reach it, such as in a locked cupboard. Keep ONDANSETRON TABLETS VIATRIS in a cool, dry place where it stays below 25° C, and away from bright

sunlight. Do not leave in a car, on window sill or in bathroom.

Keep ONDANSETRON TABLETS VIATRIS in their blister pack until it's time to take them.

Return any unused or expired medicine to your pharmacist.

#### Product description

#### What ONDANSETRON TABLETS VIATRIS look like

- ONDANSETRON TABLETS VIATRIS 4 mg tablets - Light yellow, oval, biconvex, film coated tablets embossed 'OND' on one side and '4' on other side.
- ONDANSETRON TABLETS VIATRIS 8 mg tablets - Dark yellow, oval, biconvex, film coated tablets embossed 'OND' on one side and '8' on other side.

Your ONDANSETRON TABLETS VIATRIS 4 mg tablets come in a box containing 4, 6 or 10 tablets packed in foil blisters.

Your ONDANSETRON TABLETS VIATRIS 8 mg tablets come in a box containing 4, 6 or 10 tablets packed in foil blisters.

Do NOT use your tablets if they have changed colour.

#### Ingredients

Each ONDANSETRON TABLETS VIATRIS Tablet contains either 4 or 8 milligrams of the active ingredient ondansetron. Your doctor will decide which strength you need.

ONDANSETRON TABLETS VIATRIS also contain the following inactive ingredients which help to form the tablets: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, sodium starch glycollate, magnesium stearate and Opadry Yellow 03B52375 (4 mg tablets) or Opadry Yellow 03B52246 (8 mg tablets)

#### Sponsor

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#### Distributor

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