PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ONDANSETRON 4 mg/2 ml VIATRIS (injection)

ONDANSETRON 8 mg/4 ml VIATRIS (injection)

Ondansetron

Sugar free

ONDANSETRON VIATRIS contains less than 1 mmol sodium (23 mg) per 2 mL and per 4 mL ampoule respectively that is to say essentially 'sodium free'.

Read all of this leaflet carefully before you are given ONDANSETRON VIATRIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What ONDANSETRON VIATRIS is and what it is used for
2. What you need to know before you are given ONDANSETRON VIATRIS
3. How ONDANSETRON VIATRIS will be given
4. Possible side effects
5. How to store ONDANSETRON VIATRIS
6. Contents of the pack and other information

1. What ONDANSETRON VIATRIS is and what it is used for

What ONDANSETRON VIATRIS is

ONDANSETRON VIATRIS contains the active substance ondansetron, which belongs to a group of medicines called anti-emetics.

What it is used for

- Preventing and treating nausea and vomiting caused by chemotherapy and radiotherapy for cancer.

- Preventing and treating nausea and vomiting after an operation.

2. What you need to know before you are given ONDANSETRON VIATRIS

ONDANSETRON VIATRIS should not be administered to you

- If you are hypersensitive (allergic) to ondansetron or any of the other ingredients of ONDANSETRON VIATRIS (listed in section 6).
- If you have a heart disorder (e.g. long QT syndrome).
- If you are taking or receiving apomorphine (medicine used to treat Parkinson's disease).
- If you are taking or receiving other medicines that cause long QT syndrome.
- If you have just had an operation, and are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).
- If you are within the first 12 weeks of pregnancy (see Take special care with ONDANSETRON VIATRIS).
- If you have liver problems or liver disease.

Warnings and precautions

Tell your doctor or health care provider before being given the injection if:

- You have previously had hypersensitivity reactions to similar medicines e.g. granisetron or dolasetron.
- You have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles).
- You have an uneven heartbeat (dysrhythmias).
- You are pregnant, as ONDANSETRON VIATRIS should not be taken during the first 12 weeks of pregnancy. ONDANSETRON VIATRIS increases the risk of unborn babies developing a cleft palate and/or lip (see Pregnancy, breastfeeding and fertility).
- You have liver problems or poor liver function – you may need a lower dose of ONDANSETRON VIATRIS.
- You have problems with the levels of salts in your blood, such as potassium and magnesium (this will be determined by blood tests).
- You have a blockage in your gut (when there is a delay in the time that your stomach takes to work

out and you are constipated).

- You are taking serotonin antidepressants, it may cause you to develop a condition called serotonin syndrome (this may cause you to have a high fever, feel agitated, confused, or make you tremble and you may have abrupt contractions of your muscles).

Children and adolescents

Experience is currently limited, but ONDANSETRON VIATRIS was effective and well tolerated in children over the age of 4 years to prevent nausea and vomiting from chemotherapy.

Other medicines and ONDANSETRON VIATRIS

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Cancer medicines (such as anthracyclines (doxorubicin, daunorubicin or trastuzumab) may cause heart disorders.
- Apomorphine (medicine used to treat Parkinson's disease). Together this may cause low blood pressure and fainting as well as heart disorders).
- Tramadol (for relief of pain – may reduce the pain effect).
- Phenytoin, carbamazepine (used to treat epilepsy).
- Medicines which may result in long QT syndrome (heart rhythm disorder).
- Rifampicin (medicine used to treat infections like tuberculosis (TB).
- Erythromycin (an antibiotic).
- Ketoconazole (used to treat fungal infections).
- Amiodarone (anti-arrhythmic medicine used to treat an uneven heartbeat).
- Beta-blocker medicines, such as atenolol or timolol (used to treat certain heart or eye problems, anxiety or prevent migraines).
- 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.

ONDANSETRON VIATRIS with food, drink and alcohol

You will not be able to drink or eat during the period of receiving ONDANSETRON VIATRIS.

Pregnancy, breastfeeding and fertility

You should not receive ONDANSETRON VIATRIS if you are pregnant (see Do not receive ONDANSETRON VIATRIS).

Pregnancy

Do not receive ONDANSETRON VIATRIS if you are pregnant or think that you are pregnant (see ONDANSETRON VIATRIS should not be administered to you).

ONDANSETRON VIATRIS can increase the risk of a baby being born with a cleft lip and/or a cleft palate (openings or splits in the upper lip and/or the roof of the mouth) if you are within the first 12 weeks of pregnancy.

If you are a woman of childbearing potential, you should use effective contraception to prevent becoming pregnant and continue the use of effective contraception for 2 days after stopping treatment.

If you are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ONDANSETRON VIATRIS.

Breastfeeding

You should not breastfeed your baby if you are receiving ONDANSETRON VIATRIS.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before receiving ONDANSETRON VIATRIS.

Driving and using machines

It is not always possible to predict to what extent ONDANSETRON VIATRIS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ONDANSETRON VIATRIS affects them (see section 4).

ONDANSETRON VIATRIS contains sodium

ONDANSETRON VIATRIS contains sodium, and this should be taken into consideration by patients on a sodium-restricted diet.

3. How to receive ONDANSETRON VIATRIS

Do not share medicines prescribed for you with any other person.

- You will never be expected to give yourself a ONDANSETRON VIATRIS injection. It will be given to

you by a doctor or nurse who is trained in the administration of ONDANSETRON VIATRIS.

- ONDANSETRON VIATRIS injection will usually be given to you by a doctor or nurse by slow injection into a vein (intravenously) or into the muscle (intramuscularly) before treatment.

The usual dose is:

If you are receiving chemotherapy or radiation treatment that could cause nausea and vomiting or after undergoing an operation

The dose is individual to each patient and will be determined by your doctor.

On the day of chemotherapy or radiotherapy

The usual adult dose is 8 mg given by a slow injection into your vein or an injection into your muscle, just before your treatment, and another 8 mg twelve hours later. After chemotherapy, your medicine will usually be given by mouth as 8 mg tablets.

On the following days

- The usual adult dose is 8 mg twice a day.
- This may be given for up to 5 days.

Elderly

Your doctor will determine what treatment you should receive.

Children

- Experience is currently limited, but ONDANSETRON VIATRIS was effective and well-tolerated in children over the age of 4 years. The doctor will decide on your dose depending on the child's size (body surface area) or weight.
- ONDANSETRON VIATRIS will be given as an injection into the vein, just before your child's treatment. After chemotherapy, your child's medicine will usually be given by mouth twelve hours later.

To prevent nausea and vomiting after an operation

Adults

The usual dose for adults is 4 mg given by a slow injection into your vein or an injection into your muscle after your operation. For prevention of nausea and vomiting, ONDANSETRON VIATRIS will be given to you just before your operation.

Children

For children aged over 2 years and adolescents the doctor will decide the dose. The maximum dose is 4 mg given as a slow injection into the vein after the operation. For prevention of nausea and vomiting, ONDANSETRON VIATRIS will be given just before the operation.

If you have liver disease or liver problems

Your doctor will give you a lower dose of ONDANSETRON VIATRIS (not more than 8 mg).

If you have the impression that the effect of ONDANSETRON VIATRIS is too strong or too weak, tell your doctor or pharmacist.

If you receive more ONDANSETRON VIATRIS than you should

Since a health care professional will administer ONDANSETRON VIATRIS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of ONDANSETRON VIATRIS

Since a health care provider will administer ONDANSETRON VIATRIS, it is unlikely that the dose will be missed.

4. Possible side effects

ONDANSETRON VIATRIS can have side effects.

Not all side effects reported for ONDANSETRON VIATRIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ONDANSETRON VIATRIS, please consult your health care provider for advice.

If any of the following happens, stop receiving ONDANSETRON VIATRIS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden wheezing and chest pain or chest tightness.
- Swelling of your eyelids, face, lips, mouth, throat or tongue.
- Low blood pressure (which can make you feel lightheaded or dizzy).
- Skin rash – red spots or lumps under your skin (hives) anywhere on your body.
- Shock.
- Myocardial ischaemia with symptoms such as sudden chest pain and chest tightness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ONDANSETRON VIATRIS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- An uneven heartbeat or disturbance in your heart rhythm.
- Chest pain.
- Fits (seizures).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Headache.
- A feeling of warmth or flushing.
- Changes to liver function test results (could be frequent if you receive ONDANSETRON VIATRIS with a cancer medicine called cisplatin).

The following side effects have been reported less frequently:

- Constipation.
- Pain, redness and burning at the site of injection.
- Unusual body movements or shaking.
- Dizziness (during rapid intravenous administration).
- Blurred or poor vision or temporary loss of eyesight.
- Depression.
- Hiccups.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ONDANSETRON VIATRIS.

5. How to store ONDANSETRON VIATRIS

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package/ container.
- Keep the container in the outer carton.
- Protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/ carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ONDANSETRON VIATRIS contains

- The active substance is ondansetron.
- The other ingredients are citric acid monohydrate, sodium chloride, sodium citrate and water for injection.

What ONDANSETRON VIATRIS looks like and contents of the pack

What ONDANSETRON VIATRIS looks like:

ONDANSETRON 4 mg/2 ml VIATRIS: Amber glass ampoules containing a practically odourless, colourless, clear liquid that is free of visible particles.

ONDANSETRON 8 mg/4 ml VIATRIS: Amber glass ampoules containing a practically odourless, colourless, clear liquid that is free of visible particles.

Contents of the pack:

ONDANSETRON 4 mg/2 ml VIATRIS: 1, 2, 5 or 10 amber glass ampoule/s packaged in an outer carton.

ONDANSETRON 8 mg/4 ml VIATRIS: 1, 2, 5 or 10 amber glass ampoule/s packaged in an outer carton.

Holder of Certificate of Registration and Manufacturer

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