Approved Patient Information Leaflet for
ONDANSETRON 4 mg/2 ml FRESENIUS
ONDANSETRON 8 mg/4 ml FRESENIUS

SCHEDULING STATUS: S4

ONDANSETRON 4 mg/2 ml FRESENIUS

ONDANSETRON 8 mg/4 ml FRESENIUS

Solution for injection or infusion

Ondansetron

Sugar free

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

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

What is in this leaflet

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

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

ONDANSETRON FRESENIUS belongs to a group of medicines called anti-emetics. These medicines prevent you from feeling sick (nausea) or being sick (vomiting). Treatment with

medicines for cancer (chemotherapy), radiotherapy or surgical treatments may make you feel sick or be sick. ONDANSETRON FRESENIUS may help stop these effects.

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

Do not receive ONDANSETRON FRESENIUS:

- if you are allergic (hypersensitive) to ondansetron, to any of the ingredients of ONDANSETRON FRESENIUS (listed in section 6) or to medicines from the same class
- if you are taking a medicine called apomorphine (used to treat Parkinson's disease) (see "**Other medicines and ONDANSETRON FRESENIUS**")
- during the first twelve weeks of pregnancy because there is an increased risk that your unborn baby may develop oral cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth)
- for feeling sick or being sick after having an operation, if you are pregnant
- if you have a genetic heart condition called congenital long QT syndrome, that results in irregular heartbeats.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Take special care with ONDANSETRON FRESENIUS:

- if you have previously had a hypersensitive (allergic) type reaction to other medicines in the same class as ONDANSETRON FRESENIUS
- if you have a blockage in your gut or suffer from severe constipation, as ONDANSETRON FRESENIUS can affect the mobility of the lower gut
- ONDANSETRON FRESENIUS should not be given to children under 2 years of age as insufficient data is available
- if you have heart problems
- if you have any liver impairment

- if you have any imbalance of chemicals (electrolytes) which regulate important functions in your body
- if you are having an operation involving your throat or tonsils
- if you are pregnant (see "**Do not receive ONDANSETRON FRESENIUS**").

Other medicines and ONDANSETRON FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Receiving ONDANSETRON FRESENIUS while taking these medicines may cause undesirable interactions.

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

- Antibiotics such as erythromycin.
- Antifungals such as ketoconazole.
- Any heart medicines that control the rhythm of the heart, e.g. antidysrhythmics (such as amiodarone) and beta blockers (such as atenolol or timolol).
- Apomorphine (used to treat Parkinson's disease) (see "**Do not receive ONDANSETRON FRESENIUS**").
- Carbamazepine or phenytoin (medicines to control fits/seizures).
- Doxorubicin, daunorubicin and trastuzumab (medicines used to treat cancer).
- Medicines that cause any imbalance of chemicals (electrolytes) in your body.
- Medicines that increase serotonin in the brain, called serotonergic medicines (including medicines used for depression, called SSRIs and SNRIs).
- Rifampicin (medicine used to treat tuberculosis).
- Tramadol (medicine used for severe pain).

There are no interactions between ONDANSETRON FRESENIUS and the following:

- Alcohol.
- Alfentanil, propofol and thiopental (medicines used for general anaesthesia in surgery).
- Furosemide (a water pill used for swelling or to treat high blood pressure).
- Lidocaine (medicine used for local anaesthesia).
- Morphine (medicine used for severe pain).
- Temazepam (medicine used for sleeping).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving ONDANSETRON FRESENIUS.

Pregnancy

Do not become pregnant while being treated with ONDANSETRON FRESENIUS. If you are a woman of childbearing potential, you are advised to use effective contraception while receiving ONDANSETRON FRESENIUS and for 2 days after stopping treatment.
Do not receive ONDANSETRON FRESENIUS:

- during the first twelve weeks of pregnancy because there is an increased risk that your unborn baby may develop oral cleft lip and/or cleft palate
- for feeling sick or being sick after having an operation, if you are pregnant (see "**Do not receive ONDANSETRON FRESENIUS**").

Breastfeeding

Do not breastfeed your baby while receiving ONDANSETRON FRESENIUS.

Fertility

There is no information on the effects of ONDANSETRON FRESENIUS on human fertility.

Driving and using machines

ONDANSETRON FRESENIUS may make you dizzy or cause blurred vision. Do not drive, use machinery or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely again.

It is not always possible to predict to what extent ONDANSETRON FRESENIUS 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 FRESENIUS affects them.

ONDANSETRON FRESENIUS contains sodium

ONDANSETRON FRESENIUS contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

3. How to receive ONDANSETRON FRESENIUS

You will not be expected to give yourself ONDANSETRON FRESENIUS. It will be given to you by a person who is qualified to do so.

Dosage

Adults

Your doctor will decide on the correct dose of ONDANSETRON FRESENIUS therapy for you.

The dose varies depending on your medical treatment (chemotherapy, radiotherapy or surgery), on your liver function, and on whether it is given to you by injection or infusion.

The elderly

Your doctor will adjust the dose of ONDANSETRON FRESENIUS if you are aged 65 years or older.

Children older than two years

Your doctor will decide on the correct dose of ONDANSETRON FRESENIUS therapy for your child, dependant on their age and weight.

ONDANSETRON FRESENIUS should not be given to children younger than two years.

Method and route of administration

ONDANSETRON FRESENIUS is administered as an intramuscular injection (into a muscle) or as an intravenous infusion (slow injection into a vein).

The needle must remain in the vein while the medicine is being given. If the needle comes out or becomes loose, or the solution is going into the tissue outside the vein (you may feel discomfort or pain) - **tell the doctor or healthcare provider immediately**.

Frequency of administration

Your doctor will decide on the frequency of ONDANSETRON FRESENIUS therapy for you.

Duration of treatment

Your doctor will decide on the duration of ONDANSETRON FRESENIUS therapy for you.

If you receive more ONDANSETRON FRESENIUS than you should

Since a healthcare provider will administer ONDANSETRON FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive ONDANSETRON FRESENIUS

Since a healthcare provider will administer ONDANSETRON FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

ONDANSETRON FRESENIUS can have side effects.

Not all side effects reported for ONDANSETRON FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving ONDANSETRON FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving ONDANSETRON FRESENIUS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash, hives and/or itching.
- Fainting.
- Shortness of breath.
- Tightness in chest.
- Troubled breathing.
- Wheezing.
- Chest pain.
- Abnormal or irregular heartbeat.
- Seizures (fits).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Sensation of warmth or flushing.
- Constipation, increased bowel transit time.
- Pain, redness or burning at site of injection.

Less frequent side effects:

- Involuntary and uncontrollable movements, for example of the face, arms or legs.
- Prolonged involuntary upward deviation of the eyes (oculogyric crisis).
- Unintentional sustained muscle contractions leading to abnormal postures.
- Low blood pressure.
- Dizziness or lightheadedness.
- Temporary visual disturbances such as blurred vision or blindness, which usually resolves within 20 minutes.
- Hiccups.
- Increases in liver function tests, with no symptoms.

Frequency unknown:

- Sudden chest pain or chest tightness which could be signs of lack of blood flow to the heart (myocardial ischaemia).

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

Reporting of side effects

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-

kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **Adverse Drug Reaction 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 FRESENIUS.

5. How to store ONDANSETRON FRESENIUS

Store at or below 30 °C.

Keep the ampoules in the outer container in order to protect from light.

Inspect visually prior to use. Only clear solutions without particles should be used.

The ampoules are for single use only. Any unused solution should be discarded.

If the diluted solutions are not used immediately, they should be stored at 2 – 8 °C for not longer than 7 days.

Do not use ONDANSETRON FRESENIUS after the expiry date which is stated on the carton and the ampoule after the words "Do not use after" or "exp". The first two numbers indicate the month, the last numbers indicate the year. The expiry date refers to the last day of the month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What ONDANSETRON FRESENIUS contains

The active substance is ondansetron.

Each 1 ml contains ondansetron hydrochloride dihydrate equivalent to 2 mg ondansetron.

ONDANSETRON 4 mg/2 ml FRESENIUS: Each 2 ml ampoule contains 4 mg ondansetron.

ONDANSETRON 8 mg/4 ml FRESENIUS: Each 4 ml ampoule contains 8 mg ondansetron.

The other ingredients are sodium chloride, citric acid monohydrate (for pH-adjustment), sodium citrate dihydrate (for pH-adjustment) and water for injections.
Sugar free.

What ONDANSETRON FRESENIUS looks like and contents of the pack

ONDANSETRON 4 mg/2 ml FRESENIUS: Clear, colourless solution, free of any particulate matter, in 2 ml clear glass ampoules packed in cartons of 1's, 5's or 10's.
ONDANSETRON 8 mg/4 ml FRESENIUS: Clear, colourless solution, free of any particulate matter, in 5 ml clear glass ampoules packed in cartons of 1's, 5's or 10's.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

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