

SCHEDULING STATUS

S4

ONDANSETRON 4 mg/2 mL PHARMC, Solution for injection

ONDANSETRON 8 mg/4 mL PHARMC, Solution for injection

Ondansetron hydrochloride

Sugar free

Read all of this leaflet carefully before you start are given ONDANSETRON PHARMC

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

What is in this leaflet

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

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

ONDANSETRON PHARMC contains ondansetron hydrochloride. Ondansetron belongs to a group of medicines called anti-emetics (medicines used for vomiting and nausea).

ONDANSETRON PHARMC is used for:

- Preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer.
- Preventing nausea and vomiting after surgery.

Ask your doctor or pharmacist if you would like any further explanation about these uses.

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

ONDANSETRON PHARMC should not be administered to you:

- If you are hypersensitive (allergic) to ondansetron or any of the other ingredients in ONDANSETRON PHARMC (listed in section 6).
- If you are pregnant.
- If you are using apomorphine (used for Parkinson's disease).
- If you suffer from congenital long QT syndrome (a heart condition you were born with).

Warnings and precautions

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

- If you have problems with your liver. Your doctor might change the dosage of ONDANSETRON PHARMC.
- If you have heart problems or have uneven heartbeat.
- If you have problems with the levels of salts in your blood, such as potassium, sodium, calcium and magnesium.
- If you are allergic to medicines similar to ONDANSETRON PHARMC, such as granisetron or palonosetron.
- If you have a blockage in your gut.
- If you have just had or are going to have your adenoids or tonsils removed.

Children

The daily dose for children should not exceed 4 mg. If cancer treatment is given with ONDANSETRON PHARMC, your child should be monitored more closely for liver problems.

Other medicines and ONDANSETRON PHARMC

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

- Phenytoin, or carbamazepine used to treat epilepsy.
- Rifampicin used to treat infections such as tuberculosis (TB).
- Medicines that can increase your risk of heart problems when taken together with

ONDANSETRON PHARMC

- Cancer treatments, e.g., doxorubicin, daunorubicin or trastuzumab
 - Antibiotics, e.g., erythromycin
 - Antifungals, e.g., ketoconazole
 - Antiarrhythmics, e.g., amiodarone
 - Beta blockers, e.g., atenolol or timolol
 - Apomorphine, used for Parkinson's disease (you should not receive ONDANSETRON PHARMC when you are using apomorphine).
- Tramadol, used for severe pain may be less effective when given with ONDANSETRON PHARMC.
 - Medicines used to treat depression and/or anxiety called selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs). These medicines together with ONDANSETRON PHARMC can increase your risk of side effects.

Pregnancy and breastfeeding

You should not be given ONDANSETRON PHARMC when you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before you are given ONDANSETRON PHARMC.

Driving and using machines

It is not always possible to predict to what extent ONDANSETRON PHARMC may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental

alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which ONDANSETRON PHARMC affects you.

ONDANSETRON PHARMC contains sodium

ONDANSETRON PHARMC contains 3,61 mg sodium (main component of cooking/table salt) in each 1 mL. This is less than 1 mmol sodium (23 mg) per 2 – 6 mL dose, that is to say essentially 'sodium-free'. When the dose is greater than 6 mL it cannot be considered 'sodium-free' and it should be taken into consideration if you are on a controlled sodium diet. At maximum daily dose (16 mL) ONDANSETRON PHARMC contains 58 mg of sodium. This is equivalent to approximately 2,9 % of the recommended daily dietary intake of sodium for an adult.

3. How ONDANSETRON PHARMC is given

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

ONDANSETRON PHARMC will be given to you as an injection into your vein or muscle, or as an infusion into your vein.

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

The usual dose is:

To prevent nausea and vomiting from chemotherapy or radiotherapy

Adults: On the day of chemotherapy or radiotherapy: 8 mg given by an injection into your vein or muscle, just before your treatment.

If your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you may be given more than the usual dose of ONDANSETRON PHARMC. This will be decided by your doctor.

Children over 4 years: The doctor will decide on the dose depending on your child's weight and size (body surface area). The first dose is given by 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 treat nausea and vomiting after an operation

Adults: 4 mg given by an injection into your vein or muscle, just before your operation.

Children two years and older: The doctor will decide on the dose depending on your child's weight and size (body surface area). The maximum dose is 4 mg given as a slow injection into the vein after the operation. For prevention of nausea and vomiting, ONDANSETRON PHARMC will be given just before the operation.

Elderly patients

If you are elderly, aged 75 years or older: The total daily dose should not be more than 8 mg.

If you are elderly, aged 65 to 75 years old: The total daily dose should not be more than 16 mg.

The dose will be diluted and given as an infusion into your vein. Repeated doses should be given more than 4 hours apart.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

If you keep feeling or being sick

ONDANSETRON PHARMC should start to work soon after having the injection. If you continue to be sick or feel sick, tell your doctor or nurse.

If you received more ONDANSETRON PHARMC than you should

Since a healthcare professional will administer ONDANSETRON PHARMC, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

If you missed a dose of ONDANSETRON PHARMC

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

4. Possible side effects

ONDANSETRON PHARMC can have side effects.

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

If any of the following happens, tell your doctor or nurse immediately

- A severe allergic reaction with chest tightness, difficulty to breath, low blood pressure, swelling e.g., your mouth, throat or eyes, rash or itching.
- Myocardial ischaemia occurring when blood flow to your heart is reduced, preventing the heart muscle from receiving enough oxygen. Signs include sudden chest pain, chest tightness and or a change in heart rhythm.

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

Tell your doctor if you notice any of the following

Frequent side effects

- headache
- constipation
- pain, redness or burning at the injection site.

Less frequent side effects

- unusual body movements or shaking, convulsions
- feeling dizzy or lightheaded

- blurred vision, temporary loss of eyesight
- uneven or slow heartbeat
- low blood pressure
- a feeling of warmth or flushing
- hiccups
- changes to liver function test results.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 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 PHARMC.

5. How to store ONDANSETRON PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C
- Protect from light.
- Do not use after the expiry date stated on the label/carton.

ONDANSETRON PHARMC diluted with the recommended IV solution should be used within 24 hours if stored at room temperature or used within 72 hours if stored in a refrigerator.

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 PHARMC contains

The active substance is ondansetron.

ONDANSETRON 4 mg/2 mL PHARMC: Each mL contains ondansetron hydrochloride equivalent to 2 mg ondansetron.

ONDANSETRON 8 mg/4 mL PHARMC: Each mL contains ondansetron hydrochloride equivalent to 2 mg ondansetron.

The other ingredients are citric acid, anhydrous; sodium citrate; sodium chloride; water for injection.

What ONDANSETRON PHARMC looks like and contents of the pack

ONDANSETRON PHARMC is a colourless liquid free from particulate matter.

ONDANSETRON 4 mg/2 mL PHARMC: Clear, colourless 2 mL glass ampoules with ceramic print, placed in a plastic rondo tray covered with a rondo tray sponge, packed into a carton. Each carton contains 5 ampoules.

ONDANSETRON 8 mg/4 mL PHARMC Clear, colourless 5 mL glass ampoules with ceramic print, placed in a plastic rondo tray covered with a rondo tray sponge, packed into a carton. Each carton contains 5 ampoules.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD

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Registration numbers

ONDANSETRON 4 mg/2 mL PHARMC: A39/5.10/0062

ONDANSETRON 8 mg/4 mL PHARMC: A39/5.10/0063

Access to the corresponding Professional Information

To be confirmed