

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ONDANSETRON 4 mg/2 ml BIOTECH, Injection

ONDANSETRON 8 mg/4 ml BIOTECH, Injection

Ondansetron (as hydrochloride dihydrate)

Sugar free

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

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

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

ONDANSETRON BIOTECH injection contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics.

ONDANSETRON BIOTECH is used for:

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

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

2. What you need to know before you use ONDANSETRON BIOTECH

ONDANSETRON BIOTECH injection should not be administered to you if:

- you are hypersensitive (allergic) to ondansetron or any of the other ingredients of ONDANSETRON BIOTECH injection (listed in section 6).
- you are taking apomorphine (used to treat Parkinson's disease).
- you are pregnant, especially during the first 12 weeks of pregnancy.
- if a woman is pregnant, she should avoid using this medication for post-operative nausea and vomiting because it might not be safe for the baby or the pregnancy.
- you have or have had a heart condition characterised by a prolonged QT interval (seen on an ECG, electrical recording of the heart).

Warnings and precautions

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

- if you have ever had heart problems (e.g., congestive heart failure which causes shortness of breath and swollen ankles or lack of blood flow getting to your heart muscle (myocardial ischemia))
- if you have an uneven heartbeat (dysrhythmias)
- if you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- if you have just had or are going to have your adenoids or tonsils removed
- if you have liver problems
- if you have a blockage in your gut
- if you have problems with the levels of salts in your blood, such as low levels of potassium, or sodium and magnesium
- if you show signs or symptoms of sudden chest pain or chest tightness heart problem (when the heart

muscle doesn't get enough blood flow and oxygen)

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before having ONDANSETRON BIOTECH injection.

Children and adolescents

ONDANSETRON BIOTECH was effective and well tolerated in children

- over the age of 4 years to prevent nausea and vomiting from chemotherapy
- 2 years and older to prevent nausea and vomiting after surgery under general anaesthesia

Other medicines and ONDANSETRON BIOTECH

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

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following medicines before you are given the injection:

- apomorphine: used for treating of Parkinson's disease. Apomorphine should not be taken together with ONDANSETRON BIOTECH (see "Do not take ONDANSETRON BIOTECH").
- rifampicin: used to treat infections such as tuberculosis (TB)
- antibiotics: such as erythromycin
- ketoconazole: a medicine used to treat a fungal infection
- anti-dysrhythmic medicines: used to treat an uneven heartbeat like amiodarone
- beta-blocker medicines: used to treat certain heart or eye problems, anxiety or prevent migraines, such as atenolol and timolol
- tramadol: a pain killer
- medicines that affect the heartbeat (such as haloperidol or methadone)
- cancer medicines, such as anthracyclines (e.g., doxorubicin, daunorubicin) and trastuzumab
- SSRIs (selective serotonin reuptake inhibitors): used to treat depression and/or anxiety including

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Ondansetron 8 mg /4 ml Biotech

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fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram

- SNRIs (serotonin noradrenaline reuptake inhibitors): used to treat depression and/or anxiety including venlafaxine, duloxetine

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having ONDANSETRON BIOTECH injection.

ONDANSETRON BIOTECH injection should not be given in the same syringe or infusion (drip) as any other medication.

Pregnancy, breastfeeding and fertility

You should not take ONDANSETRON BIOTECH during the first 12 weeks of pregnancy.

ONDANSETRON BIOTECH can increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth).

If you are a woman of childbearing potential, you should use effective contraception to prevent becoming pregnant.

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before having ONDANSETRON BIOTECH.

Do not breastfeed if you are using ONDANSETRON BIOTECH. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Driving and using machines

ONDANSETRON BIOTECH causes nervous system and eye disorders which may adversely affect your ability to drive or operate machines.

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

ONDANSETRON BIOTECH contains sodium

ONDANSETRON BIOTECH contains less than 1 mmol sodium (23 mg) per 4 ml ampoule (3,56 mg per ml), that is to say essentially “sodium free”.

3. How to use ONDANSETRON BIOTECH

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

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

To prevent nausea and vomiting from chemotherapy or radiotherapy

Adults:

On the day of chemotherapy or radiotherapy:

- the usual adult dose is 8 mg given by a slow infusion into your vein or an injection into your 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 BIOTECH. Your doctor will decide on this.

Children:

The doctor will decide on the dose depending on the child’s size (body surface area) or weight.

Elderly patients

The doctor will decide on the dose depending on whether you are older or younger than 75 years of age.

To prevent and treat nausea and vomiting after an operation:

Adult:

The usual dose for adults is 4 mg given by a slow infusion into your vein or an injection into your muscle after your operation. For prevention of nausea and vomiting, this will be given 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 infusion into the vein after the operation.

For prevention of nausea and vomiting, ONDANSETRON BIOTECH will be given just before the operation.

Elderly patients

The doctor will decide on the dose depending on whether you are older or younger than 75 years of age.

If you have moderate or severe liver problems:

Your total daily dose will not be more than 8 mg.

If you receive more ONDANSETRON BIOTECH than you should

Since a health care provider will administer ONDANSETRON BIOTECH, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use ONDANSETRON BIOTECH

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

4. Possible side effects

ONDANSETRON BIOTECH can have side effects.

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

If any of the following happens, after you have received ONDANSETRON BIOTECH go to the casualty department at your nearest hospital:

- sudden wheezing and chest pain or chest tightness
- swelling of your hands, feet, ankles, eyelids, face, lips, mouth, throat or tongue, which may cause difficulty in swallowing or breathing
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- fainting, collapse.

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

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

- experiencing a slower than normal heartbeat
- hypotension (low blood pressure), with or without loss of consciousness
- shortness of breath
- vision disturbances or blurred vision predominantly during IV

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

Tell your doctor if you notice any of the following:

Frequent

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Injection

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- headache
- a feeling of warmth or flushing
- constipation, increase in bowel transit time
- changes to liver function test results (if you have ONDANSETRON BIOTECH injection with a medicine called cisplatin, otherwise this side effect is less frequent)
- irritation and redness at the site of injection.

Less frequent

- unusual body movements or shaking
- fits
- feeling dizzy or light-headed (when ONDANSETRON BIOTECH is injected quickly into the vein)
- blurred vision
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.
- uneven or slow heartbeat (dysrhythmia or bradycardia).
- chest pain
- disturbance in heart rhythm (QTc prolongation, sometimes causing a sudden loss of consciousness).
- low blood pressure, which can make you feel faint or dizzy
- hiccups
- changes to liver function test results

Frequency unknown

- myocardial ischemia (signs include sudden chest pain or chest tightness).

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. 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 BIOTECH.

5. How to store ONDANSETRON BIOTECH

Store all medicines out of reach of children.

Do not use ONDANSETRON BIOTECH injection after the expiry date which is stated on the pack after 'EXP'.

The expiry date refers to the last day of that month.

- Store ONDANSETRON BIOTECH injection below 25 °C.

Protect from light.

- *When ONDANSETRON BIOTECH injection is diluted in intravenous fluids:*
- it must be stored at 2-8 °C for not more than 24 hours
- it does not need to be protected from light during infusion

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 BIOTECH contains

- The active ingredient is ondansetron.
- Each 2 ml ONDANSETRON BIOTECH injection ampoule contains ondansetron 4 mg.
- Each 4 ml ONDANSETRON BIOTECH injection ampoule contains ondansetron 8 mg.
- The other ingredients are sodium chloride, citric acid, sodium citrate, sodium chloride and Water for Injections.

What ONDANSETRON BIOTECH looks like and contents of the pack

Ondansetron 4 mg /2 ml Biotech

Ondansetron 8 mg /4 ml Biotech

Injection

Ondansetron (as hydrochloride dihydrate)

A clear, colourless solution, practically free from visible particles.

ONDANSETRON 4 mg/ 2 ml BIOTECH:

2 ml clear glass ampoules (5 ampoules packed into a carton).

ONDANSETRON 8 mg/4 ml BIOTECH:

4 ml clear glass ampoules (5 ampoules packed into a carton).

Holder of Certificate of Registration

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