

APPROVED PATIENT INFORMATION LEAFLET
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

EMISTOP 4 mg solution for injection

EMISTOP 8 mg solution for injection

Ondansetron

EMISTOP is sugar-free

Read all of this leaflet carefully before you are given EMISTOP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- EMISTOP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What EMISTOP is and what it is used for
2. What you need to know before you use EMISTOP
3. How to use EMISTOP
4. Possible side effects
5. How to store EMISTOP

APPROVED PATIENT INFORMATION LEAFLET

6. Contents of the pack and other information

1. What EMISTOP is and what it is used for

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

EMISTOP injection is used to prevent and treat nausea and vomiting caused by chemotherapy or radiotherapy and for the prevention and treatment of nausea and vomiting after surgery.

2. What you need to know before you are administered

EMISTOP

EMISTOP should not be administered:

Tell your doctor or healthcare professional before being given the injection if:

- if you are hypersensitive (allergic) to ondansetron or any of the other ingredients of EMISTOP (see section 6)
- if you are pregnant (see Pregnancy, breastfeeding and fertility)
- during the first 12 weeks of your pregnancy
- if you have congenital long QT syndrome, which is seen on an electrocardiogram (ECG), an electrical recording of the heart operated by your healthcare provider
- if you are taking medicine called apomorphine which is used for treatment of Parkinson's disease.

APPROVED PATIENT INFORMATION LEAFLET

Warnings and precautions

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

- if you or your child has liver problems, as it may take longer for EMISTOP to be excreted, in this case, your doctor will give you the correct dose for your condition
- if you have had abnormal levels of electrolytes such as magnesium or potassium in your body, this may have symptoms such as, muscle weakness that can result in paralysis, respiratory failure, low blood pressure, muscle twitching, cramping during exercise and convulsions. EMISTOP may prolong your QT interval, which is seen on an electrocardiogram (ECG) performed by your healthcare provider, due to abnormalities in your heart rhythm. Your healthcare provider will take special precautions when giving you EMISTOP
- if you have signs of intestinal obstruction (blockage) – you will need to be monitored as EMISTOP is known to delay the time it takes for ingested food to travel through the human gut
- if you have dysrhythmias or cardiac conduction disorders (heartbeat disorders) or are being treated with antidysrhythmic (for irregular heartbeat)

APPROVED PATIENT INFORMATION LEAFLET

- if you, after administration of EMISTOP, suddenly feel chest pain or tightness of the chest, shortness of breath, sweating and you have a rapid heartbeat
- if you are taking other serotogenic medicines (medicines that are used to treat altered mental status, involuntary nervous system and neuromuscular abnormalities) as they may affect your mental health
- if you had tonsil surgery, using EMISTOP to stop vomiting and nausea may cause invisible bleeding
- if you or your child have problems with the levels of salts in your blood, such as potassium, sodium and magnesium
- if you or your child are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- if you are within the first 12 weeks of pregnancy, as EMISTOP increases the risk of your baby developing oral cleft palate and/or lip (openings or splits in the upper lip, the roof of the mouth or both).

Other medicines and EMISTOP

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

The following medicines may interact with your EMISTOP injection:

APPROVED PATIENT INFORMATION LEAFLET

- apomorphine (used to treat Parkinson's disease), when used together with EMISTOP, may lower your blood pressure, you may have symptoms such as dizziness or light-headedness, fainting (syncope), blurred vision, nausea, fatigue, lack of concentration and may also result in loss of consciousness, this may also affect your heart rhythm. Apomorphine should not be used with EMISTOP (see EMISTOP should not be administered)
- phenytoin, carbamazepine (treatments for epilepsy) and rifampicin (an antibiotic for treatment of tuberculosis (TB) because they are known to reduce the levels of EMISTOP in the blood
- tramadol (painkiller), as EMISTOP is known to reduce its effect on pain
- anthracyclines (medicines used for heart problems) such as doxorubin, daunorubicin or trastuzumab, antibiotics such as erythromycin, antifungal medicines such as ketoconazole, antiarrhythmics (medicines that treat abnormal heart rate) such as amiodarone and beta blockers (medicines that slow heart rate) such as atenolol or timolol, may affect your heart rate, when used together with EMISTOP

APPROVED PATIENT INFORMATION LEAFLET

- serotonergic medicines which are medicines that are used to treat altered mental status, involuntary nervous system and neuromuscular abnormalities, including SSRIs (selective serotonin reuptake inhibitors) and SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression, may cause serotonin syndrome when used with EMISTOP. Symptoms of serotonin syndrome may include high body temperature, agitation, increased reflexes, tremor, sweating, dilated pupils, and diarrhoea.

EMISTOP with food and, drink

EMISTOP can be administered with or without food.

Pregnancy, breastfeeding and fertility

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

EMISTOP should not be administered to you if you are pregnant (see EMISTOP should not be administered).

EMISTOP should not be administered to you during the first 12 weeks of pregnancy as this medicine has been associated with an increased risk of developing oral cleft palate and/or lip to your baby.

APPROVED PATIENT INFORMATION LEAFLET

Women of childbearing potential to use contraception while taking EMISTOP and for 2 days after stopping treatment.

Ondansetron, as in EMISTOP, passes into breast milk, therefore nursing mothers should not breastfeed their babies.

Driving and using machines

EMISTOP is not expected to interfere with your ability to drive or use machines.

However, vision problems (such as blurred vision or poor vision or temporary loss of eyesight) and dizziness are possible side effects, therefore, you should not drive or use machines until you know how EMISTOP affect you.

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

EMISTOP contains sodium

EMISTOP contains 3,6 mg, 14,4 mg and 57,6 mg sodium per 1 mL, 4 mL and 16 mL, respectively. This is equivalent to 0,18 %, 0,72 % and 2,88% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take EMISTOP

APPROVED PATIENT INFORMATION LEAFLET

EMISTOP injection is for intravenous (into a vein) and intramuscular (into the muscle) use.

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

Your doctor will decide on the correct dose for you based on your condition.

To prevent nausea and vomiting from chemotherapy or radiotherapy

Adults:

On the day of chemotherapy or radiotherapy the recommended adult dose is 8 mg given by a slow injection into your vein or muscle, just before your treatment, and another 8 mg twelve hours later.

The usual adult intravenous dose does not exceed 8 mg.

On the following days, if your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you or your child may be given more than the usual dose of EMISTOP. Your doctor will decide this.

Children and adolescents

The doctor will decide the dose based on the child's weight or size (body surface area). On the day of chemotherapy, the first dose is given by a slow injection into the vein, just before your child's treatment. On the following days oral dosing can commence twelve hours after the last intravenous dose and may be continued for up to 5 days.

APPROVED PATIENT INFORMATION LEAFLET

To prevent and treat 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. For prevention this will be given just before your operation.

Children:

Your doctor will decide on the dose to be given. The maximum dose is 4 mg given as a slow injection into the vein. For prevention this will be given just before your operation.

Patients with moderate or severe liver problems

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

Your doctor will tell you how long your treatment with EMISTOP will last. If you have the impression that the effect of EMISTOP is too strong or too weak, tell your doctor or pharmacist.

If you are administered more EMISTOP than you should

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

APPROVED PATIENT INFORMATION LEAFLET

If a dose of EMISTOP is missed

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

4. Possible side effects

EMISTOP can have side effects.

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

Should your general health worsen, or if you experience any untoward effects while using EMISTOP, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

APPROVED PATIENT INFORMATION LEAFLET

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

- seizures (fits or convulsions)
- disturbance in heart rhythm, abnormally rapid heartbeat (tachycardia), uneven heartbeat, slow heartbeat
- if you suddenly feel pain in your neck, jaw, shoulder or chest or tightness of the chest, shortness of breath, sweating fast heartbeat and fatigue (myocardial ischaemia).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- hot flushes
- constipation, diarrhoea, stomach pain or stomach cramps
- allergic reaction around the injection site, rash.

Less frequent side effects:

- movement disorders, dizziness
- blurred vision, poor vision or temporary loss of eyesight, which usually comes back within 20 minutes
- your eyes may become fixed upwards, involuntarily (oculogyric crisis)

APPROVED PATIENT INFORMATION LEAFLET

- low blood pressure
- hiccups, spasm of the vocal cords
- 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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of EMISTOP. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store EMISTOP

Store all medicines out of reach of children.

APPROVED PATIENT INFORMATION LEAFLET

Your doctor or pharmacist knows how to store EMISTOP. For single use only. Discard any unused portion. Store at or below 30 °C keep well closed. Do not refrigerate or freeze. Keep ampoules in the outer carton, in order to protect from light.

Do not use EMISTOP injection after the expiry date shown on the carton.

Only clear solutions, free from particles, should be used. Do not use if ampoule is damaged.

Do not use after the expiry date stated on the 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 EMISTOP contains

The active substance is ondansetron.

EMISTOP 4 mg: Each 2 mL ampoule contains ondansetron hydrochloride dihydrate equivalent to 4 mg ondansetron (2 mg/mL).

EMISTOP 8 mg: Each 4 mL ampoule contains ondansetron hydrochloride dihydrate equivalent to 8 mg ondansetron (2 mg/mL).

The other ingredients are

Citric acid monohydrate, sodium chloride, sodium citrate, water for injection.

APPROVED PATIENT INFORMATION LEAFLET

What EMISTOP looks like and contents of the pack

EMISTOP 4 mg is a clear and colourless solution, free from visible particles.

EMISTOP 8 mg is a clear and colourless solution, free from visible particles.

EMISTOP 4 mg is packed into a 2 mL clear and colourless type I glass ampoule with a blue dot. Each ampoule contains 2 mL solution for injection. 5 ampoules are packed into an outer carton.

EMISTOP 8 mg is packed into a 5 mL clear and colourless type I glass ampoule with a blue dot. Each ampoule contains 4 mL solution for injection. 5 ampoules are packed into an outer carton.

Holder of Certificate of Registration

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APPROVED PATIENT INFORMATION LEAFLET

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EMISTOP 4 mg: A45/5.10/0386

EMISTOP 8 mg: A45/5.10/0387

All strengths are not necessarily marketed.

NAMIBIA

EMISTOP 4 mg: NS215/5.10/0178

EMISTOP 8 mg: NS215/5.10/0179

ZAMBIA

EMISTOP 4 mg: POM 051/016

EMISTOP 8 mg: POM 051/017