PATIENT INFORMATION LEAFLET

EMISTOP RANGE

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

EMISTOP 4 mg solution for injection

EMISTOP 8 mg solution for injection

Read all of this leaflet carefully before EMISTOP is administered to you.

Keep this leaflet. You may need to read it again.

If you have any questions, please ask your doctor or pharmacist.

EMISTOP has been prescribed for you and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. 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, nitrogen, sodium citrate, sodium chloride, water for injection.

2. WHAT EMISTOP IS USED FOR:

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.

3. BEFORE YOU ARE GIVEN EMISTOP:

You should not be given EMISTOP if:

- you are hypersensitive (allergic) to ondansetron or any of the ingredients of **EMISTOP** (see **WHAT EMISTOP CONTAINS**).
- if you have congenital long QT syndrome.
- **EMISTOP** contains sodium. If you are on a sodium-controlled diet, speak to your doctor before being given this medicine.

Take special care with EMISTOP injection if:

- you have signs of intestinal obstruction (blockage) – you will need to be monitored.
- you have dysrhythmias or cardiac conduction disorders (heartbeat disorders) or are being treated with antidysrhythmic (for irregular heartbeat).

Pregnancy and breastfeeding:

Please tell your doctor if you are pregnant or planning to be pregnant.

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

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before using EMISTOP.

Driving and using machines:

EMISTOP has no effect on your ability to drive or use machines.

Important information about some of the ingredients of EMISTOP:

EMISTOP contains sodium. This should be taken into consideration if you are on a strictly controlled salt diet.

Taking other medicines with EMISTOP:

Please 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:

- Phenytoin, carbamazepine (treatments for epilepsy).
- Rifampicin (an antibiotic for treatment of tuberculosis (TB)).
- Tramadol (painkiller).
- Beta-blockers (medicines that slow heart rate).
- Apomorphine (used to treat Parkinson's disease).

4. HOW EMISTOP WILL BE ADMINISTERED:

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.

If you receive more EMISTOP than you should:

Since a healthcare provider will administer **EMISTOP**, they will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

5. 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 receiving **EMISTOP**, please consult your healthcare provider for advice.

Treatment with EMISTOP should be stopped immediately, should any of the following side effects occur:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty breathing.
- Serious allergic reactions including skin reactions, fever, low blood pressure (dizziness), allergic pneumonitis (cough or other lung symptoms), shock (cold, clammy skin, irregular breathing, weakness, anxiety).

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.

Tell your doctor or healthcare provider immediately if you notice any of the following:

Frequent side effects:

- constipation
- sensation of warmth or flushing
- headache.

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Less frequent side effects:

- Allergic reaction around the injection site, rash, itching, hiccups.
- Movement disorders, dizziness, heartbeat disturbances, low blood
- pressure, slow heartbeat, blurred vision.
- Temporary changes in heartbeat.

If you notice any side effect not listed, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF EMISTOP:

Your doctor or pharmacist knows how to store **EMISTOP**. Store at or below 30 °C in a dry place. 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.

Medicines should not be disposed of via wastewater or household waste. Return the expired medicine to you pharmacist for safe disposal.

Store all medicines out of reach of children.