The name of the medicinal product is Ondansetron 2 mg/ml Solution for Injection. Solution for Injection but will be referred to as Ondansetron recommended. Ondansetron passes into mother's milk. Therefore mothers receiving ondansetron should NOT breast-feed. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Ondansetron has no or negligible effect on the ability to drive or use machines.

Ondansetron 2 mg/ml contains sodium
This medicinal product contains 2.3 mmol (53.5 mg) sodium per maximum daily dose of 32 mg. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE ONDANSETRON 2 MG/ML
Method of administration
Ondansetron is administered by intravenous injection (into a vein) or, after dilution, as intravenous infusion (for a longer time). It will usually be given by a doctor or a nurse. Dosage
Your doctor will decide on the correct dose of ondansetron therapy for you. The dose varies depending on your medicinal treatment (chemotherapy or surgery), on your liver function and on whether it is given by injection or infusion.

In case of chemotherapy or radiotherapy the usual dose in adults is 35-32 mg ondansetron a day. For treatment of post-operative nausea and vomiting a single dose of 4 mg ondansetron is usually given.

Use in children and adolescents
Children aged over 6 months and adolescents
The doctor will decide the dose. In cases of chemotherapy or radiotherapy the usual dose in children and adolescents is 4 mg

Children aged over 1 month and adolescents
The doctor will decide the dose. For treatment of post-operative nausea and vomiting a maximum dose of 4 mg is given into a vein.

Dose adjustment
Patients with hepatic impairment
In patients having hepatic problems the dose has to be adjusted to a maximum daily dose of 8 mg ondansetron.

Elderly
There is limited experience in the use of ondansetron in the prevention and treatment of post-operative nausea and vomiting (PONV) in the elderly. However, ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

Patients with renal impairment or poor sparteine/desipramine metabolism:
No alteration of daily dosage or frequency of dosing or route of administration is required.

Duration of treatment
Your doctor will decide on the duration of ondansetron therapy for you.

After intravenous administration of Ondansetron 2 mg/ml the therapy may be continued with other dosage forms.

If you use more Ondansetron 2 mg/ml than you should
Little is known at present about overdosage with ondansetron. In a few patients, the following effects were observed after overdose: visual disturbances, severe constipation, low blood pressure and unconsciousness. In all cases, the symptoms disappeared completely.

If there is no specific antidote to ondansetron; for that reason, if overdose is suspected, only the symptoms should be treated.

Tell your doctor if any of these symptoms occur.

Your doctor or nurse will give you or your child Ondansetron 2 mg/ml so it is unlikely that you or your child will receive too much. If you think you or your child have been given too much or have missed a dose, tell your doctor or nurse.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

PREPARATION GUIDE FOR:

Ondansetron 2 mg/ml Injection

It is important that you read the entire contents of this guide prior to the preparation of this medicinal product.

Therapeutic indications
Ondansetron is indicated for the prevention and treatment of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, and for the prevention and treatment of post-operative nausea and vomiting (PONV).

Paediatric Population:
Ondansetron is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged 6 months and for the prevention and treatment of PONV in children aged ≥1 month.

For full prescribing information please consult the Summary of Product Characteristics (SmPC).

Prescribers intending to use ondansetron in the prevention of delayed nausea and vomiting associated with chemotherapy or radiotherapy in adults, adolescents or children should take into consideration current practice and appropriate guidelines.

Administration
Ondansetron is administered by intravenous injection or by intravenous infusion after dilution.

Incompatibility
This medicinal product must not be mixed with other medicinal products except those detailed below (see Dilution).
4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The frequency of side effects is classified into the following categories:

Very common: in more than 1 in 10 patients
Common: in more than 1 in 100, but less than 1 in 10 patients
Uncommon: in more than 1 in 1,000, but less than 1 in 100 patients
Rare: in more than 1 in 10,000, but less than 1 in 1,000 patients
Very rare: in less than 1 in 10,000 patients, including isolated reports
Not known: cannot be established from the available data

Immunological disorders

Rare: Immediate allergic (hypersensitivity) reactions (reaction in which the body reacts with an exaggerated immune response to a foreign agent), including life-threatening anaphylactic reaction. These reactions may be: swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Additionally rash or itching and hives.

Alterated hypersensitivity reactions were also observed in patients, who were sensitive to medicinal products from the same class.

Cardiac disorders

Uncommon: Chest pain, cardiac arrhythmias (changes in the way your heart beats) and bradycardia (slow heart rate). Chest pain and cardiac arrhythmias may be fatal in individual cases. Inform your doctor immediately if you experience any symptoms suggestive of an allergic reaction.

Cardiac disorders

Rare: Transitory changes in the electrocardiogram (ECG) predominantly after intravenous application of ondansetron. QTc prolongation (including Torsades de Pointes)

Nervous system disorders

Very Common: Headache.
Uncommon: Involuntary movement disorders, e.g. spastic movement of eyelids, abnormal muscle contractions that may cause twisting or jerking movements of the body, seizures (e.g. epileptic spasms).
Rare: Dizziness during rapid intravenous administration.
Very rare: Depression.

Eye disorders

Rare: Transient visual disturbances (e.g. blurred vision) during rapid intravenous administration.
Very rare: In individual cases transitory blindness was reported in patients receiving chemotherapeutic agents including cisplatin. Most reported cases resolved within 20 minutes. Some cases of transient blindness were reported as cortical in origin.

Vascular disorders

Common: Hypo- or hypertension (low blood pressure).
Uncommon: Hypotension (low blood pressure), including life-threatening anaphylactic reaction. These reactions may be: swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Additionally rash or itching and hives.

Respiratory, thoracic and mediastinum disorders

Uncommon: Hiccups.

Gastrointestinal disorders

Common: Ondansetron is known to increase the occurrence of diarrhoea (e.g. rash, urticaria, itching) which may occur, sometimes extending along the drug administration vein.

Hepatobiliary disorders

Uncommon: Asymptomatic increases of liver function.

These reactions were particularly observed in patients under chemotherapy with cisplatin. These reactions were particularly observed in patients receiving chemotherapeutic agents including cisplatin.

Uncommon: Hypersensitivity reactions around the injection site (e.g. rash, urticaria, itching) may occur, sometimes extending along the drug administration vein.

Skin and subcutaneous tissue disorders

Uncommon: Hypersensitivity reactions around the injection site (e.g. rash, urticaria, itching) may occur, sometimes extending along the drug administration vein.

General disorders and administration site conditions

Common: Local reactions at the IV injection site.
If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any 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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ONDANSETRON 2 MG/ML

Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the ampoule label and carton. The expiry date refers to the last day of that month.
Keep the ampoules in the outer carton, in order to protect from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ondansetron 2 mg/ml contains

The active substance is ondansetron.

Each ampoule with 2 ml contains 4 mg ondansetron.
Each ampoule with 4 ml contains 8 mg ondansetron.
Each millilitre contains 2 mg ondansetron hydrochloride dihydrate.
The other ingredients are sodium chloride, sodium citrate dihydrate, citric acid monohydrate and water for injections.

What Ondansetron 2 mg/ml looks like and contents of the pack

Ondansetron 2 mg/ml is a clear and colourless solution in colourless glass ampoules containing 2 ml or 4 ml of solution for injection.
Pack sizes: 5 and 10 ampoules
Not all pack sizes may be marketed.