

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ondansetron 2 mg / mL solution for injection

ondansetron

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Ondansetron 2 mg / mL solution for injection.

In the rest of this leaflet Ondansetron 2 mg / mL solution for injection is called Ondansetron injection.

What is in this leaflet:

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

1. What ondansetron injection is and what it is used for

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

Ondansetron injection is used for:

- preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer in adults
- preventing and treating nausea and vomiting after surgery in adults.
- preventing nausea and vomiting caused by chemotherapy for cancer in children and adolescents aged from 6 months to 17 years.
- preventing and treating nausea and vomiting after surgery in children and adolescents aged 1 month to 17 years.

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

Ondansetron injection should start to work soon after having the injection. You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take ondansetron injection

Do not take Ondansetron injection if:

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before having Ondansetron injection.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ondansetron injection if:

- you have ever had heart problems
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron (known as 'Kytril')

- you have liver problems
- you have a blockage in your gut
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

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

Tell your doctor or pharmacist immediately if you get any of these symptoms during and after the treatment with Ondansetron injection

- if you experience sudden chest pain or chest tightness (myocardial ischemia).

Other medicines and Ondansetron injection

Tell your doctor pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Ondansetron injection can affect the way some medicines work. Also, some other medicines can affect the way Ondansetron injection works.

In particular, talk to your doctor, pharmacist or nurse if you are taking any of the following medicines:

- carbamazepine or phenytoin used to treat epilepsy, as these medicines may reduce the effect of Ondansetron injection
- rifampicin used to treat infections such as tuberculosis (TB), as this medicine may reduce the effect of Ondansetron injection
- antibiotics such as erythromycin or antifungals such as ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat, as these medicines may interact with Ondansetron injection and effect the rhythm of the heart
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines, as these medicines may interact with Ondansetron injection and effect the rhythm of the heart
- tramadol, a pain killer, as Ondansetron injection may reduce the effect of tramadol
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines), as these medicines may interact with Ondansetron injection to cause heart arrhythmias
- medicines used to treat depression and/or anxiety:
 - SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
 - SNRIs (serotonin noradrenaline reuptake inhibitors) including venlafaxine, duloxetine

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

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

Pregnancy, breastfeeding and fertility

You should not use Ondansetron injection during the first trimester of pregnancy. This is because Ondansetron injection can slightly 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 already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron injection. If you are a woman of childbearing potential, you may be advised to use effective contraception.

Do not breast-feed if you have Ondansetron injection. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Driving and using machines

Ondansetron injection is not expected to impair the ability to drive or use machines. However, if any of the side effects (listed section 4) affect you (e.g., dizziness, blurred vision) caution is advisable. **Do not drive or operate machines if you are feeling unwell.**

Ondansetron injection contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

3. How to take ondansetron injection

Ondansetron injection is normally given by a doctor or nurse . The dose you have been prescribed will depend on the treatment you are having.

To prevent nausea and vomiting from chemotherapy or radiotherapy

Adults

On the day of chemotherapy or radiotherapy

- A single dose should not be more than 16 mg.
- the usual adult dose is 8 mg given by an injection into your vein over at least 30 seconds or muscle, just before your treatment, and possibly another two 8 mg doses given by injection into your vein over at least 30 seconds or muscle four hours apart, depending on the strength of your chemotherapy or radiotherapy. After chemotherapy, your medicine will usually be given by mouth as an 8 mg Ondansetron tablet or 10 mL (8 mg) Ondansetron syrup.

On the following days

- the usual adult dose is one 8 mg tablet or 10 mL (8 mg) syrup taken twice a day
- this may be given for up to 5 days

If your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you may be given more than the usual dose of Ondansetron. Your doctor will decide this.

Elderly

If you are over 65 years of age, your doctor will adjust your dose as required.

Children and adolescents (aged 6 months to 17 years)

To prevent nausea and vomiting from chemotherapy only.

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

On the day of chemotherapy

- the first dose is given by an injection into the vein (up to 8mg), just before your child's treatment. After chemotherapy, 12 hours after the initial injection your child's medicine will usually be given by mouth in tablet format up to 4mg twice a day or 5 ml (4 mg) ondansetron syrup.

On the following days

- up to one 4 mg tablet or 5 mL (4 mg) syrup every 12 hours
- these doses can be given for up to five days.

To prevent nausea and vomiting after an operation

- The usual dose for adults is 4 mg given by an injection into your vein or muscle. This will be given just before your operation.
- For children aged over 1 month and adolescents the doctor will decide the dose. The maximum dose is 4 mg given as an injection into the vein. This will be given just before the operation.

To treat nausea and vomiting after an operation

- The usual dose for adults is 4 mg given by an injection into your vein or muscle.
- For children aged over 1 month and adolescents, the doctor will decide the dose. The maximum dose is 4 mg given as an injection into the vein.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg. If you have blood tests to check how your liver is working this medicine may affect the results.

If you take more Ondansetron injection than you should

Your doctor or nurse will give you or your child Ondansetron injection so it is unlikely that you or your child will receive too much. If you think you 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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious

STOP treatment with ondansetron and seek medical help immediately if you or your child experience any of the following:

Allergic reactions

These reactions are rare in people taking ondansetron. If you have an allergic reaction, tell your doctor or a member of the medical staff straight away. The signs may include:

- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash - red spots or lumps under your skin (hives) anywhere on your body
- collapse

Myocardial ischemia: Signs include:

- sudden chest pain or
- chest tightness

Other possible side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or nurse:

Very common (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

- a feeling of warmth or flushing
- constipation
- changes to liver function test results (if you have Ondansetron injection with a medicine called cisplatin, otherwise this side effect is uncommon)
- irritation and redness at the site of injection

Uncommon (may affect up to 1 in 100 people)

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat
- slow heart rate
- chest pain
- fits
- unusual body movements or shaking

Rare (may affect up to 1 in 1 000 people)

- feeling dizzy or light headed during the injection into your vein
- blurred vision

- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare (may affect up to 1 in 10 000 people)

- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes

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

For UK: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For IE: HPRa Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ondansetron injection

Keep this medicine out of the sight and reach of children.

Use within 4 months after opening the protective pouch.

Do not use this medicine if you notice signs of deterioration such as discolouration.

Store below 25°C. Store in the original package in order to protect from light.

When you open the protective pouch:

- note the date of opening.
- add 4 months to this date. This will be the ‘discard after’ date.
- write the “discard after” date in the space provided on the pouch
- do not use any unused ampoules remaining from that pouch after the ‘discard after’ date, return them to your pharmacist for destruction.
- if the pouch has not been opened, do not use this medicine after the expiry date, which is stated on the ampoule label, carton or foil after ‘EXP’. The expiry date refers to the last day of that month.
- if you are told to stop taking this medicine return any unused Ondansetron injection to your pharmacist to be discarded.

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 to protect the environment.

6. Contents of the pack and other information

What Ondansetron injection contains

- The active substance is ondansetron (as hydrochloride dihydrate).

Each 1-mL (millilitre) will contain 2 mg (milligram) of ondansetron.

Each 2-mL ampoule will contain 4 mg of ondansetron.

Each 4-mL ampoule will contain 8 mg of ondansetron.

- The other ingredients are citric acid monohydrate, sodium citrate dihydrate, sodium chloride and water for injections.

What Ondansetron injection looks like and contents of the pack

Ondansetron injection is a clear, colourless solution for injection which can be diluted before use.

Each plastic or glass ampoule (container) will contain 2mL (millilitres) or 4mL of your medicine.

Glass ampoules are packed in plastic cases inside cartons. Packs of 5 glass ampoules are available.

Plastic ampoules are overwrapped in individual aluminium foil blisters and placed in cartons.

Alternatively, plastic ampoules are packed in strips of 5 inside a pouch and placed in cartons. Packs of 5, 10 or 50 plastic ampoules are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, Nicosia 1065, Cyprus.

Manufacturer: DEMO S.A. PHARMACEUTICAL INDUSTRY, 21st Km National Road Athens–Lamia, 14568 Krioneri, Attiki, Greece, T: +30 210 8161802, F: +30 2108161587.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

United Kingdom (Northern Ireland): Ondansetron 2 mg / mL Solution for injection

Ireland: Ondansetron 2 mg / mL Solution for injection

Germany: Ondansetron Noridem 2 mg/ml Injektionslösung

Austria: Ondansetron Noridem 2 mg/ml Injektionslösung

Greece: ONDANSETRON/NORIDEM Ενέσιμο διάλυμα 2 mg / mL

This leaflet was last revised in February 2024.

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The following information is intended for healthcare professionals only:

Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

Each 1-mL contains ondansetron hydrochloride dihydrate equivalent to 2 mg of ondansetron.

Each 2-mL ampoule contains 4 mg of ondansetron.

Each 4-mL ampoule contains 8 mg of ondansetron.

Pharmaceutical form

Solution for injection. Clear and colourless aqueous solution.

Posology and method of administration

Chemotherapy and Radiotherapy induced nausea and vomiting (CINV and RINV)

The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used. The selection of dose regimen should be determined by the severity of the emetogenic challenge.

CINV and RINV in adults

The dose range of Ondansetron injection is 8 to 32 mg a day and selected as shown below.

Emetogenic chemotherapy and radiotherapy:

For most patients receiving emetogenic chemotherapy or radiotherapy, ondansetron 8 mg should be administered as a slow intravenous injection (in not less than 30 seconds) or intramuscular injection, immediately before treatment, followed by 8 mg orally twelve hourly.

Highly emetogenic chemotherapy: For patients receiving highly emetogenic chemotherapy, a maximum initial ondansetron dose of 16 mg IV infused over 15 minutes may be used. A single IV dose greater than 16 mg should not be given due to dose dependent increase of QT-prolongation risk (see sections 4.4, 4.8 and 5.1 of the SmPC).

Ondansetron has been shown to be equally effective in the following dose schedules over the first 24 hours of chemotherapy:

- A single dose of 8 mg by slow intravenous injection (in not less than 30 seconds) or intramuscular injection immediately before chemotherapy.
- A dose of 8 mg by slow intravenous injection (in not less than 30 seconds) or intramuscular injection immediately before chemotherapy, followed by two further intravenous injections (in not less than 30 seconds) or intramuscular doses of 8 mg four hours apart, or by a constant infusion of 1 mg/hour for up to 24 hours.
- -A maximum initial intravenous dose of 16 mg diluted in 50 – 100 mL of 0.9% Sodium Chloride Injection or other compatible infusion fluid (see section 6.6 of the SmPC) and infused over not less

than 15 minutes immediately before chemotherapy. The initial dose of Ondansetron may be followed by two additional 8 mg intravenous doses (in not less than 30 seconds) or intramuscular doses four hours apart.

The efficacy of Ondansetron in highly emetogenic chemotherapy may be enhanced by the addition of a single intravenous dose of dexamethasone sodium phosphate, 20 mg administered prior to chemotherapy.

Oral treatment is recommended to protect against delayed or prolonged emesis after the first 24 hours. The recommended oral dose is 8 mg to be taken twice daily.

The selection of dose regimen should be determined by the severity of the emetogenic challenge.

Paediatric population

CINV in children and adolescents (aged 6 months to 17 years)

The dose for CINV can be calculated based on body surface area (BSA) or weight. Weight-based dosing results in higher total daily doses compared to BSA-based dosing (section 4.4 and 5.1 of the prescribing information).

In paediatric clinical studies, ondansetron was given by IV infusion diluted in 25 to 50 ml of saline or other compatible infusion fluid (see section 6.6 of the SmPC) and infused over not less than 15 minutes.

There are no data from controlled clinical trials on the use of ondansetron for radiotherapy-induced nausea and vomiting in children.

Dosing by Body Surface Area (BSA)

Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 5 mg/m². The single intravenous dose must not exceed 8 mg.

Oral dosing can commence 12 hours later and may be continued for up to 5 days (see Table 1).

The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32 mg.

Table 1: BSA-based dosing for CINV (aged ≥ 6 months to 17 years)

BSA	Day 1 ^(a,b)	Days 2 – 6 ^(b)
< 0.6 m ²	5 mg / m ² IV plus 2 mg syrup after 12 h	2 mg syrup every 12 h
≥ 0.6 m ²	5 mg / m ² IV plus 4 mg syrup or tablet after 12 h	4 mg syrup or tablet every 12 h

^a The intravenous dose must not exceed 8 mg.

^b The total dose over 24 hours must not exceed adult dose of 32 mg.

Dosing by bodyweight

Weight-based dosing results in higher total daily doses compared to BSA-based dosing (sections 4.4 and 5.1 of the SmPC).

Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 0.15 mg/kg. The single intravenous dose must not exceed 8 mg.

On Day 1, two further intravenous doses may be given in 4-hourly intervals.

Oral dosing can commence 12 hours later and may be continued for up to 5 days (see Table 2).

The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32 mg.

Table 2: Weight-based dosing for CINV (aged ≥ 6 months to 17 years)

Weight	Day 1 ^(a,b)	Days 2 – 6 ^(b)
≤ 10 Kg	Up to 3 doses of 0.15 mg / kg IV every 4 h	2 mg syrup every 12 h
> 10 Kg	Up to 3 doses of 0.15 mg / kg IV every 4 h	4 mg syrup or tablet every 12 h

^a The intravenous dose must not exceed 8 mg.

^b The total dose over 24 hours must not exceed adult dose of 32 mg.

CINV and RINV in elderly

In patients 65 to 74 years of age, the dose schedule for adults can be followed. All intravenous doses should be diluted in 50 – 100 mL of 0.9% sodium chloride solution or other compatible infusion fluid (see section 6.6 of the SmPC) and infused over 15 minutes.

In patients 75 years of age or older, the initial intravenous dose of Ondansetron should not exceed 8 mg. All intravenous doses should be diluted in 50 – 100 mL of 0.9% sodium chloride solution or other compatible infusion fluid (see section 6.6 of the SmPC) and infused over 15 minutes. The initial dose of 8 mg may be followed by two further intravenous doses of 8 mg, infused over 15 minutes and given no less than four hours apart. (see section 5.2 of the SmPC)

Post-Operative Nausea and Vomiting (PONV)

Adults

For the prevention of PONV the recommended dose of ondansetron is a single dose of 4 mg given by intramuscular or slow intravenous injection at induction of anaesthesia.

For treatment of established PONV, a single dose of 4 mg given by intramuscular or slow intravenous injection is recommended.

Paediatric population

Children and adolescents (aged 1 month to 17 years)

For prevention of PONV in paediatric patients having surgery performed under general anaesthesia, a single dose of Ondansetron may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1 mg / kg up to a maximum of 4 mg either prior to, at or after induction of anaesthesia.

For the treatment of PONV after surgery in paediatric patients having surgery performed under general anaesthesia, a single dose of Ondansetron may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1 mg / kg up to a maximum of 4 mg.

Elderly

There is limited experience in the use of ondansetron in the prevention and treatment of PONV in the elderly, however, ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

Patients with renal impairment

No alteration of daily dosage or frequency of dosing, or route of administration are required.

Patients with hepatic impairment

Clearance of ondansetron is significantly reduced and serum half-life significantly prolonged in subjects with moderate or severe impairment of hepatic function. In such patients a total daily dose of 8 mg should not be exceeded.

Patients with poor sparteine/debrisoquine metabolism

The elimination half-life of ondansetron is not altered in subjects classified as poor metabolisers of sparteine and debrisoquine. Consequently, in such patients repeat dosing will give drug exposure levels no different from those of the general population. No alteration of daily dosage or frequency of dosing are required.

Overdose

Symptoms and signs

There is limited experience of Ondansetron overdose. In the majority of cases symptoms were similar to those already reported in patients receiving recommended doses (see section 4.8 *of the prescribing information*). Manifestations that have been reported include visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second-degree AV block. Ondansetron prolongs QT interval in a dose-dependent fashion. ECG monitoring is recommended in cases of overdose. Cases consistent with serotonin syndrome have been reported in young children following oral overdose.

Treatment

There is no specific antidote for Ondansetron, therefore in cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate. Further management should be as clinically indicated or as recommended by the national poisons centre, where available. The use of ipecacuanha to treat overdose with Ondansetron is not recommended, as patients are unlikely to respond due to the anti-emetic action of Ondansetron itself.

Special precautions for disposal and other handling

Ondansetron should not be autoclaved.

Any unused product or waste material should be disposed of in accordance with local requirements.

Reconstitution and dilution of Ondansetron injection

Compatibility with intravenous fluids

Ondansetron injection should only be mixed with those infusion solutions which are recommended:

Diluent
Sodium chloride solution for infusion 0.9% w/v
Glucose solution for infusion 5% w/v
Mannitol solution for infusion 10% w/v
Ringers solution for infusion
Potassium chloride 0.3% w/v and sodium chloride 0.9% w/v solution for infusion
Potassium chloride 0.3% w/v and glucose 5% w/v solution for infusion

In complying with good pharmaceutical practice, dilutions of ondansetron injection in intravenous fluids should be prepared at the time of infusion. However, it has been demonstrated that dilutions of ondansetron in polyethylene bottles with the following intravenous infusion fluids remain stable for 24 hours at room temperature ($25 \pm 2^\circ\text{C}$) or for 36 hours in the refrigerator ($2 - 8^\circ\text{C}$).

Compatibility with other medicinal products

Ondansetron may be administered by intravenous infusion at 1 mg / hour, e.g. from an infusion bag or syringe pump. The following drugs may be administered via the Y-site of the ondansetron giving set for ondansetron concentrations of 16 to 160 micrograms / mL (e.g., 8 mg / 500 mL and 8 mg / 50 mL respectively):

Cisplatin

Concentrations up to 0.48 mg / mL (e.g., 240 mg in 500 mL) administered over one to eight hours.

5-Fluorouracil

Concentrations up to 0.8 mg / mL (e.g., 2.4 g in 3 litres or 400 mg in 500 mL) administered at a rate of at least 20 mL per hour (480 mL per 24 hours). Higher concentrations of 5-fluorouracil may cause precipitation of ondansetron. The 5-fluorouracil infusion may contain up to 0.045% w/v magnesium chloride in addition to other excipients shown to be compatible.

Carboplatin

Concentrations in the range 0.18 mg / mL to 9.9 mg / mL (e.g., 90 mg in 500 mL to 990 mg in 100 mL), administered over ten minutes to one hour.

Etoposide

Concentrations in the range 0.14 mg / mL to 0.25 mg / mL (e.g., 70 mg in 500 mL to 250 mg in 1L), administered over thirty minutes to one hour.

Ceftazidime

Doses in the range 250 mg to 2000 mg reconstituted with Water for Injections as recommended by the manufacturer (e.g., 2.5 mL for 250 mg and 10 mL for 2 g ceftazidime) and given as an intravenous bolus injection over approximately five minutes.

Cyclophosphamide

Doses in the range 100 mg to 1 g, reconstituted with Water for Injections , 5 mL per 100 mg cyclophosphamide, as recommended by the manufacturer and given as an intravenous bolus injection over approximately five minutes.

Doxorubicin

Doses in the range 10 – 100 mg reconstituted with Water for Injections , 5 mL per 10 mg doxorubicin, as recommended by the manufacturer and given as an intravenous bolus injection over approximately 5 minutes.

Dexamethasone

Dexamethasone sodium phosphate 20 mg may be administered as a slow intravenous injection over 2 – 5 minutes via the Y-site of an infusion set delivering 8 or 16 mg of ondansetron diluted in 50 – 100 mL of the following infusion fluids:

- Sodium Chloride solution for infusion 0.9% w/v
- Glucose solution for infusion 5% w/v
- Sodium chloride solution for infusion 0.9% w/v and glucose solution for infusion 5% w/v over approximately 15 minutes.

Compatibility between dexamethasone sodium phosphate and ondansetron has been demonstrated supporting administration of these drugs through the same giving set resulting in concentrations in line of 32 microgram – 2.5 mg / mL for dexamethasone sodium phosphate and 8 microgram – 1 mg / mL for ondansetron.

Ondansetron injection should not be administered in the same syringe of infusion as any other medicinal product.

Special Precautions for Storage

Store below 25°C. Store in the original package in order to protect from light.

Dilutions of Ondansetron injection in compatible intravenous infusion fluids are stable under normal room lighting conditions or daylight for at least 24 hours, thus no protection from light is necessary while infusion takes place.