# PACKAGE LEAFLET: INFORMATION FOR THE USER

## ONDANSETRON 2 mg/ml SOLUTION FOR INJECTION
Ondansetron (as hydrochloride dihydrate)

The name of your medicine is Ondansetron 2 mg/ml Solution for Injection, which will be called Ondansetron Injection or Ondansetron throughout this leaflet.

**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 about your illness or your medicine, 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 symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

**What is in this leaflet:**


**1. What Ondansetron Injection is and what it is used for**
Ondansetron Injection is a clear solution containing the active ingredient ondansetron, which is an anti-emetic (prevents nausea [feeling sick] and vomiting).
Ondansetron Injection is used for:

- preventing nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- preventing nausea and vomiting after surgery.

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

**2. What you need to know before you have Ondansetron Injection**
**Do not have Ondansetron Injection if:**
- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or to other selective 5HT3 receptor antagonists (e.g. granisetron, dolasetron) or any of the other ingredients in Ondansetron injection ( listed in section 6).

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

**Warnings and precautions**

Check with your doctor, pharmacist or nurse before having Ondansetron injection if:
- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- 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, nurse or pharmacist before having Ondansetron injection.

**Other medicines and Ondansetron Injection**
Please tell your doctor, pharmacist or nurse if you are taking , or 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, tell your doctor, pharmacist or nurse if you are taking any of the following medicines:
- carbamazepine or phenytoin used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- tramadol, a pain killer
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines and trastuzumab).
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including 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 injection.

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

**Pregnancy, breast-feeding and fertility**
Only use during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. 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 are might be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before having 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 mother's milk, Ask your doctor or midwife for advice.

**Driving and using machines**
Ondansetron Injection has no effect on your ability to drive or use machines.

**Important information about some of the ingredients in Ondansetron Injection**
Ondansetron injection contains Sodium citrate and sodium chloride.
This product contains 3.6mg/ml of sodium. Ondansetron contains 2.52 mmol (57.6 mg) sodium per maximum daily dose of 32 mg.
To be taken into consideration by patients on a controlled sodium diet.

**3. How to have 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 in adults**

On the day of chemotherapy or radiotherapy
- the usual 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. After chemotherapy, your medicine will usually be given by mouth as an ondansetron syrup or a ondansetron tablet.

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 injection. Your doctor will decide this.

**To prevent nausea and vomiting from chemotherapy in children aged over 6 months and adolescents**

The doctor will decide the dose depending on the child's size (body surface area) or weight. Look at the label for more information

On the day of chemotherapy
the first dose is given by an injection into the vein, just before your child's treatment. After chemotherapy, your child's medicine will usually be given by mouth twelve hours later, as ondansetron syrup or an ondansetron tablet.

On the following days
- 2.5 ml (2 mg) syrup twice a day for small children and those weighing 10 kg or less
- one 4 mg tablet or 5 ml (4 mg) syrup twice a day for larger children and those weighing more than 10 kg
- two 4 mg tablets or 10 ml (8 mg) syrup twice a day for

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Package leaflet: Information for the physician

**Ondansetron 2 mg/ml solution for injection**
**Ondansetron (as hydrochloride dihydrate)**

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

**Qualitative and Quantitative Composition**
Each ml contains 2 mg ondansetron as ondansetron hydrochloride dihydrate.

Each glass ampoule of 2ml contains 4mg ondansetron (as hydrochloride dihydrate) in aqueous solution for intramuscular or intravenous administration.

Each glass ampoule of 5ml (containing 4 ml of solution) contains 8mg Ondansetron (as hydrochloride dihydrate) in aqueous solution for intramuscular or intravenous administration.

**Posology and method of administration**
**Chemotherapy and radiotherapy induced nausea and vomiting**
**Adults**
The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used. The route of administration and dose of Ondansetron 2mg/ml Solution for Injection or infusion should be flexible in the range of 8-32mg a day and selected as shown below.
*Emetogenic chemotherapy and radiotherapy:*
Ondansetron can be given either by rectal, oral (tablets or syrup), intravenous or intramuscular administration.
For most patients receiving emetogenic chemotherapy or radiotherapy, Ondansetron injection 8mg should be administered as a slow intravenous injection, (in not less than 30 seconds) or intramuscular injection immediately before treatment, followed by 8mg orally twelve hourly.
To protect against delayed or prolonged emesis after the first 24 hours, oral or rectal treatment with ondansetron injection should be continued for up to 5 days after a course of treatment.
*Highly emetogenic chemotherapy*:
For patients receiving highly emetogenic chemotherapy, e.g. high-dose cisplatin, Ondansetron injection can be given either by rectal, intravenous or intramuscular administration. Ondansetron injection has been shown to be equally effective in the following dose schedules over the first 24 hours of chemotherapy:

A single dose of 8mg by slow intravenous injection (in not less than 30 seconds) or intramuscular injection immediately before chemotherapy.

A dose of 8mg by slow intravenous injection (in not less than 30 seconds) or intramuscular injection immediately before chemotherapy, followed by two further intravenous injection (in not less than 30 seconds) or intramuscular doses of 8mg four hours apart, or by a constant infusion of 1mg/hour for up to 24 hours.

A maximum initial dose of 16 mg diluted in 50-100 ml of saline or other compatible infusion fluid *(see section 6.6*) and infused over not less than 15 minutes immediately before chemotherapy. The initial dose of Ondansetron 2mg/ml Solution for Injection may be followed by two additional 8 mg intravenous doses (in not less than 30 seconds) or intramuscular doses four hours apart.

A single dose greater than 16 mg must not be given due to dose dependent increase of QT_prolongation risk ( see sections 4.4, 4.8 and 5.1).

The selection of dose regimen should be determined by the severity of the emetogenic challenge.
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.
To protect against delayed or prolonged emesis after the first 24 hours, ondansetron treatment with dosage forms other than intravenous and intramuscular should be continued for up to 5 days after a course of treatment.
**Paediatric Population:**
***CINV in children aged ≥ 6 months and adolescents***

The dose for CINV can be calculated based on body surface area (BSA) or weight – see below.

Ondansetron injection should be diluted in 5% dextrose or 0.9% sodium chloride or other compatible infusion fluid (see section 6.6) and infused intravenously over not less than 15 minutes.

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

*Dosing by BSA:*

Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 5 mg/m$^2$. The single intravenous dose must not exceed 8 mg.
Oral dosing can commence twelve hours later and may be continued for up to 5 days (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 Chemotherapy - Children aged ≥6 months and adolescents

| BSA | Day 1 (a,b) | Days 2-6(b) |
|---|---|---|
| <0.6 m$^2$ | 5 mg/m$^2$ IV plus 2 mg syrup after 12 hrs | 2 mg syrup every 12 hrs |
| ≥0.6 m$^2$ to ≤ 1.2 m$^2$> | 5 mg/m$^2$ IV. plus 4 mg syrup or tablet after 12 hrs | 4 mg syrup or tablet every 12 hrs |
| 1.2 m$^2$ | 5 mg/m$^2$ or 8 mg IV plus 8 mg syrup or tablet after 12 hours | 8 mg syrup or tablet every 12 hours |

a The intravenous dose must not exceed 8mg.
b The total daily dose 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
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.
Two further intravenous doses may be given in 4-hourly intervals. Oral dosing can commence twelve hours later and may be continued for up to 5 days.
The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32 mg.

Table 2: Weight-based dosing for Chemotherapy - Children aged ≥6 months and adolescents

| Weight | Day 1(a,b) | Days 2-6(b) |
|---|---|---|
| ≤10 kg | Up to 3 doses of 0.15 mg/kg every 4 hrs | 2 mg syrup every 12 hrs |
| >10 kg | Up to 3 doses of 0.15 mg/kg every 4 hrs | 4 mg syrup or tablet every 12 hrs |

a The intravenous dose must not exceed 8mg.
b The total daily dose must not exceed adult dose of 32 mg.

**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 saline or other compatible infusion fluid (see section 6.6) and infused over 15 minutes.

**In patients 75 years of age or older**, the initial intravenous dose of ondansetron injection should not exceed 8 mg. All intravenous doses should be diluted in 50-100 ml of saline or other compatible infusion fluid (see section 6.6) 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)

**Post-operative nausea and vomiting (PONV):**
**Adults:**
For the prevention of PONV ondansetron injection can be administered orally or by intravenous or intramuscular injection.
Ondansetron injection may be administered as a single dose of 4mg given by intramuscular or slow intravenous

teenagers (or those with a large body surface area)
- these doses can be given for up to five days

**To prevent and treat nausea and vomiting after an operation**

Adult:
- The recommended 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:
- For children aged over 1 month and adolescents the doctor will decide the dose. The maximum dose is 4 mg given as a slow injection into the vein. For prevention, this will be given just before the operation.

**Patients with moderate or severe liver problems**
The total daily dose should not be more than 8 mg.

**If you keep feeling or being sick**
Ondansetron injection should start to work soon after having the injection. If you continue to be sick or feel sick, tell your doctor or nurse.

**If you have 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 or your child have been given too much or have missed a dose, tell your doctor or nurse.

**4. Possible side effects**
Like all medicines, ondansetron injection can cause side effects, although not everybody gets them.

**Serious side effects**
**If you develop any of the following side effects, tell your doctor immediately:**
- chest pain

The following side effects have been reported:

**Allergic reactions**

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.

**Other side effects include:**

**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
- chest pain
- fits
- unusual body movements or shaking.

**Rare (may affect up to 1 in 1,000 people)**
- feeling dizzy or light headed
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

**Very rare (may affect up to 1 in 10,000 people)**
- 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 or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via {insert information on the relevant 'national reporting system' – details will be defined at national level} By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517
Website: www.hpra.ie, e-mail: medsafety@hpra.ie

**5. How to store Ondansetron Injection**
- Keep this medicine out of the sight and reach of children.
- Your doctor or pharmacist knows how to store Ondansetron Injection.
- This medicinal product does not require any special storage temperature. Keep ampoules in the outer carton, in order to protect from light.
- Do not use ondansetron injection after the expiry date which is stated on the pack after "Exp". The expiry date refers to the last day of that month.
- Only clear solutions practically free from particles should be used. Do not use if container is damaged.
- 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 Injection contain:**
The active substance in Ondansetron Injection is ondansetron (as hydrochloride dihydrate). Each ml of solution for injection contains 2 mg ondansetron (as ondansetron hydrochloride dihydrate).
Each glass ampoule of 2ml contains 4mg ondansetron (as hydrochloride dihydrate).
Each glass ampoule of 5ml (containing 4 ml of solution) contains 8mg ondansetron (as hydrochloride dihydrate).

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

**What Ondansetron Injection looks like and contents of the pack**
Ondansetron Injection is clear, colourless solution and it comes in clear colourless glass ampoules of 2ml containing 2 ml of solution and 5 ml containing 4 ml of solution..

2 ml ampoule containing 4mg/2ml of solution.
5 ml ampoule containing 8mg/4ml of solution.

Each pack contains 25 ampoules of 2 ml or 5ml capacity glass ampoule.
Each pack contains 5 ampoules of 2 ml or 5ml capacity glass ampoule

Not all pack sizes may be marketed

**Marketing Authorisation Holder:**
**United Kingdom:**
Baxter Healthcare Limited
Caxton way
Thetford
Norfolk
IP24 3SE
**Ireland:**
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht, Netherlands

**Manufacturer:**
Peckforton Pharmaceuticals Limited,
The Courtyard Barns, Choke Lane,
Cookham Dean, Maidenhead, Berkshire,
SL6 6PT, United Kingdom
or
UAB Norameda
Meistru 8a, 02189,
Vilnius, Lithuania
or
Bieffe Medital S.p.A.
Via Nuova Provinciale 23034 Grossotto (SO) Italy

This medicinal product is authorized in the Member States of EEA under the following name:
Ondansetron 2mg/ml Solution for Injection – UK, Ireland.
Ondansetron – Germany, Luxembourg.
Ondansetron Baxter – Portugal.
Ondansetron Baxter – Estonia, Latvia, Lithuania, Poland.
Ondansetron Baxter 2mg/ml oplossing voor injectie – Netherlands
Ondansetron Baxter 4mg/2 ml raztopina za injiciranje ali infundiranje – Slovenia
Ondansetron Baxter 8mg/4 ml raztopina za injiciranje ali infundiranje – Slovenia
EMISTOP – Italy

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injection at induction of anesthesia. For Treatment of established PONV A single dose of 4mg given by intramuscular or slow intravenous injection is recommended.

**Children (aged over 1 month and adloscents):**
Injection:
For prevention of PONV in pediatric patients having surgery performed under general anesthesia, a single dose of ondansetron injection may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg either prior to, at or after induction of anesthesia.
For treatment of PONV after surgery in paediatric patients, having surgery performed
under general anaesthesia, a single dose of ondansetron injection may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg.
There are no data on the use of ondansetron injection in the treatment of PONV in children below 2 years of age.
**Elderly**
There is limited experience in the use of ondansetron injection in the prevention and treatment of PONV in the elderly, however Ondansetron injection is well tolerated in patients over 65 years receiving chemotherapy.

**For all indications:**
***Renal impairment***
No alteration of daily dosage or frequency of dosing, or route of administration are required.

***Hepatic impairment***
Clearance of ondansetron injection 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 8mg should not be exceeded.

***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 frequencies of dosing are required.

**Special precautions for disposal and other handling**
The solution must not be sterilised in an autoclave.
**Compatibility with intravenous fluids:** 0.08mg/ml concentration of Ondansetron with each diluents at the storage of 2-8 ºC for 36 hours.

The solution is to be visually inspected prior to use (also after dilution). Only clear solutions practically free from particles should be used. Do not use if container is damaged.
The diluted solutions should be stored protected from light.

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

Ondansetron 2mg/ml Solution for Injection should only be admixed with those infusion solutions, which are recommended:
Sodium Chloride Intravenous Infusion BP 0.9%w/v
Glucose Intravenous Infusion BP 5%w/v
Mannitol Intravenous Infusion BP 10%w/v
Ringers Intravenous Infusion
Potassium Chloride 0.3%w/v and Sodium Chloride 0.9%w/v Intravenous Infusion BP
Potassium Chloride 0.3%w/v and Glucose 5%w/v Intravenous Infusion BP

Compatibility studies have been undertaken in polyvinyl chloride infusion bags, Non polyvinyl chloride infusion bags, Ph. Eur. Type I glass bottles and polyvinyl chloride administration sets. It is considered that adequate stability would also be conferred by the use of polyethylene infusion bags or Type 1 glass bottles.
Dilutions of Ondansetron injection in sodium chloride 0.9%w/v or in glucose 5%w/v have been demonstrated to be stable in polypropylene syringes. It is considered that Ondansetron injection diluted with other compatible infusion fluids would be stable in polypropylene syringes.

***Compatibility with other drugs:***
Ondansetron 2mg/ml Solution for Injection may be administered by intravenous infusion at 1mg/hour, e.g. from an infusion bag or syringe pump. The following drugs may be administered via the Y-site of the Ondansetron 2mg/ml Solution for Injection 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 (500 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. 72 mg in 500 ml to 250 mg in 1 litres), administered over thirty minutes to one hour.
***Ceftazidime****:*
Doses in the range 250 mg to 2000 mg reconstituted with Water for Injections BP as recommended by the manufacturer (e.g. 2.5 ml for 250 mg and 10 ml for 2g 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 BP, 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 BP, 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 a compatible infusion fluid 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.
**Shelf life**
Unopened
3 years

Injection
After first opening the medicinal product should be used immediately.

Infusion
Chemical and physical in-use stability has been demonstrated for 36 hours at 2-8ºC with the solutions given in section 6.6.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8ºC, unless dilution has taken place in controlled and validated aseptic conditions.
**Special precautions for storage**
*As packaged for sale:*
This medicinal product does not require any special storage temperature.
Keep ampoules in the outer carton, in order to protect from light.

For storage conditions of the diluted medicinal product, see section 6.3.
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