

Ondansetron
(as hydrochloride dihydrate)
4 mg/2 mL solution for injection
(DEMO S.A.), HA597

WHOPAR part 3
supplier's submission of the
SRA approved text

September 2024

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZOPHRALEN 4mg /2mL solution for injection

ZOPHRALEN 8mg /4mL 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.

What is in this leaflet:

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

1. What ZOPHRALEN is and what it is used for

ZOPHRALEN belongs to a group of medicines called antiemetics. Certain medications or therapeutic treatments may release a substance that can cause nausea and vomiting. ZOPHRALEN prevents the action of this substance, thereby preventing nausea or vomiting.

ZOPHRALEN is a 5-HT₃ receptor. It functions by inhibiting the 5-HT₃ receptors on neurons located in the body's peripheral and central nervous system.

Adults: ZOPHRALEN is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. ZOPHRALEN is also indicated for the prevention and treatment of post-operative nausea and vomiting.

Pediatric Population: ZOPHRALEN is indicated for the management of chemotherapy- induced nausea and vomiting in children aged ≥ 6 months and for the prevention and treatment of post-operative nausea and vomiting in children aged ≥ 1 month. Intravenous administration is recommended for the prevention and treatment of post-operative nausea and vomiting.

2. What you need to know before taking ZOPHRALEN

Do not take ZOPHRALEN if:

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

If any of these apply to you, inform your doctor or pharmacist before taking ZOPHRALEN.

Hypersensitivity reactions have been reported in patients who have demonstrated hypersensitivity to other 5-HT₃ receptor antagonists.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking ZOPHRALEN:

- if you are allergic to medicines similar to ZOPHRALEN, such as granisetron or palonosetron.
- if you have ever had heart problems, including irregular heartbeats (arrhythmia),
- if you have gut problems
- if you have a liver disease, your doctor may reduce the dose of ondansetron for you

Respiratory side effects should be managed symptomatically, and physicians should exercise particular caution with these as they may be precursors to hypersensitivity reactions.

Ondansetron prolongs the QT interval in a dose-dependent manner. In addition, post-marketing cases of Torsade de Pointes have been reported in patients using ondansetron. Ondansetron should be avoided in patients with a congenital long QT syndrome. Ondansetron should be administered with caution in patients who have or may develop QTc prolongation, including patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias, or patients taking other medicinal products leading to QT prolongation or electrolyte abnormalities.

Hypokalemia and hypomagnesemia should be corrected prior to ondansetron administration.

As ondansetron increases transit time in the colon, patients with symptoms of intestinal obstruction should be monitored after its administration.

In patients undergoing tonsillectomy and/or adenoidectomy, the prevention of nausea and vomiting with ZOPHRALEN may mask underlying bleeding. Therefore, such patients should be closely monitored after the administration of ondansetron.

Children:

Pediatric patients receiving ondansetron with hepatotoxic chemotherapeutic agents should be closely monitored for hepatic dysfunction.

Other medicines and ZOPHRALEN

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines even if not prescribed to you with a medical prescription.

There is no evidence to suggest that ondansetron induces or inhibits the metabolism of other drugs commonly administered with it. Special studies have shown that there are no interactions when ondansetron is administered with alcohol, temazepam, fluoxetine, alfentanil, tramadol, morphine, lidocaine, thiopental, or propofol.

Ondansetron is metabolized by various hepatic enzymes of the cytochrome P-450 family: CYP3A4, CYP2D6, and CYP1A2. Due to the diversity of metabolic enzymes capable of metabolizing ondansetron, the inhibition of one enzyme or reduced activity of one enzyme (e.g., genetic deficiency in CYP2D6) is usually compensated by other enzymes and typically results in a small or insignificant change in the overall clearance of ondansetron or the required dose.

Apomorphine

Based on reports of severe hypotension and loss of consciousness when ondansetron was co-administered with apomorphine hydrochloride, co-administration with apomorphine is contraindicated.

Phenytoin, carbamazepine (used for the treatment of epilepsy), and rifampicin (used for the treatment of infections such as tuberculosis)

In patients receiving potent inducers of CYP3A4 (i.e., phenytoin, carbamazepine, and rifampicin), the oral clearance of ondansetron increased, and blood concentrations of ondansetron decreased.

Fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram (SSRIs: selective serotonin reuptake inhibitors), and venlafaxine, duloxetine serotonin-norepinephrine reuptake inhibitors (SNRIs: serotonin-norepinephrine reuptake inhibitors) (used for the treatment of depression and/or anxiety). Serotonin syndrome (including altered mental status, autonomic instability, and neuromuscular abnormalities) has been reported following the coadministration of ondansetron with other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs).

Tramadol (analgesic)

Data from small studies indicate that ondansetron may reduce the analgesic effect of tramadol.

Caution is required when ondansetron is co-administered with drugs that prolong the QT interval and/or cause electrolyte abnormalities. (see paragraph 2).

The use of ZOPHRALEN with drugs that prolong the QT interval may lead to additional QT prolongation. Co-administration of ZOPHRALEN with cardiotoxic drugs (e.g., anthracyclines) may increase the risk of arrhythmia.

Pregnancy, breastfeeding and fertility

If you are pregnant, breastfeeding, think you may be pregnant, or are planning to have a baby, consult your doctor before taking this medication.

Pregnancy

You should not use ZOPHRALEN during the first trimester of pregnancy. This is because ZOPHRALEN 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). ZOPHRALEN may harm your unborn baby. If you are a woman of childbearing potential, you may be advised to use effective contraception.

If you become pregnant during treatment with ondansetron, inform your doctor.

The safety of ondansetron use during human pregnancy has not been established. Evaluation of experimental studies in animals does not show directly or indirectly harmful effects on embryonic development, the course of pregnancy, and prenatal and postnatal development. However, as animal studies do not always predict the response in humans, the use of ondansetron during pregnancy is not recommended.

Breastfeeding

Studies have shown that ondansetron is excreted in the milk of animals. Breastfeeding is not recommended during ZOPHRALEN treatment. The ingredients can pass into your breast milk and may affect your baby. Discuss this with your doctor.

Fertility

If you are a woman of reproductive age, your doctor will confirm if you are pregnant, and a pregnancy test will be conducted if necessary before starting treatment with ZOPHRALEN. If you can become pregnant, you should use effective contraception during the treatment. Consult your doctor regarding options for effective contraception.

Driving and using machines

In psychomotor tests, ondansetron does not reduce the ability to perform tasks nor does it cause sedation. The pharmacology of ondansetron does not predict harmful actions in such activities.

ZOPHRALEN solution for injection contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, they are what we call “sodium-free”. If your doctor uses a common salt solution to dilute ZOPHRALEN, then the dose of sodium intake will be higher.

3. How to take ondansetron injection

Always take this medicine strictly according to your doctor's instructions. If you have doubts, ask your doctor or pharmacist.

ZOPHRALEN solution for injection is administered intravenously.

On the day of treatment: ZOPHRALEN will be administered by a doctor or nurse just before the treatment. ZOPHRALEN can be given as an intravenous injection or as a drip.

In the following days: your doctor may give you ondansetron tablets* or syrup* for you to take as corresponding treatment. Follow the respective instructions provided in the packaging. Take this medicine exactly as your doctor has told you.

*The pharmaceutical product ZOPHRALEN is not available in tablets or syrup. Therefore, your doctor should prescribe you another ondansetron product, which is available in these forms.

Chemotherapy and Radiotherapy induced Nausea and Vomiting

Adults

For patients receiving emetogenic chemotherapy or radiation therapy, ZOPHRALEN can be used by intravenous injection. The recommended intravenous dose of ZOPHRALEN is 8 mg and is given as a slow intravenous injection immediately before treatment.

For highly emetogenic chemotherapy, a maximum starting dose of 16 mg IV infusion over 15 minutes can be used. A single intravenous dose of more than 16 mg should not be given because of a dose-related increase in the risk of QT prolongation.

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

Intravenous doses greater than 8 mg and up to a maximum of 16 mg must be diluted in 50 - 100 mL of 0.9% Sodium Chloride Injection or 5% Dextrose Injection prior to administration and infused over no less than 15 minutes. Doses of ondansetron 8 mg or less need not be diluted and may be given as a slow intravenous injection over not less than 30 seconds.

The initial dose of ondansetron may be followed by 2 additional intravenous doses (over no less than 30 seconds) of 8 mg 4 hours apart, or by a constant infusion of 1 mg/h for up to 24 hours.

Oral or rectal treatment is recommended to protect against delayed or prolonged injection after the first 24 hours.

In order to protect against delayed or prolonged emesis after the first 24 hours, oral or rectal treatment with ondansetron should be continued for up to 5 days after treatment.

Pediatric population

Use in children ≥ 6 months of age and adolescents: Chemotherapy-induced nausea and vomiting

The dose for chemotherapy-induced nausea and vomiting can be calculated based on body surface area (BSA) or body weight - see below.

ZOPHRALEN Solution for injection should be diluted in 5% dextrose or 0.9% sodium chloride or other compatible infusion fluid 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 chemotherapy-induced nausea and vomiting. There are no controlled clinical trial data on the use of ondansetron in radiotherapy-induced nausea and vomiting in children.

Dosage based on BSA

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

Oral dosing can commence twelve hours later and can be continued for up to 5 days (table 1).

The total daily dose should not exceed the adult dose of 32 mg.

Table 1: BSA-based dosing for Chemotherapy - Children aged ≥ 6 months and adolescents

BSA	Day 1 ^(1,2)	Days 2 – 6 ⁽²⁾
< 0.6 m ²	5 mg/m ² IV plus 2 mg syrup ⁽³⁾ after 12 hrs	2 mg syrup ⁽³⁾ every 12 hrs
≥ 0.6 m ² to \leq 1.2 m ²	5 mg/m ² IV plus 4 mg syrup ⁽³⁾ or tablet after 12 hrs	4 mg syrup ⁽³⁾ or tablet ⁽³⁾ every 12 hrs
>1.2 m ²	5 mg/m ² or 8 mg IV plus 8 mg syrup ⁽³⁾ or tablet ⁽³⁾ after 12 hrs	8 mg syrup ⁽³⁾ or tablet ⁽³⁾ every 12 hrs

¹ The intravenous dose must not exceed 8 mg.

² The total dose over 24 hours must not exceed the adult dose of 32 mg.

³ ZOPHRALEN is not available as a syrup or tablet. Therefore, please refer to other ondansetron products available in these formulations.

Dosage based on body weight:

Dosing based on body weight results in higher daily doses compared to BSA (see above).

Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 0.15 mg/kg. A single intravenous dose should not exceed 8 mg. On the first day, two additional intravenous doses may be given at 4-hour intervals.

Oral dosing of ondansetron can commence twelve hours later and can be continued for up to 5 days (Table 2).

The total daily dose should not exceed the adult dose of 32 mg.

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

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

¹ The intravenous dose must not exceed 8 mg.

² The total dose over 24 hours must not exceed the adult dose of 32 mg.

³ ZOPHRALEN is not available as a syrup or tablet. Therefore, please refer to other ondansetron products available in these formulations.

Elderly:

In patients 65 years of age and older, all intravenous doses should be diluted and infused over 15 minutes and if repeated administered over an interval of not less than 4 hours.

In patients 65 to 74 years of age, initial intravenous doses of ondansetron 8 mg or 16 mg, infused over 15 minutes, may be followed by 2 doses of 8 mg infused over 15 minutes and administered no less than 4 hours apart.

In patients 75 years of age and older, the initial intravenous dose of ondansetron should not exceed 8 mg infused over 15 minutes. The initial dose of 8 mg may be followed by 2 doses of 8 mg, infused at an interval of 15 minutes and given at an interval of not less than 4 hours.

Post-operative Nausea and Vomiting

Adults

For the prevention of post-operative nausea and vomiting, ZOPHRALEN can be administered by intravenous injection.

ZOPHRALEN solution for injection may be administered as a single dose of 4 mg given by slow intravenous injection at induction of anaesthesia.

For treatment of established post-operative nausea and vomiting, a single dose of 4 mg given by slow intravenous injection is recommended.

Paediatric population

Use in children aged ≥ 1 month and adolescents: Post-operative nausea and vomiting

No studies have been conducted on the use of oral ondansetron for the prevention or treatment of post-operative nausea and vomiting. Therefore, an intravenous injection (not less than 30 seconds) is recommended.

For the prevention of post-operative nausea and vomiting in paediatric patients who have undergone surgery under general anesthesia, a single dose of ondansetron can be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1 mg/kg, with a maximum dose of 4 mg either before or after induction of anesthesia or after surgery.

For the treatment of post-operative nausea and vomiting in paediatric patients who have undergone surgery under general anesthesia, a single dose of ondansetron can be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1 mg/kg, with a maximum dose of 4 mg.

No studies have been conducted on the use of oral ondansetron in the prevention or treatment of post-operative nausea and vomiting. A slow intravenous injection (not less than 15 minutes) is recommended.

Elderly patients

There is limited experience in the use of ondansetron for the prevention and treatment of post-operative nausea and vomiting in the elderly, however ondansetron is well tolerated in patients over 65 years of age receiving chemotherapy.

Patients with renal impairment:

There is no need to change the daily dose, frequency of dosing or route of administration.

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 these patients the total daily intravenous dose of 8 mg should not be exceeded.

Patients with poor Sparteine/Debrisoquine metabolism:

In individuals classified as poor metabolisers of sparteine and debrisoquine, the half-life of ondansetron remains unchanged. Therefore, in these patients, repeat dosing will give drug exposure levels no different from those of the general population. There is no need to change the daily dosage or frequency of dosing.

If you take more ZOPHRALEN than you should

There is limited experience of ondansetron overdose. In the majority of cases the symptoms were similar to those already reported in patients receiving recommended doses. Manifestations that have been reported include visual disturbances, severe constipation, hypotension, and vasovagal episode with transient second-degree AV block.

Ondansetron prolongs the QT interval in a dose-dependent manner. In cases of overdose, ECG monitoring is recommended.

There is no specific antidote for ondansetron, therefore, in all cases of suspected overdose, symptomatic and supportive treatment should be given.

The use of ipecacuanha to treat ondansetron overdose is not recommended as patients are unlikely to respond due to the anti-emetic action of ondansetron itself.

Your doctor or nurse will give you **or your child** ondansetron solution for injection so that you **or your child** are unlikely to get an overdose. If you think you or your child has been given too much or a dose has been missed, tell your doctor or nurse.

If you forget to take ZOPHRALEN

If you miss a dose and have nausea or vomiting, take another dose as soon as possible and then continue as before.

Do not take a double dose to make up for a forgotten dose.

If you are not sure what to do, ask your doctor or pharmacist.

Do not stop ZOPHRALEN without your doctor's advice.

Continue taking ZOPHRALEN for as long as your doctor recommends it. Do not stop unless your doctor advises you to.

4. Possible side effects

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

Serious allergic reactions:

These are rare in people taking ondansetron. Symptoms include:

- itching and rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse

Contact your doctor immediately if you experience these symptoms. Stop taking ZOPHRALEN.

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
- local reactions at the site of injection

Uncommon (may affect up to 1 in 100 people)

- epileptic seizures
- movement disorders (including extrapyramidal reactions such as dystonic reactions, oculogyric crisis and dyskinesia)
- arrhythmias or bradycardia
- chest pain with or without ST segment depression
- hypotension
- hiccups
- asymptomatic elevations in liver function tests (*These conditions have been seen frequently in patients receiving chemotherapy with cisplatin*)

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

- immediate hypersensitivity reactions, sometimes severe, including anaphylaxis
- feeling dizzy or light headed during quick intravenous administration
- transient visual disturbances (e.g. blurred vision) mainly during intravenous administration
- QTc prolongation (including Torsade de Pointes) which may lead to loss of consciousness

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

- transient blindness mainly during intravenous administration
- a widespread skin rash including toxic epidermal necrolysis

The adverse event profiles in children and adolescents were comparable to that seen in adults.

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 adverse reactions directly to the National Organisation for Medicines (284, Mesogeion Ave., GR-15562, Chologos, Athens, Tel: + 30 21 32040380/337, Fax: + 30 21 06549585, Website: <http://www.eof.gr>).

By reporting side effects you can help gather more information about the safety of this medicine.

5. How to store ZOPHRALEN

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

Do not use this medicine after the expiry date which is stated on the label after "EXP". The expiry date is the last day of the month mentioned there.

Store below 25°C.

Do not wash down unused medicine in the sink or toilet or household waste. Ask your pharmacist on how to dispose unused medicines. These measures shall help protect the environment.

6. Contents of the package and other information

What ZOPHRALEN contains

- The active substance is 2 mg ondansetron per mL (in the form of hydrochloride dehydrate).
- The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride and water for injections.

What ZOPHRALEN looks like and contents of the package

ZOPHRALEN solution for injection is packed in glass or plastic polypropylene ampoules and in a cardboard box.

Each pack contains:

1 ampoule of 2 mL or 4 mL
or
20 ampoules of 2 mL or 4 mL
Or
50 ampoules of 2 mL or 4 mL

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

DEMO S.A.

21st km of Athens-Lamia National Road,
GR-145 68 Kryoneri (Attica Greece),
T: +30 210 8161802, F: +30 210 8161587.

Manufacturer:

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This leaflet was last revised on October 2023.

The following information is intended for healthcare professionals only:

ZOPHRALEN solution for injection should not be administered in the same syringe or drip with any other medicine.

ZOPHRALEN solution for injection should only be mixed with recommended intravenous infusion solutions.

ZOPHRALEN injection ampoules should not be placed in an autoclave for sterilization.

Compatibility with intravenous fluids

ZOPHRALEN solution for injection should only be diluted in recommended infusion solutions. For compliance with good pharmaceutical practice, intravenous solutions should be prepared at the time of infusion. However, ZOPHRALEN injection has been found to be stable for seven days at room temperature (below 25°C) exposed to fluorescent lighting or in a refrigerator with the following intravenous fluids used for infusion:

Sodium chloride solution for intravenous infusion 0.9% w/v
Glucose solution for intravenous infusion 5% w/v
Mannitol solution for intravenous infusion 10% w/v
Ringer's solution for intravenous infusion
Potassium chloride 0.3% w/v and sodium chloride 0.9% w/v solution for intravenous infusion
Potassium chloride 0.3% w/v and glucose 5% w/v solution for intravenous infusion

Compatibility studies of Ondansetron have been performed with polyvinyl chloride bags and devices used for infusions. Satisfactory stability is also provided by using polyethylene bags or type 1 glass vials.

Solutions of Ondansetron in sodium chloride 0.9% w/v or in glucose 5% w/v are stable in polypropylene syringes.

Ondansetron solution for injection when mixed with other compatible infusion fluids is considered stable in polypropylene syringes.

Note: The preparation must be kept in suitable aseptic conditions when an extension of its preservation time is required.

Compatibility with other medicinal products: ZOPHRALEN 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 an infusion set for ZOPHRALEN 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. 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 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 micrograms – 2.5 mg/mL for dexamethasone sodium phosphate and 8 micrograms – 1 mg/mL for ondansetron.