For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only OR for Specialist Use only

Ondansetron Tablets USP 4 mg

Emeset-4

Composition
Each film-coated tablet contains
Ondansetron Hydrochloride USP equivalent to Ondansetron ..... 4 mg
Colour: Titanium Dioxide
Excipients with known effects: Lactose

Dosage Form
Tablet

PHARMACOLOGY
Pharmacodynamics
Pharmacotherapeutic group: Antiemetics and antinauseants, Serotonin (5-HT_3) antagonists.

ATC Code: A04AA01

Ondansetron is a potent, highly selective 5-HT_3 receptor-antagonist.

Its precise antiemetic and antinauseal mechanism of action is not known. Chemotherapeutic agents and radiotherapy may cause release of 5-HT in the small intestine initiating a vomiting reflex by activating vagal afferents via 5-HT_3 receptors. Ondansetron blocks the initiation of this reflex. Activation of vagal afferents may also cause a release of 5-HT in the area postrema, located on the floor of the fourth ventricle, and this may also promote emesis through a central mechanism. Thus, the effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of 5-HT_3 receptors on neurons located both in the peripheral and central nervous system. The mechanisms of action in post-operative nausea and vomiting are not known but there may be common pathways with cytotoxic induced nausea and vomiting. In a pharmaco-psychological study in volunteers ondansetron has not shown a sedative effect.

Ondansetron does not alter plasma prolactin concentrations.

The role of ondansetron in opiate-induced emesis is not yet established.

Clinical Studies

Paediatric population:
<u>**Chemotherapy-induced nausea and vomiting**</u>
The efficacy of ondansetron in the control of emesis and nausea induced by cancer chemotherapy was assessed in a double-blind randomised trial in 415 patients aged 1 to 18 years. On the days of chemotherapy, patients received either ondansetron 5 mg/m² i.v. + after 8-12 hrs ondansetron 4 mg p.o. or ondansetron 0.45 mg/kg i.v. + after 8-12 hrs placebo per oral. Post-chemotherapy both groups received 4 mg ondansetron syrup twice daily for 3 days. Complete control of emesis on worst day of chemotherapy was 49% (5 mg/m² i.v. + ondansetron 4 mg p.o.) and 41% (0.45 mg/kg i.v. + placebo p.o.). Post-chemotherapy both groups received 4 mg ondansetron syrup twice daily for 3 days.

A double-blind randomised placebo-controlled trial in 438 patients aged 1 to 17 years demonstrated complete control of emesis on worst day of chemotherapy in 73% of patients when ondansetron was administered intravenously at a dose of 5 mg/m² i.v. together with 2-4 mg dexamethasone p.o. and in 71% of patients when ondansetron was administered as syrup at a dose of 8 mg + 2-4 mg dexamethasone p.o. on the days of chemotherapy. Post-chemotherapy both groups received 4 mg ondansetron syrup twice daily for 2 days.

The efficacy of ondansetron in 75 children aged 6 to 48 months was investigated in an open-label, non-comparative, single-arm study. All children received three 0.15 mg/kg doses of intravenous ondansetron, administered 30 minutes before the start of chemotherapy and then at four and eight hours after the first dose. Complete control of emesis was achieved in 56% of patients.

Another open-label, non-comparative, single-arm study investigated the efficacy of one intravenous dose of 0.15 mg/kg ondansetron followed by two oral ondansetron doses of 4 mg for children aged < 12 yrs and 8 mg for children aged ≥12 yrs (total no. of children n= 28). Complete control of emesis was achieved in 42% of patients.

<u>**Prevention of post-operative nausea and vomiting**</u>
The efficacy of a single dose of ondansetron in the prevention of post-operative nausea and vomiting was investigated in a randomised, double-blind, placebo-controlled study in 670 children aged 1 to 24 months (post-conceptual age ≥44 weeks, weight ≥3 kg). Included subjects were scheduled to undergo elective surgery under general anaesthesia and had an ASA status ≤ III. A single dose of ondansetron 0.1 mg/kg was administered within five minutes following induction of anaesthesia. The proportion of subjects who experienced at least one emetic episode during the 24-hour assessment period (ITT) was greater for patients on placebo than those receiving ondansetron (28% vs. 11%, p <0.0001).

Pharmacokinetics
Following oral administration, ondansetron is passively and completely absorbed from the gastrointestinal tract and undergoes first pass metabolism (bioavailability is about 60%). Peak plasma concentrations of about 30 ng/ml are attained approximately 1.5 hours after an 8 mg dose. For doses above 8 mg the increase in ondansetron systemic exposure with dose is greater than proportional; this may reflect some reduction in first pass metabolism at higher oral doses.

Bioavailability, following oral administration, is slightly enhanced by the presence of food but unaffected by antacids. Studies in healthy elderly volunteers have shown slight, but clinically insignificant, age-related increases in both oral bioavailability (65%) and half-life (5 hours) of ondansetron. Gender differences were shown in the disposition of ondansetron, with females having a greater rate and extent of absorption following an oral dose and reduced systemic clearance and volume of distribution (adjusted for weight).

The disposition of ondansetron following oral, intramuscular(IM) and intravenous(IV) dosing is similar with a terminal half-life of about 3 hours and steady state volume of distribution of about 140 L. Equivalent systemic exposure is achieved after IM and IV administration of ondansetron.

The protein binding of ondansetron is 70-76%. A direct effect of plasma concentration and anti-emetic effect has not been established. Ondansetron is cleared from the systemic circulation predominantly by hepatic metabolism through multiple enzymatic pathways. Less than 5% of the absorbed dose is excreted unchanged in the urine. The absence of the enzyme CYP2D6 has no effect on ondansetron's pharmacokinetics. The pharmacokinetic properties of ondansetron are unchanged on repeat dosing.

Special Patient Populations:
Pediatric population
Children and Adolescents (aged 1 month to 17 years)
In paediatric patients aged 1 to 4 months (n=19) undergoing surgery, weight normalised clearance was approximately 30% slower than in patients aged 5 to 24 months (n=22) but comparable to the patients aged 3 to 12 years. The half-life in the patient population aged 1 to 4 month was reported to average 6.7 hours compared to 2.9 hours for patients in the 5 to 24 month and 3 to 12 year age range. The differences in pharmacokinetic parameters in the 1 to 4 month patient population can be explained in part by the higher percentage of total body water in neonates and infants and a higher volume of distribution for water soluble drugs like ondansetron.

In paediatric patients aged 3 to 12 years undergoing elective surgery with general anaesthesia, the absolute values for both the clearance and volume of distribution of ondansetron were reduced in comparison to values with adult patients. Both parameters increased in a linear fashion with weight and by 12 years of age, the values were approaching those of young adults. When clearance and volume of distribution values were normalized by body weight, the values for these parameters were similar between the different age group populations. Use of weight-based dosing compensates for age-related changes and is effective in normalizing systemic exposure in paediatric patients.

Population pharmacokinetic analysis was performed on 74 paediatric cancer patients aged 6 to 48 months and 41 surgery patients aged 1 to 24 months following intravenous administration of ondansetron. Based on the population pharmacokinetic parameters for patients aged 1 month to 48 months, administration of the adult weight based dose (0.15 mg/kg intravenously every 4 hours for 3 doses) would result in a systemic exposure (AUC) comparable to that observed in paediatric surgery patients (aged 5 to 24 months), paediatric cancer patients (aged 4 to 18 years), and surgical patients (aged 3 to 12 years), at similar doses, as shown in Table 1. This exposure (AUC) is consistent with the exposure-efficacy relationship described previously in paediatric cancer subjects, which showed a 50% to 90% response rate with AUC values ranging from 170 to 250 ng.h/mL.

Table 1. Pharmacokinetics in Paediatric Patients 1 Month to 18 Years of age

Study	Patient Population (Intravenous dose)	Age	N	AUC (ng.h/L)	CL (L/h/kg)	Vd_{ss} (L/kg)	$T_{1/2}$ (h)
				Geometric Mean			Mean
S3A40319[2]	Surgery (0.1 or 0.2mg/kg)	1 to 4 months	19	360	0.401	3.5	6.7
S3A40319[2]	Surgery (0.1 or 0.2mg/kg)	5 to 24 months	22	236	0.581	2.3	2.9
S3A40320 & S3A40319 Pop PK [2,3]	Cancer/ Surgery (0.15mg/kg q4h/ 0.1 or 0.2mg/kg)	1 to 48 months	115	257	0.582	3.65	4.9
S3KG02[4]	Surgery (2 mg or 4 mg)	3 to 12 years	21	240	0.439	1.65	2.9
S3A-150	Cancer (0.15 mg/kg q 4h)	4 to 18 years	21	247	0.599	1.9	2.8

[1] Ondansetron single intravenous dose: 0.1 or 0.2 mg/kg
[2] Population PK Patients: 64% cancer patients and 36% surgery patients.
[3] Population estimates shown; AUC based on dose of 0.15 mg/kg.
[4] Ondansetron single intravenous dose: 2 mg (3 to 7 years) or 4 mg (8 to 12 years)

Patients with hepatic impairment
Following oral, intravenous or intramuscular dosing in patients with severe hepatic impairment, ondansetron's systemic clearance is markedly reduced with prolonged elimination half-lives (15-32 h) and an oral bioavailability approaching 100% due to reduced pre-systemic metabolism.

Indications
<u>Adults:</u>
- Emeset 4 is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.
- Emeset 4 is also indicated for the prevention and treatment of post-operative nausea and vomiting (PONV).

<u>Paediatric Population</u>:
- Emeset 4 is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥6 months and for the prevention and treatment of post-operative nausea and vomiting in children aged ≥ 1 month.

Dosage and Method of Administration
Oral use

For the different dosage regimens appropriate strengths and formulations are available.

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 Emeset 4 should be flexible and selected as shown below.

<u>Emetogenic chemotherapy and radiotherapy:</u>
For patients receiving emetogenic chemotherapy or radiotherapy ondansetron can be given either by oral or intravenous administration.

For most patients receiving emetogenic chemotherapy or radiotherapy, ondansetron should initially be administered intravenously immediately before treatment, followed by 8 mg orally twelve hourly.

For oral administration: 8 mg 1-2 hours before treatment, followed by 8 mg orally 12 hours later.

To protect against delayed or prolonged emesis after the first 24 hours, oral treatment with ondansetron should be continued for up to 5 days after a course of treatment. The recommended oral dose is 8 mg to be taken twice daily.

<u>Highly emetogenic chemotherapy:</u>
For patients receiving highly emetogenic chemotherapy, e.g. high-dose cisplatin, ondansetron can be given by intravenous administration.

The recommended oral dose is 24 mg taken together with oral dexamethasone sodium phosphate 12 mg, 1 to 2 hours before treatment.

To protect against delayed or prolonged emesis after the first 24 hours, oral treatment with ondansetron should be continued for up to 5 days after a course of treatment. The recommended dose for oral administration is 8 mg twice daily.

Paediatric Population
<u>Chemotherapy-induced nausea and vomiting in children aged ≥6 months and adolescents:</u>
The dose for chemotherapy-induced nausea and vomiting can be calculated based on body surface area (BSA) or weight – see below. Weight-based dosing results in higher total daily doses compared to BSA-based dosing - see *Warnings and Precautions* and *Pharmacodynamics*.

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

<u>Dosing by BSA</u>:
Ondansetron should be administered immediately before chemotherapy as a single intravenous dose of 5 mg/m². The intravenous dose must not exceed 8 mg.

Oral dosing can commence twelve hours later and may be continued for up to 5 days - see Table 2 below. The total daily dose must not exceed adult dose of 32 mg.

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

BSA	**Day 1** [a,b]	**Days 2-6**[b]
< 0.6 m²	5 mg/m² i.v. 2 mg syrup after 12 hrs	2 mg syrup or tablet every 12 hours
≥ 0.6 m²	5 mg/m² i.v. 4 mg syrup or tablet after 12 hours	4 mg syrup or tablet every 12 hours

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

<u>Dosing by body weight</u>:
Weight-based dosing results in higher total daily doses compared to BSA-based dosing (see *Warnings and Precautions and Pharmacodynamics*).

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

Two further intravenous doses may be given in 4-hourly intervals. The total daily dose must not exceed adult dose of 32 mg.

Oral dosing can commence twelve hours later and may be continued for up to 5 days (see Table 3 below).

Table 3: 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 at 4-hourly intervals	2 mg syrup or tablet every 12 hours
> 10 kg	Up to 3 doses of 0.15 mg/kg at 4 hourly intervals	4 mg syrup or tablet every 12 hours

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

Elderly
Ondansetron is well tolerated by patients over 65 years and no alteration of dosage, dosing frequency or route of administration are required.

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 and therefore parenteral or oral administration is recommended.

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.

Post-operative nausea and vomiting (PONV)
Adults
<u>Prevention of post-operative nausea and vomiting:</u>
For the prevention of PONV, ondansetron can be administered orally or by intravenous injection.

<u>For oral administration:</u>
16 mg one hour prior to anaesthesia.

Alternatively, 8 mg one hour prior to anaesthesia followed by two further doses of 8 mg at eight hourly intervals.

<u>Treatment of established PONV</u>
For the treatment of established PONV, administration by injection is recommended.

Paediatric population
Post-operative nausea and vomiting in children aged ≥1 month and adolescents

No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; slow i.v. injection is recommended for this purpose.
There are no data on the use of ondansetron in the treatment of post-operative nausea and vomiting in children under 2 years of age.

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
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 and therefore parenteral or oral administration is recommended.

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 medicinal product exposure levels no different from those of the general population. No alteration of daily dosage or frequency of dosing are required.

Contraindications
Hypersensitivity to ondansetron or to other selective 5-HT3-receptor antagonists (e.g. granisetron, dolasetron).

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SAP Caode : 21094412
Leaflet Size: 380 x 264 mm
Size After folding : 38 x 44 mm
Colour:
Black
Pharmacode: 8432_mini
Reference : 21069806
Country : QCIL Uganda
Date: 16-6-2022

Concomitant use with apomorphine (see *Drug Interactions*).

Hypersensitivity to any component of the preparation.

Warnings and Precautions

Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonists. Respiratory events should be treated symptomatically and clinicians should pay particular attention to them as precursors of hypersensitivity reactions.

Rarely transient ECG changes including QT interval prolongation have been reported in patients receiving ondansetron. Ondansetron prolongs the QT interval in a dose-dependent manner (see *Pharmacodynamics*). In addition, post-marketing cases of *Torsade de Pointes* have been reported in patients using ondansetron. Avoid ondansetron in patients with congenital long QT syndrome. Ondansetron should be administered with caution to patients who have or may develop prolongation of QTc. These conditions include patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias or patients taking other medicinal products that lead to QT prolongation or electrolyte abnormalities. Therefore caution should be exercised in patients with cardiac rhythm or conduction disturbances, in patients treated with anti-arrhythmic agents or beta-adrenergic blocking agents and in patients with significant electrolyte disturbances.

Hypokalaemia and hypomagnesaemia should be corrected prior to ondansetron administration.

There have been post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the concomitant use of ondansetron and other serotonergic drugs (including selective serotonin reuptake inhibitors (SSRI) and serotonin noradrenaline reuptake inhibitors (SNRIs). If concomitant treatment with ondansetron and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised.

As ondansetron is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.

In patients with adenotonsillar surgery prevention of nausea and vomiting with ondansetron may mask occult bleeding. Therefore, such patients should be followed carefully after ondansetron.

Since there is little experience to date of the use of ondansetron in cardiac patients, caution should be exercised if ondansetron is co-administered with anaesthetics to patients with arrhythmias or cardiac conduction disorders or to patients who are being treated with antiarrhythmic agents or beta-blockers.

Excipients

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Paediatric Population

Paediatric patients receiving ondansetron with hepatotoxic chemotherapeutic agents should be monitored closely for impaired hepatic function.

Chemotherapy-induced nausea and vomiting (CINV)

When calculating the dose on an mg/kg basis and administering three doses at 4-hour intervals, the total daily dose will be higher than if one single dose of 5 mg/m^2 followed by an oral dose is given. The comparative efficacy of these two different dosing regimens has not been investigated in clinical trials. Cross-trial comparison indicates similar efficacy for both regimens (*see Pharmacodynamics*).

Drug Interactions

There is no evidence that ondansetron either induces or inhibits the metabolism of other medicinal products commonly co-administered with it. Specific studies have shown that ondansetron does not interact with alcohol, temazepam, furosemide, alfentanil, tramadol, morphine, lignocaine, propofol and thiopental.

Ondansetron is metabolised by multiple hepatic cytochrome P-450 enzymes: CYP3A4, CYP2D6 and CYP1A2. Due to the multiplicity of metabolic enzymes capable of metabolising ondansetron, enzyme inhibition or reduced activity of one enzyme (e.g. CYP2D6 genetic deficiency) is normally compensated by other enzymes and should result in little or no significant change in overall ondansetron clearance or dose requirement.

Phenytoin, Carbamazepine and Rifampicin: In patients treated with potent inducers of CYP3A4 (i.e. phenytoin, carbamazepine and rifampicin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.

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

Use of ondansetron with QT prolonging drugs may result in additional QT prolongation. Concomitant use of ondansetron with cardiotoxic drugs (e.g. anthracyclines such as doxorubicin, daunorubicin or trastuzumab), antibiotics (such as erythromycin or ketoconazole), antiarrhythmics (such as amiodarone) and beta blockers (such as atenolol or timolol) may increase the risk of arrhythmias (see *Warnings and Precautions*).

There have been post-marketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the concomitant use of ondansetron and other serotonergic drugs (including SSRIs and SNRIs) (See *Warnings and Precautions*).

Apomorphine

Based on reports of profound hypotension and loss of consciousness when ondansetron was administered with apomorphine hydrochloride, concomitant use with apomorphine is contraindicated.

Pregnancy and lactation

Pregnancy

Use in pregnancy has not been established and is not recommended. To date, no other relevant epidemiological data are available. The safety of ondansetron for use in human pregnancy has not been established. Evaluation of experimental animal studies does not indicate direct or indirect harmful effects with respect to the development of the embryo, or foetus, the course of gestation and peri- and post-natal development. However as animal studies are not always predictive of human response the use of ondansetron in pregnancy is not recommended. If it is absolutely necessary that ondansetron be given caution should be exercised when prescribing to pregnant women especially in the first trimester. A careful risk/benefit assessment should be performed.

Lactation

Tests have shown that ondansetron passes into the milk of lactating animals. It is therefore recommended that mothers receiving ondansetron should not breast-feed their babies.

Undesirable Effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1000 to < 1/100), rare (≥ 1/10,000 to <1 /1000) and very rare (< 1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. The incidence in placebo was taken into account. Rare and very rare events were generally determined from post-marketing spontaneous data.

The following frequencies are estimated at the standard recommended doses of ondansetron according to indication and formulation. The adverse event profiles in children and adolescents were comparable to that seen in adults.

Immune system disorders

Rare: Immediate hypersensitivity reactions sometimes severe, including anaphylaxis.

Nervous system disorders

Very common: Headache.
Uncommon: Seizures, movement disorders (including extrapyramidal reactions such as oculogyric crisis / dystonic reactions and dyskinesia) [1]
Rare: Dizziness during rapid intravenous administration.

Eye disorders

Rare: Transient visual disturbances (eg. blurred vision) predominantly during rapid intravenous administration.
Very rare: transient blindness predominantly during intravenous administration[2].

Cardiac disorders

Uncommon: Arrhythmias, chest pain with or without ST segment depression, Bradycardia.
Rare: Transient ECG changes including QT interval prolongation (including *Torsade de Pointes*).

Vascular disorders

Common: Sensation of warmth or flushing.
Uncommon: Hypotension.

Respiratory, thoracic and mediastinal disorders

Uncommon: Hiccups.

Gastrointestinal disorders

Common: Constipation.

Hepatobiliary disorders

Uncommon: Asymptomatic increases in liver function tests[3].

General disorders and administration site conditions

Common: Local intravenous injection site reactions

[1] Observed without definitive evidence of persistent clinical sequelae.
[2] The majority of the blindness cases reported resolved within 20 minutes. Most patients had received chemotherapeutic agents, which included cisplatin. Some cases of transient blindness were reported as cortical in origin.
[3] These events were observed commonly in patients receiving chemotherapy with cisplatin.

Paediatric population

The adverse event profile in children and adolescents was comparable to that seen in adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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 *Undesirable Effects*). Manifestations that have been reported include visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second degree AV block. In all instances, the events resolved completely. Ondansetron prolongs QT interval in a dose-dependent manner. ECG monitoring is recommended in cases of overdose.

Treatment

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

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.

Incompatibility

NA

Storage

Do not store above 30°C. Store in the original packaging to protect from light.

Packaging Information:

Strip of 10 tablets each.

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CiplaQCi

Supplier & Manufacturer
Mfd. by
CiplaQCIL
Plot 1-7, 1st Ring Road,
Luzira Industrial Park,
P.O. Box 34871, Kampala, Uganda
Phone : +256-312341100/65
E-mail : info@ciplaqcil.co.ug
Website : www.ciplaqcil.co.ug

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