WHO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS

This summary of product characteristics focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.[*]

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

[*]https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

1. NAME OF THE MEDICINAL PRODUCT

[HA596 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated contains ondansetron (as hydrochloride dihydrate) 8 mg

Excipients with potential clinical effect

Each tablet contains 182 mg of lactose monohydrate

3. PHARMACEUTICAL FORM

Film-coated tablets

Yellow, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets are plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[HA596 trade name] can be used in patients with HIV for:

- managing nausea and vomiting induced by cytotoxic chemotherapy in adults and in adolescents and children weighing at least 10 kg (body surface area at least 0.6 m^2)
- managing nausea and vomiting induced by radiotherapy in adults
- preventing postoperative nausea and vomiting in adults

4.2 Posology and method of administration

Posology

Oral use

Chemotherapy- and radiotherapy-induced nausea and vomiting

Adults

The recommended dose is 2 tablets 1 to 2 hours before chemotherapy or radiation treatment, followed by 2 tablets every 12 hours for up to 5 days to protect against delayed or prolonged emesis.

For highly emetogenic chemotherapy a single dose of up to 6 tablets ondansetron 1 to 2 hours before chemotherapy, may be used. The dose may be given together with dexamethasone. Treatment may be continued at a dose of 2 tablets every 12 hours for up to 5 days to protect against delayed or prolonged emesis.

Children and adolescents aged 6 months up to 17 years

In children, treatment is started immediately before chemotherapy and is given by the intravenous route on the first day. It is then given by mouth for up to 5 days.

Ondansetron doses may be based on the patient's body surface area or weight.

Dosing in children by body surface area

The total dose must not exceed 8 tablets over 24 hours.

Body surface area	Day1	Days 2–6

† Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

0.6 m^2 up to 1.2 m^2	Initial dose given by the intravenous route	1 tablet every 12 hours*
More than 1.2 m^2		2 tablets every 12 hours
*For children who cannot swallow tablets, availability of other strengths and formulations should be checked		

Dosing in children by body weight

The total dose must not exceed 8 tablets over 24 hours.

Weight	**Day 1**	**Days 2-6**
Up to 10 kg	Initial doses given by the intravenous route	Tablet not appropriate
More than 10 kg		1 tablet every 12 hours

Elderly

No dose adjustment is required for the elderly.

Postoperative nausea and vomiting

Adults

For preventing postoperative nausea and vomiting the recommended dose of ondansetron is 4 tablets given 1 hour before anaesthesia.

[HA596 trade name] is not recommended for treating established postoperative nausea and vomiting.

Children and adolescents aged 6 months up to 17 years

Ondansetron is generally given by injection for preventing postoperative nausea and vomiting in children and adolescents aged up to 17 years.

Elderly

There is limited experience on the use of ondansetron for preventing and treating postoperative nausea and vomiting in the elderly; however, ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

Renal impairment

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

Hepatic impairment

Clearance of ondansetron is significantly reduced and serum half-life significantly prolonged in patients with moderate or severe hepatic impairment. The maximum dose for patients with moderate or severe hepatic impairment is 8 mg daily.

Method of administration

The tablets should be swallowed whole with liquid.

4.3 Contraindications

Hypersensitivity to the ondansetron or to any of the excipients listed in section 6.1.

Concomitant use with apomorphine is contraindicated (see section 4.5)

4.4 Special warnings and precautions for use

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

Ondansetron prolongs the QT interval in a dose-dependent manner (see section 5.1) and torsade de pointes has been reported in patients using ondansetron. Ondansetron should be avoided in patients with congenital long QT syndrome. It should be used with caution in patients who have or may develop prolongation of QTc, including patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias or patients taking other medicines that lead to QT prolongation or electrolyte abnormalities.

Cases of myocardial ischemia have been reported in patients treated with ondansetron. In some patients, especially on intravenous administration, symptoms appeared immediately after administration of ondansetron. Patients should be alerted to the signs and symptoms of myocardial ischemia.

Hypokalaemia and hypomagnesaemia should be corrected before starting ondansetron.

There have been reports of serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) after concomitant use of ondansetron and other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRI) and serotonin noradrenaline reuptake inhibitors (SNRIs) (see section 4.5). If concomitant treatment with ondansetron and other serotonergic drugs is clinically warranted, close observation of the patient is advised.

As ondansetron can increase large bowel transit time, patients with 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.

Paediatric population

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

When calculating the dose on weight basis and administering 3 doses at 4-hour intervals, the total daily dose will exceed a single dose of 5 mg/m^2 followed by an oral dose. The comparative efficacy of these two dosing regimens has not been investigated in clinical trials. Cross-trial comparison indicates similar efficacy for both regimens (see section 5.1)

Excipients

Patients with congenital lactase deficiency, galactosaemia or glucose-galactose intolerance must not be given this medicine unless strictly necessary. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance in other patients.

Patients who are allergic to cow's milk proteins must not be given this medicine unless strictly necessary.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

4.5 Interaction with other medicinal products and other forms of interaction

There is no evidence that ondansetron either induces or inhibits the metabolism of other drugs commonly co-administered with it. Specific studies have shown that there are no interactions when ondansetron is administered with alcohol, alfentanil, furosemide, lidocaine, morphine, propofol, temazepam, thiopental and tramadol.

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

Serotonergic Drugs

Serotonergic drugs include antidepressants that are selective serotonin reuptake inhibitors (SSRIs e.g. citalopram, escitalopram fluoxetine, fluvoxamine, paroxetine, sertraline) and serotonin noradrenaline reuptake inhibitors (SNRIs e.g. duloxetine, venlafaxine). There have been reports of patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following concomitant use of ondansetron and other serotonergic drugs (including SSRIs and SNRIs).

CYP3A4 inducers

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

Medicines affecting QT interval

Caution should be exercised when ondansetron is co-administered with drugs that prolong the QT interval or cause electrolyte abnormalities. (See section 4.4)

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 daunorubicin, doxorubicin) or trastuzumab), antibiotics (such as erythromycin), antifungals (such as itraconazole), antiarrhythmics (such as amiodarone), beta blockers (such as atenolol or timolol), haloperidol and methadone may increase the risk of arrhythmias.

Other interactions

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

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

4.6 Fertility, pregnancy and breast-feeding

Women of childbearing potential

Women of childbearing potential should consider the use of contraception.

Pregnancy

Based on epidemiological studies, ondansetron is suspected to cause orofacial malformations when used during the first trimester of pregnancy.

In one cohort study including 1.8 million pregnancies, first trimester ondansetron use was associated with an increased risk of oral clefts (3 additional cases per 10 000 women treated; adjusted relative risk, 1.24, (95% CI 1.03–1.48)).

Epidemiological studies on cardiac malformations show conflicting results. Animal studies do not indicate direct or indirect reproductive toxicity (see section 5.3).

Ondansetron should not be used during the first trimester of pregnancy.

Breast-feeding

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

4.7 Effects on ability to drive and use machines

[HA596 trade name] is unlikely to affect the ability to drive or operate machinery.

However, patients should be advised to consider if their clinical status, including any undesirable effects of the medicine, allows them to perform skilled tasks safely.

4.8 Undesirable effects

Adverse reactions [HA596 trade name] are listed below by body system or organ. Frequencies are defined as follows: very common (at least 1 in 10), common (1 in 100 to 1 in 10) uncommon (1 in 1000 to 1 in 100),

rare (1 in 10 000 to 1 in 1000), very rare (less than 1 in 10 000) or not known (frequency cannot be estimated from available data).

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)
Rare	dizziness predominantly during rapid intravenous administration
Eye disorders	
Rare	transient visual disturbances (e.g. blurred vision) predominantly during intravenous administration
Very rare	transient blindness predominantly during intravenous administration
Cardiac disorders	
Uncommon	arrhythmias, chest pain with or without ST segment depression, bradycardia
Rare	QTc prolongation (including torsade de pointes)
Not known	myocardial ischemia (see section 4.4)
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

Paediatric population

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

Reporting of suspected adverse reactions

Health care providers are asked to report adverse reactions that may be linked to a medicine, to the marketing authorisation holder, or, if available, to the national reporting system. Reports of suspected adverse reactions to a medicine are important for the monitoring of the medicine's benefits and risks.

4.9 Overdose

Symptoms and Signs

There is limited experience of ondansetron overdose. In most cases, symptoms were similar to those already reported in patients receiving recommended doses (see section 4.8). Reported effects include visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second-degree AV block.

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

Paediatric population

Paediatric cases consistent with serotonin syndrome have been reported after inadvertent oral overdoses of ondansetron (exceeded estimated ingestion of 4 mg/kg) in infants and children aged 12 months to 2 years.

Management

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

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Serotonin (5-HT3) antagonists, ATC Code: A04AA01

Mechanism of action

Ondansetron is a potent, highly selective 5-HT3 receptor-antagonist.

Its precise mode of action in the control of nausea and vomiting 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-HT3 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-HT3 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.

Ondansetron does not alter plasma prolactin concentrations.

Clinical safety and efficacy

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

QT Prolongation

The effect of ondansetron on the QTc interval was evaluated in a double-blind, randomised, placebo- and positive- (moxifloxacin-) controlled, crossover study in 58 healthy men and women.

Ondansetron doses included 8 mg and 32 mg infused intravenously over 15 minutes. At the highest tested dose of 32 mg, the maximum mean (upper limit of 90% CI) difference in QTcF from placebo after baseline correction was 19.6 ms (21.5 ms). At the lower tested dose of 8 mg, the maximum mean (upper limit of 90% CI) difference in QTcF from placebo after baseline-correction was 5.8 ms (7.8 ms). In this study, there were no QTcF measurements greater than 480 ms and no QTcF prolongation was greater than 60 ms.

Paediatric population

Chemotherapy-induced nausea and vomiting

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 (S3AB3006). On the days of chemotherapy, patients received either ondansetron 5 mg/m^2 intravenously and ondansetron 4 mg orally after 8 to 12 hours or ondansetron 0.45 mg/kg intravenously and placebo orally after 8 to 12 hours. After 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/m^2 intravenously and ondansetron 4 mg orally) and 41% (0.45 mg/kg intravenously and placebo orally). After chemotherapy, both groups received 4 mg

ondansetron syrup twice daily for 3 days. There was no difference in the overall incidence or nature of adverse events between the two treatment groups.

A double-blind randomised placebo-controlled trial (S3AB4003) 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/m^2 intravenous together with 2–4 mg dexamethasone orally
- 71% of patients when ondansetron was administered as syrup at a dose of 8 mg together with 2–4 mg dexamethasone orally on the days of chemotherapy.

After chemotherapy, both groups received 4 mg ondansetron syrup twice daily for 2 days. There was no difference in the overall incidence or nature of adverse events between the two treatment groups.

The efficacy of ondansetron in 75 children aged 6 to 48 months was investigated in an open-label, non-comparative, single-arm study (S3A40320). All children received three 0.15-mg/kg doses of intravenous ondansetron, administered 30 minutes before the start of chemotherapy and then 4 and 8 hours after the first dose. Complete control of emesis was achieved in 56% of patients.

Another open-label, non-comparative, single-arm study (S3A239) investigated the efficacy of one intravenous dose of 0.15 mg/kg ondansetron followed by 2 oral ondansetron doses of 4 mg for children aged under 12 years and 8 mg for children aged at least 12 years (total 28 children). Complete control of emesis was achieved in 42% of patients.

Postoperative nausea and vomiting

The efficacy of a single dose of ondansetron in the prevention of postoperative nausea and vomiting was investigated in a randomised, double-blind, placebo-controlled study in 670 children aged 1 to 24 months (post-conceptual age at least 44 weeks, weight at least 3 kg). Patients were scheduled to undergo elective surgery under general anaesthesia and had an ASA status up to III. A single dose of ondansetron 0.1 mg/kg was administered within 5 minutes following induction of anaesthesia. The proportion of patients who had 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%, $p < 0.0001$).

Four double-blind, placebo-controlled studies have been performed in 1469 male and female patients (2 to 12 years of age) undergoing general anaesthesia. Patients were randomised to either single intravenous doses of ondansetron (0.1 mg/kg for paediatric patients weighing 40 kg or less, 4 mg for paediatric patients weighing more than 40 kg; number of patients = 735) or placebo (number of patients = 734). Study drug was administered over at least 30 seconds, immediately prior to or following anaesthesia induction. Ondansetron was significantly more effective than placebo in preventing nausea and vomiting. The results of these studies are summarised in table below.

Prevention and treatment of PONV in Paediatric Patients – Treatment response over 24 hours

Study	**Endpoint**	**Ondansetron**	**Placebo**	**p value**
S3A380	no emetic episodes, rescue or withdrawal	68%	39%	≤ 0.001
S3GT09		61%	35%	≤ 0.001
S3A381		53%	17%	≤ 0.001
S3GT11	no nausea	64%	51%	0.004
S3GT11		60%	47%	0.004

5.2 Pharmacokinetic properties

Pharmacokinetic variable	**Mean value* (±standard deviation)**
	Ondansetron
Maximum concentration (Cmax) ng/mL	35.9 ± 9.5

Area under the curve ($AUC_{0-\infty}$), a measure of the extent of absorption ng.h/mL	244 ± 87
Time to attain maximum concentration (T_{max}) hour	1.70 ± 0.67

Absorption

Following oral administration, ondansetron is passively and completely absorbed from the gastrointestinal tract and undergoes first-pass metabolism. Peak plasma concentrations of about 30 ng/mL are attained about 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. Mean bioavailability in healthy male subjects, following oral administration of a single 8-mg tablet, is around 55 to 60%. Bioavailability, following oral administration, is slightly enhanced by the presence of food but unaffected by antacids.

The disposition of ondansetron following oral, intramuscular and intravenous 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 intramuscular and intravenous administration of ondansetron.

A 4-mg intravenous infusion of ondansetron given over 5 minutes results in peak plasma concentrations of about 65 ng/mL. Following intramuscular administration of ondansetron, peak plasma concentrations of about 25 ng/mL are attained within 10 minutes of injection.

Following administration of ondansetron suppository, plasma ondansetron concentrations become detectable between 15 and 60 minutes after dosing.

Concentrations rise in an essentially linear fashion, until peak concentrations of 20–30 ng/mL are attained, typically 6 hours after dosing. Plasma concentrations then fall, but at a slower rate than observed following oral dosing due to continued absorption of ondansetron. The absolute bioavailability of ondansetron from the suppository is about 60% and is not affected by gender. The half-life of the elimination phase following suppository administration is determined by the rate of ondansetron absorption, not systemic clearance and is about 6 hours. Females show a small, clinically insignificant, increase in half-life in comparison with males.

Distribution

Ondansetron is not highly protein bound (70-76%).

Biotransformation and Elimination

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 (the debrisoquine polymorphism) has no effect on ondansetron's pharmacokinetics. The pharmacokinetic properties of ondansetron are unchanged on repeat dosing.

Special Patient Populations

Gender

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).

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 patients aged 1 to 4 month was reported to average 6.7 hours compared to 2.9 hours for patients aged 5 to 24 month and 3 to 12 years. The differences in pharmacokinetic parameters in patients aged 1 to 4 months 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 compared to 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 normalised by body weight, the values for these parameters were similar between the different age groups. Use of weight-based dosing compensates for age-related changes and is effective in normalising systemic exposure in paediatric patients.

Population pharmacokinetic analysis was performed on 428 subjects (cancer patients, surgery patients and healthy volunteers) aged 1 month to 44 years following intravenous administration of ondansetron. Based on this analysis, systemic exposure (AUC) of ondansetron following oral or intravenous dosing in children and adolescents was comparable to adults, except for infants aged 1 to 4 months. Volume of distribution was related to age and was lower in adults than in infants and children. Clearance was related to weight but not to age except for infants aged 1 to 4 months. It is unclear if there was an additional reduction in clearance related to age in infants 1 to 4 months or simply inherent variability due to the low number of subjects studied in this age group. Since patients aged less than 6 months will only receive a single dose for postoperative nausea and vomiting, decreased clearance is not likely to be clinically relevant.

Elderly

Early Phase I studies in healthy elderly volunteers showed a slight age-related decrease in clearance, and an increase in half-life of ondansetron. However, wide inter-subject variability resulted in considerable overlap in pharmacokinetic parameters between young (aged under 65 years) and elderly subjects (aged at least 65 years) and there were no overall differences in safety or efficacy between young and elderly cancer patients in chemotherapy-induced nausea and vomiting clinical trials to support a different dosing recommendation for the elderly.

Based on more recent ondansetron plasma concentrations and exposure-response modelling, a greater effect on QTcF is predicted in patients aged at least 75 years compared to young adults. Specific dosing information is provided for patients aged over 65 years and over 75 years for intravenous dosing.

Renal impairment

In patients with renal impairment (creatinine clearance 15–60 mL/minute), both systemic clearance and volume of distribution are reduced following intravenous administration of ondansetron, resulting in a slight, but clinically insignificant, increase in elimination half-life (5.4 hours). A study in patients with severe renal impairment who required regular haemodialysis (studied between dialyses) showed ondansetron's pharmacokinetics to be essentially unchanged following intravenous administration.

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 hours) and oral bioavailability approaching 100% due to reduced pre-systemic metabolism. The pharmacokinetics of ondansetron following administration as a suppository have not been evaluated in patients with hepatic impairment.

5.3 Preclinical safety data.

Embryo-fetal development studies in rats and rabbits did not show evidence of harm to the fetus when ondansetron was administered during the period of organogenesis at about 6 and 24 times, respectively, the maximum recommended human oral dose of 24 mg daily, based on body surface area. In a prenatal and postnatal developmental toxicity study, there were no effects on pregnant rats and the prenatal and postnatal development of their offspring, including reproductive performance at about 6 times the maximum recommended human oral dose of 24 mg daily, based on body surface area.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet: Lactose monohydrate
Microcrystalline cellulose
Pregelatinised starch
Sodium starch glycolate
Colloidal anhydrous silica
Magnesium stearate

Film coat: Titanium dioxide
Hypromellose
Triacetin
Iron oxide yellow

This medicine is essentially 'sodium-free'. It contains less than 1 mmol sodium (23 mg) per tablet

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30ºC. Protect from light.

6.5 Nature and contents of container

Blisters

Aluminium blister card sealed with aluminium foil, containing 10 or 30 tablets. Available in packs of 1x10, 2x10, 3x10, 5x10, 6x10, 9x10, 10x10 and 30x10 tablets or 1x30, 2x30, 3x30 and10x30 tablets.

6.6 Special precautions for disposal and other handling

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

7. SUPPLIER

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8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

HA596

9. DATE OF PREQUALIFICATION

27 August 2015

10. DATE OF REVISION OF THE TEXT

March 2025

References

Ondansetron 4 mg film-coated tablets (Bristol Laboratories Ltd): summary of product characteristics. MHRA; 20 August 2024 (https://products.mhra.gov.uk, accessed 20 September 2024).

Ondansetron film-coated tablets (Bristol Laboratories Ltd): package leaflet. MHRA; August 2022 ((https://products.mhra.gov.uk, accessed 20 September 2024).

Zofran injection: summary of product characteristics. MHRA; 30 January 2023 (https://products.mhra.gov.uk, accessed 20 September 2024).

Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products