AUSTRALIAN PRODUCT INFORMATION
GRANISETRON KABI (GRANISETRON HYDROCHLORIDE)

1 NAME OF THE MEDICINE
Granisetron hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Granisetron hydrochloride is a white to off-white crystalline powder which is freely soluble in water and sodium chloride 0.9% at 20°C.

Granisetron Kabi Concentrated Injection contains granisetron hydrochloride equivalent to granisetron free base 1 mg/mL.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM
Concentrated Injection

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
- Prevention and treatment of nausea and vomiting induced by cytotoxic chemotherapy in adults and children.
- Prevention of nausea and vomiting induced by radiotherapy in adults only.
- Prevention and treatment of post-operative nausea and vomiting in adults only.

4.2 DOSE AND METHOD OF ADMINISTRATION
Granisetron Kabi is for intravenous administration only.

Chemotherapy induced nausea and vomiting
Adults: For prevention of nausea and vomiting in adults, a single dose of 3 mg of Granisetron Kabi should be administered as an intravenous infusion, diluted in 20 to 50 mL infusion fluid and administered over 5 minutes prior to the start of chemotherapy. The infusion should be commenced within 30 minutes before the start of chemotherapy.

Prophylactic administration of Granisetron Kabi should be completed prior to the start of chemotherapy.

In clinical trials, the majority of patients have required only a single dose of granisetron to control nausea and vomiting over 24 hours.

For treatment of established nausea and vomiting in adults, a single dose of 1 mg of Granisetron Kabi should be administered as a 5 minute infusion. Further treatment doses of Granisetron Kabi may be administered if required at least 10 minutes apart. The maximum dose of Granisetron Kabi is 9 mg/24 hours.

In trials, patients have received a total dose of 160 µg/kg of intravenous granisetron in one day. There is also clinical experience in patients receiving a total of 600 µg/kg of intravenous Granisetron Kabi over 5 days.

Children: The recommended intravenous dose of Granisetron Kabi in children is 20 µg to 40 µg/kg body weight (up to 3 mg), which should be administered as an intravenous infusion, diluted in 10 to 30 mL infusion fluid and administered over 5 minutes, no more than 30 minutes before the start of chemotherapy.

Radiotherapy induced nausea and vomiting
Adults: For prevention of nausea and vomiting in adults, a single dose of 3 mg of Granisetron Kabi should be administered as an intravenous infusion, diluted in 20 to 50 mL infusion fluid and administered over 5 minutes prior to the start of radiotherapy.

Post-operative Nausea and Vomiting
Adults: Prevention of post-operative nausea and vomiting in adults:
A single dose of 1 mg of Granisetron Kabi should be administered as a 30 second intravenous injection prior to induction of anaesthesia.

Treatment of established post-operative nausea and vomiting in adults:
A single dose of 1 mg of Granisetron Kabi should be administered by intravenous injection over 30 seconds.

Patients undergoing anaesthesia for elective surgery have received a total dose of 3 mg granisetron intravenous in one day.

Special dosage instructions
No dosage adjustment is required for the elderly, renally impaired or hepatically impaired (see section 5.2 *Pharmacokinetics in Special Populations*).

Combination with a corticosteroid
The efficacy of IV Granisetron Kabi can be enhanced by the addition of an intravenous corticosteroid. For example, 8 to 20 mg of dexamethasone administered prior to the start of cytostatic therapy, or 250 mg methlyprednisolone prior to the start of chemotherapy and again just after the end of chemotherapy.

Preparation and administration
Granisetron Kabi is for single use in one patient only. Discard any residue. The injectable presentations contain no antimicrobial agent.

Adults: To prepare the dose of 3 mg, withdraw 3 mL from the ampoule and dilute with a compatible infusion fluid (see below) to a total volume of 20 to 50 mL, in any of the following solutions: sodium chloride 0.9%, glucose 5%, Lactated Ringers Solution.

Children: To prepare the dose of 40 µg/kg, the appropriate volume (up to 3 mL from the ampoule) is diluted with infusion fluid (as for adults) to a total volume of 10 to 30 mL.

Granisetron Kabi has been shown to be stable for at least 24 hours in the cited solutions when stored at ambient temperature in normal indoor illumination (natural daylight supplemented by fluorescent light). In order to reduce microbiological

hazards it is recommended that the prepared infusion be commenced as soon as practicable after its preparation and should be completed within 24 hours.

As a general precaution, Granisetron Kabi should not be mixed in solution with other drugs other than dexamethasone sodium phosphate.

Granisetron is compatible with dexamethasone sodium phosphate in a concentration of 10 to 60 µg/mL of Granisetron and 80 to 480 µg/mL dexamethasone phosphate diluted in sodium chloride 0.9% or Glucose 5% solution over a period of 24 hours.

Parenteral drug products should be inspected visually for particulate matter and discolouration before administration wherever solution and container permit.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance granisetron hydrochloride, or to any of the excipients in Granisetron Kabi.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

As granisetron may reduce lower bowel motility, patients with signs of sub-acute intestinal obstruction should be monitored following administration of Granisetron Kabi.

As for other 5-HT_3 antagonists, cases of ECG modifications including QT prolongation have been reported with granisetron. The ECG changes with granisetron were minor, generally not of clinical significance and specifically, there was no evidence of proarrhythmia. However, in patients with pre-existing arrhythmias or cardiac conduction disorders, this might lead to clinical consequences. Therefore, caution should be exercised in patients with cardiac co-morbidities, on cardio-toxic chemotherapy and/or with concomitant electrolyte abnormalities.

In healthy subjects, no clinically relevant effects on resting EEG or on the performance of psychometric tests were observed after IV granisetron at any dose tested (up to 200 µg/kg).

Cross-sensitivity between 5-HT3 antagonists has been reported.

As with other 5-HT_3 antagonists, cases of serotonin syndrome (including altered mental status, autonomic dysfunction and neuromuscular abnormalities) have been reported following the concomitant use of granisetron and other serotonergic drugs. If concomitant treatment with granisetron and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised (see section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS)

Use in renal impairment
No special precautions are required

Use in hepatic impairment
No special precautions are required

Use in the elderly
No special precautions are required.

Paediatric use
See section 4.2 DOSE AND METHOD OF ADMINISTRATION.

Effects in laboratory tests
No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Granisetron does not induce or inhibit the cytochrome P_{450} drug metabolising enzyme system in rodent studies. In humans, hepatic enzyme induction with phenobarbital resulted in an increase in total plasma clearance of intravenous granisetron of approximately one-quarter.

In healthy human subjects, granisetron has been safely administered with benzodiazepines, neuroleptics, and anti-ulcer medications commonly prescribed with anti-emetic treatments. Additionally, granisetron has shown no apparent drug interaction with emetogenic cancer chemotherapies.

No specific interaction studies have been conducted in anaesthetised patients, but granisetron injections have been safely administered with commonly used anaesthetic and analgesic agents. In addition, *in vitro* human microsomal studies have shown that the cytochrome P_{450} subfamily 3A4 (involved in the metabolism of some of the main narcotic analgesic agents) is not modified by granisetron.

As for other 5-HT_3 antagonists, cases of ECG modifications including QT prolongation have been reported with granisetron. The ECG changes with granisetron were minor, generally not of clinical significance and specifically, there was no evidence of proarrhythmia. However, in patients concurrently treated with drugs known to prolong QT interval and/or are arrhythmogenic, this may lead to clinical consequences.

As with other 5-HT_3 antagonists, cases of serotonin syndrome (including altered mental status, autonomic dysfunction and neuromuscular abnormalities) have been reported following the concomitant use of granisetron and other serotonergic drugs. If concomitant treatment with granisetron and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE)

4.6 FERTILITY, PREGNANCY AND LACTATION

Use in pregnancy (Category B1)
There is no experience of granisetron in human pregnancy. Animal studies have shown no teratogenic effects in rats or rabbits at intravenous doses up to 9 and 3 mg/kg/day respectively. Time weighted systemic exposure (maternal plasma AUC) at the highest intravenous dose in rats was about 7 times higher than that in humans at therapeutic dose levels, but insufficient data are available for a similar comparison in rabbits. Because of the low safety margin indicated by the animal studies and

because animal reproduction studies are not always predictive of human response, granisetron should be used during pregnancy only if clearly needed.

Use in lactation
A study in lactating rats showed that the rate of excretion in milk after IV dosing is less than 1% of the dose per hour, and that at least some of this is absorbed by the offspring.

There are no data on the excretion of granisetron in human breast milk, therefore use of the drug during lactation should be limited to situations where the potential benefit to the mother justifies the potential risk to the nursing infant.

Effects on fertility
No data available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
There are no data on the effect of granisetron on the ability to drive, however there have been occasional reports of somnolence in clinical studies which should be taken into account.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)
Granisetron has been well tolerated in human studies. The most frequently reported adverse reactions for granisetron are headache and constipation which may be transient. ECD changes including QT prolongation have been reported with granisetron (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

As with other 5-HT_3 antagonists, cases of serotonin syndrome (including altered mental status, autonomic dysfunction and neuromuscular abnormalities) have been reported following the concomitant use of granisetron and other serotonergic drugs. If concomitant treatment with granisetron and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE and section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS)

The following table gives the comparative frequencies of the five commonly reported adverse events (>3%) in patients receiving granisetron injection, 40 µg/kg, in single-day chemotherapy trials. These patients received chemotherapy, primarily cisplatin, and intravenous fluids during the 24-hour period following granisetron injection administration.

Table 1 : Principal adverse events in clinical trials single-day chemotherapy

Adverse Event	Percent of patients with an event	
	Granisetron Injection[1] 40 µg/kg (n = 1,268)	Comparator[2] (n = 422)

Headache	14%	6%
Asthenia	5%	6%
Somnolence	4%	15%
Diarrhoea	4%	6%
Constipation	3%	3%

[1] Adverse events were generally recorded over 7 days post-granisetron Injection administration.

[2] Metoclopramide/dexamethasone and phenothiazines/dexamethasone.

In the absence of a placebo group, there is uncertainty as to how many of these events should be attributed to granisetron, except for headache, which was clearly more frequent than in comparison groups.

Adverse events reported in clinical trials other than those in the table above are listed below. All adverse experiences are included in the list except those reported in terms so general as to be uninformative and those experiences for which the drug cause was remote. It should however be noted that causality has not necessarily been established.

Events are listed within body systems and categorised by frequency according to the following definitions: very common events reported at a frequency of greater or equal to 1/10 patients; common events reported at a frequency of greater or equal to 1/100 patients; uncommon events reported at a frequency of less than 1/100 but greater or equal to 1/1,000 patients; rare events reported at a frequency of less than 1/1,000 patients.

Body as a whole: *Common:* fever

Cardiovascular: *Common:* hypertension;
Uncommon: QT prolongation
Rare: hypotension, arrhythmias, sinus bradycardia, atrial fibrillation, varying degrees of A-V block, ventricular ectopy including non-sustained tachycardia, ECG abnormalities, angina pectoris, syncope.

Hypersensitivity: *Uncommon:* hypersensitivity reactions (e.g. anaphylaxis, shortness of breath, hypotension, urticaria).

Gastrointestinal disorders: *Very common:* constipation

Hepatic: *Common:* transient increases in AST and ALT. These are generally within the normal range and have been reported at similar frequency in patients receiving comparator therapy.

Nervous system: *Very common: headache*
Common: agitation, anxiety, CNS stimulation, dizziness, insomnia, somnolence;

Uncommon: serotonin syndrome
Rare: extrapyramidal syndrome (only in presence of other drugs associated with this syndrome).

Dermatological: *Uncommon:* skin rashes.

Special Senses: *Common:* taste disorder.

Other common events often associated with chemotherapy also have been reported: leukopaenia, decreased appetite, anaemia, alopecia, thrombocytopaenia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE
There is no specific antidote for Granisetron Kabi. In the case of overdosage, symptomatic treatment should be given. Overdose with the intravenous formulation has occurred. Overdosage of up to 38.5 mg of granisetron as a single injection has been reported without symptoms or only the occurrence of a slight headache.

For information on the management of overdose, contact the Poisons Information Centre on 131126.

5 PHARMACOLOGICAL PROPERTIES
5.1 PHARMACODYNAMIC PROPERTIES
Mechanism of Action
Granisetron is a potent anti-emetic and highly selective antagonist of 5-hydroxytryptamine (5-HT_3) receptors. Radioligand binding studies have demonstrated that granisetron has negligible affinity for other receptor types, including 5-HT, alpha$_1$ and alpha$_2$, beta-adrenoreceptors, histamine H_1, picrotoxin, benzodiazepine, opioid and dopamine D_2 binding sites.

Antagonism of 5-HT_3 receptors located peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone in the area postrema, is one of the most effective pharmacological methods of preventing cytotoxic-induced emesis. Mucosal enterochromaffin cells release serotonin during chemotherapy-induced emesis. Serotonin stimulates 5-HT_3 receptors and evokes a vagal afferent discharge to subsequently induce emesis. Animal pharmacological studies have shown that in binding to 5-HT_3 receptors, granisetron blocks serotonin stimulation, and is effective in alleviating the retching and vomiting evoked by cytostatic treatment. In the ferret animal model, a single granisetron injection prevented vomiting due to high-dose cisplatin or arrested vomiting within 5 to 30 seconds.

In healthy subjects, granisetron produced no consistent or clinically important changes in pulse rate, blood pressure or ECG. Granisetron did not affect the plasma levels of prolactin or aldosterone.

Granisetron injection showed no effect on gut transit time in normal volunteers given single doses up to 200 µg/kg.

Clinical Trials

Single-day chemotherapy

Cisplatin-Based Chemotherapy: In a double-blind, placebo-controlled study in 28 patients, granisetron injection administered as a single intravenous infusion of 40 µg/kg, was significantly more effective than placebo in preventing nausea and vomiting induced by cisplatin chemotherapy.

Granisetron injection was also evaluated in a randomised dose response study of cancer patients receiving cisplatin >75 mg/m^2. Additional chemotherapeutic agents included: anthracyclines, carboplatin, cytostatic antibiotics, folic acid derivatives, methylhydralazine, nitrogen mustard analogs, podophyllotoxin derivatives, pyrimidine analogs and vinca alkaloids. Granisetron injection doses of 10 and 40 µg/kg were superior to 2 µg/kg in preventing cisplatin-induced nausea and vomiting.

Moderately Emetogenic Chemotherapy: Granisetron injection, 40 µg/kg, was compared with the combination of chlorpromazine (50 to 200 mg/24 hours) and dexamethasone (12 mg) in patients treated with moderately emetogenic chemotherapy, including primarily carboplatin >300 mg/m^2, cisplatin 20 to 50 mg/m^2 and cyclophosphamide >600 mg/m^2. Granisetron injection was superior to the chlorpromazine/dexamethasone regimen in preventing nausea and vomiting.

Repeat cycle chemotherapy

In an uncontrolled trial, 75 cancer patients received granisetron injection, 40 µg/kg prophylactically, for three cycles of chemotherapy. 31 patients received it for at least four cycles and 8 patients received it for at least six cycles. Granisetron Injection efficacy remained relatively constant over the first six repeat cycles, with complete response rates (no vomiting and no moderate or severe nausea in 24 hours) of 65 to 70%. No patients were studied for more than 9 cycles.

During the clinical trial programme, there were 26 reports of cardiac arrest. Of these, 25 were considered to be unrelated to granisetron administration and were attributed to the underlying disease or concomitant cytostatic medication with time of onset up to 4 months after initiation of therapy.

In the one case where granisetron administration was causally related, the patient experienced cardiac arrest as part of a severe allergic reaction. This event was not related to any direct cardiotoxic effect of granisetron. A full recovery was made on discontinuation of therapy.

Of the 40 reports of renal failure, causality was assigned in 37 cases. All 37 were considered to be unrelated to granisetron administration and were attributed to the underlying disease or cisplatin, a known nephrotoxic agent.

Paediatric

Granisetron injection 20 µg/kg was compared to chlorpromazine (0.5 mg/kg) plus dexamethasone (2 mg/m^2) in 88 paediatric patients treated with ifosfamide >3 g/m^2

for two or three days. Granisetron was administered on each day of ifosfamide treatment. At 24 hours, 22% of granisetron patients achieved complete response (no vomiting and no moderate or severe nausea in 24 hours) compared with 10% on the chlorpromazine/dexamethasone regimen. The median number of vomiting episodes was significantly lower in patients receiving granisetron than in patients receiving the combination of chlorpromazine/dexamethasone (1.5 vs 7).

The efficacy and safety of intravenous doses of 10, 20 and 40 µg/kg were compared in 80 children undergoing highly emetogenic chemotherapy. The median number of vomiting episodes were 2, 3, and 1 and the percentage of patients with no more than one vomiting episode were 48%, 42% and 56% respectively. There were no dose related safety issues.

Very limited data are available on the use of granisetron in the treatment of children with nausea and vomiting induced by cytostatic chemotherapy.

Radiotherapy

Granisetron injection 3 mg was compared to a combination of intravenous (IV) metoclopramide (20 mg), dexamethasone (6 mg/m^2), and lorazepam (2 mg) in 30 patients to assess the efficacy and safety of granisetron for prophylaxis and control of radiotherapy induced emesis. The study drug was administered 1 hour before starting radiation therapy. The anti-emetic efficacy of granisetron was significantly more effective than the standard regimen of metoclopramide/dexamethasone/lorazepam in preventing radiotherapy induced emesis.

Very limited data are available on the use of granisetron in the treatment of nausea and vomiting induced by radiotherapy.

Post-operative nausea and vomiting Prevention:

Prevention: Granisetron injection 0.1 mg, 1.0 mg or 3.0 mg, was compared to placebo in a double-blind study to assess the efficacy and safety of granisetron injection in the prevention of postoperative nausea and vomiting (PONV) in 538 patients. Granisetron injection was given as a 30 second injection prior to induction of anaesthesia. Patient groups receiving 1.0 mg and 3.0 mg granisetron injection responded significantly better than those in the 0.1 mg group.

Treatment: granisetron injection 0.1 mg, 1.0 mg or 3.0 mg, was compared to placebo in a double-blind study to assess the efficacy and safety of granisetron injection in 519 patients experiencing post-operative vomiting or severe nausea. In the 24 hour period after the day of surgery, patients receiving granisetron injection were less likely to experience nausea and vomiting than those receiving placebo.

5.2 PHARMACOKINETIC PROPERTIES

A linear pharmacokinetic relationship was found after IV administration up to 4-fold the recommended dose.

Distribution
Granisetron is extensively distributed, with a mean volume of distribution of approximately 3 L/kg; plasma protein binding is approximately 65%, and granisetron distributes freely between plasma and red blood cells.

Metabolism
Granisetron clearance is predominantly via hepatic metabolism and is rapid in most subjects. Granisetron metabolism involves N-demethylation and aromatic ring oxidation followed by conjugation. Animal studies suggest some metabolites of granisetron may also have 5-HT_3 receptor antagonist activity. However, in humans the metabolites are present in very low concentrations and are thought not to contribute to the pharmacological action.

Excretion
Mean plasma half-life of granisetron in patients is approximately 9 hours, with a wide inter-subject variability. The plasma concentration of granisetron is not clearly correlated with anti-emetic efficacy. Clinical benefit may be conferred even when granisetron is not detectable in plasma.

Urinary excretion of unchanged granisetron averages 12% of dose in 48 hours, whilst the remainder is excreted as metabolites; 47% in the urine and 34% in the faeces.

Pharmacokinetics in special populations
Elderly
In elderly subjects after single intravenous doses, pharmacokinetic parameters were within the range found for younger healthy volunteers.

Renal impairment
In patients with severe renal failure, data indicate that pharmacokinetic parameters after a single intravenous dose are generally similar to those in normal subjects.

Hepatic impairment
In patients with hepatic impairment due to neoplastic liver involvement, total clearance of Granisetron was approximately halved compared to patients without hepatic impairment. However, no dose adjustment is recommended.

5.3 PRECLINICAL SAFETY DATA
Carcinogenicity
In a 24 month carcinogenicity study, mice were treated with granisetron in the diet at 1, 5 or 50 mg/kg/day. There was a statistically significant increase in the incidence of hepatocellular carcinomas in males and of hepatocellular adenomas in females dosed with 50 mg/kg/day. The incidence of hepatic tumours was not affected at 1 mg/kg/day.

In a 24 month carcinogenicity study, rats were treated with granisetron in the diet at 1, 5 or 50 mg/kg/day (reduced to 25 mg/kg/day at week 59 because of toxicity). Systemic exposure at the highest dose level was 1.7 times higher than that in humans at the recommended dose. There was a statistically significant increase in the incidence of hepatocellular carcinomas and adenomas in males dosed with 5

mg/kg/day and above, and in females dosed with 50 mg/kg/day. No increase in liver tumours was observed in rats at a dose of 1 mg/kg/day in males and 5 mg/kg/day in females.

Genotoxicity

Experimental evidence in rats shows that granisetron exhibits the characteristics of a promoter of liver tumours with a clear no-effect dose of 1 mg/kg. The probable mechanism for this effect is sustained liver cell hyperplasia. In a study in which rats were treated for 12 months with 100 mg/kg/day, the observed promoting effects were reversible upon cessation of treatment. Additionally, there was no adverse effect on the liver of dogs treated orally for 12 months with granisetron 5 mg/kg/day.

Granisetron did not cause gene mutation in bacterial assays in *Salmonella* and *E.coli* or in a mouse lymphoma cell assay. No evidence of chromosomal damage was observed in human lymphocytes *in vitro*, or in a mouse micronucleus test. There was no evidence of DNA damage in assays of unscheduled DNA synthesis (UDS) in rat hepatocytes *in vitro*, or *ex vivo*. There was an apparent increase in UDS in HeLa cells exposed to granisetron *in vitro* when DNA synthesis was measured by scintillation counting of incorporated radioactive thymidine. However, when this test was repeated using a more definitive autoradiographic method, the test was negative for UDS. It is likely that the apparent UDS in the initial study was, in fact, a reflection of DNA synthesis in cells undergoing normal division (mitogenic activity).

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Contains: sodium chloride, citric acid monohydrate, hydrochloric acid, sodium hydroxide and water for injections.

6.2 INCOMPATABILITIES

Granisetron Kabi is a concentrated solution for infusion intended for dilution with Sodium Chloride 0.9% Injection, Glucose 5% Injection or Lactated Ringer's Solution prior to intravenous infusion. It is a clear, colourless solution free of visible particles.

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

The expiry date (month/year) is stated on the package after the word EXP.

To reduce microbiological hazard, use as soon as possible after dilution. If storage is necessary after dilution hold at 2°C to 8°C for not more than 24 hours.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store the ampoules in the original carton below 25ºC. Protect from light. Do not freeze. Single use only. Discard unused portion.

6.5 NATURE AND CONTENTS OF CONTAINER

Granisetron Kabi is available in packs of 1, 5 and 10 ampoules in the following presentations:

Granisetron Kabi 1 mg/1 mL	AUST R 159273
Granisetron Kabi 3 mg/3 mL	AUST R 159274

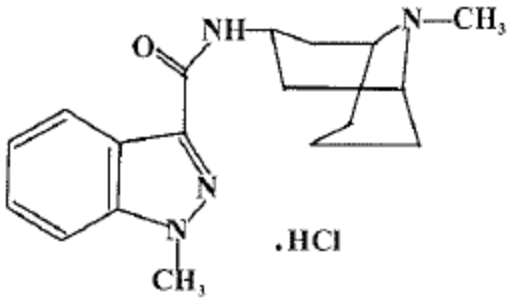
Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSIOCHEMICAL PROPERTIES

Chemical structure:



Empirical formula: $C_{18}H_{24}N_4O.HCl$

Molecular weight: 348.9

The systematic chemical name is endo-N-(9-methyl-9-azabicyclo [3.3.1] non-3-yl)-1-methyl-1H-indazole-3-carboxamide hydrochloride.

CAS Number:
107007-99-0

7. MEDICINE SCHEDULE (POISONS STANDARD)

S4- Prescription Only Medicine

8. SPONSOR

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Australia
Telephone: (02) 9391 5555

9. DATE OF FIRST APPROVAL

2 August 2010

10. DATE OF REVISION

9 October 2023

Summary table of changes

Section changed	Summary of new information
All	Minor editorial changes made.
8	NZ sponsor details removed.