DROLEPTAN® INJECTION

(DROPERIDOL)

1 NAME OF THE MEDICINE

Droperidol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Droleptan injection contains 2.5 mg/mL droperidol as the active ingredient.

Droperidol is a cream-coloured, light-sensitive, crystalline, hygroscopic substance, slightly soluble in water and alcohol, and soluble in aqueous solutions with pH < 4.

For the full list of excipients, see Section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Droleptan injection is presented as a 1 mL solution in an ampoule.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Anaesthesia

Droleptan injection is indicated to produce tranquillisation and to reduce the incidence of nausea and vomiting in surgical and diagnostic procedures; for premedication, induction, and as an adjunct in the maintenance of general and regional anaesthesia; in neuroleptanalgesia in which Droleptan injection is given concurrently with a narcotic analgesic, to aid in producing tranquillity and decreasing anxiety and pain.

Psychiatry

The management of severe agitation, hyperactivity, or aggressiveness in psychotic disorders, including schizophrenic reaction and the manic type of manic depressive illness, or in disturbed states, such as some types of acute brain syndrome and in nonpsychotic acute excitation states.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dosage should be individualised. Some of the factors to be considered in determining the dose are age, bodyweight, physical status, underlying pathological condition, use of other drugs, type of anaesthesia to be used and the surgical procedure involved.

Vital signs should be monitored routinely. To minimise the risk of ventricular arrhythmia, an electrocardiograph (ECG) should be performed and examined for evidence of QT prolongation before any operation commences. ECG monitoring should continue during the surgical procedure and subsequently for a period of time consistent

with best medical judgment. This should be at least 7 hours after the end of the procedure (see Section 4.3 Contraindications and Section 4.4 Special Warnings and Precautions for Use).

Anaesthesia

Usual *ADULT* dosage:

1. Premedication

To be appropriately modified in the elderly, debilitated and those who have received other depressant drugs - 2.5 to 10 mg may be administered intravenously 30 to 60 minutes pre-operatively.

2. Adjunct to general anaesthesia

Induction - 2.5 mg per 10 kg may be administered (usually intravenously) along with an analgesic and/or general anaesthetic.

Maintenance - 1.25 mg to 2.5 mg given intravenously (see Section 4.4 Special Warnings and Precautions for Use regarding use with concomitant narcotic analgesic indication and the possibility of widely differing durations of action).

3. Use without a general anaesthetic in diagnostic and minor surgical procedures

Administer the appropriate premedication (see Section 4.2 Dose and Method of Administration, Premedication) 30 to 60 minutes before the procedure. For maintenance as in 2, see above.

Note: When Droleptan injection is used in certain procedures, such as bronchoscopy, appropriate topical anaesthesia is still necessary.

4. Adjunct to regional anaesthesia

2.5 to 5 mg may be administered intramuscularly or by slow intravenous injection when additional sedation is required.

Usual *PAEDIATRIC* dosage:

For children two to twelve years of age a reduced dose as low as 1.0 to 1.5 mg per 10 kg is recommended for induction of anaesthesia.

See Section 4.4 Special Warnings and Precautions for Use of droperidol with other CNS depressants and in patients with altered response.

Psychiatry

ADULT dosage:

As a neuroleptic for motor restraint or relief of acute symptomatology. Droleptan injection is usually given by the intramuscular route in doses of 5 to 25 mg. For most cases, a dose of 10 to 25 mg is recommended. Repeat doses may be given every 4-6 hours if necessary.

Intravenous administration - In certain circumstances Droleptan injection may be administered by slow intravenous drip infusion in normal saline, 5% glucose or lactated ringer's solution, in doses of 50 to 125 mg daily, divided into two infusions of 250 mL, each over a period of twenty minutes.

4.3 CONTRAINDICATIONS

Droleptan injection is contraindicated in:

- Known hypersensitivity to this drug or its metabolites
- Severe central nervous system depression
- Comatose states from any cause
- Parkinson's disease
- Phaeochromocytoma
- Breast feeding

Droleptan injection should not be used in female patients with a QTc of greater than 450 msec or male patients with a QTc of greater than 440 msec (see Section 4.4 Special Warnings and Precautions for Use).

Droleptan injection is contraindicated in patients with acquired long QT interval, such as that associated with concomitant use of drugs known to prolong the QT interval, known hypokalaemia, or hypomagnesaemia, or clinically significant bradycardia (see Section 4.5 Interactions with Other Medicines and Other Forms of Interactions).

Droleptan injection is also contraindicated in patients with known congenital long QT interval or family history of congenital long QT syndrome.

Relative contraindication: acute alcohol intoxication.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Fluids and other counter measures to manage hypotension should be readily available.

The benefits of using Droleptan injection should be weighed against the potential risk.

Droleptan injection should only be used under appropriate medical supervision.

Patients with, or suspected of having, the following risk factors for cardiac arrhythmia should be carefully evaluated prior to the administration of Droleptan injection:

- A history of significant cardiac disease, including serious ventricular arrhythmia, second or third degree atrioventricular block, sinus node dysfunction, congestive heart failure or ischaemic heart disease and left ventricular hypertrophy.
- A family history of sudden death.
- Renal failure (particularly with chronic dialysis).
- Significant chronic obstructive pulmonary disease and respiratory failure.
- Risk factors for electrolyte disturbances as seen in patients taking laxatives, glucocorticoids, potassium-wasting diuretics, in association with the administration of insulin in acute settings or in patients with persistent vomiting and/or diarrhoea. In these patients, an ECG and an assessment of serum electrolytes (potassium and magnesium) and renal function should be performed as part of this evaluation and the presence of QT prolongation excluded prior to administration of droperidol. Continuous pulse oximetry

should be performed in patients with identified or suspected risk of ventricular arrhythmia and should continue for 30 minutes following single i.v. administration. In a hospital setting, ECG monitoring should be started, when possible, before the administration of Droleptan injection for anaesthesia (see Section 4.3 Contraindications). For patients with acute mania or agitation, it is recognised that performing an ECG prior to the initial dose(s) may be difficult. However, an ECG should be performed as soon as the patient's acute symptoms have subsided. Although the possibility of developing QT prolongation and torsade de pointes with the use of Droleptan injection is low, ECG monitoring and full cardiac resuscitation facilities should be available.

- Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Droleptan injection and preventive measures undertaken.

Outside the hospital setting, Droleptan injection should only be used for the management of the psychiatric crisis e.g. acute mania or severe agitation. A single injection should be administered intramuscularly (not greater than 5 mg) and the patient should then be transferred immediately to a hospital facility by an ambulance equipped for cardiac resuscitation.

As with other CNS depressant drugs, patients who have received Droleptan injection should have appropriate surveillance.

Patients with a history of alcohol abuse, or recent high intakes, are at the risk of increased arrhythmia.

If Droleptan injection is administered with a narcotic analgesic, the user should familiarise himself with the special properties of each drug, particularly with the widely differing durations of action. In addition, when such a combination is used, resuscitative equipment and a narcotic antagonist should be readily available to manage apnoea.

Narcotic analgesics may cause muscle rigidity, particularly involving the muscles of respiration. This effect is related to the speed of injection. Its incidence can be reduced by the use of slow intravenous injection. Once the effect occurs, it is managed by the use of assisted or controlled respiration and by a neuromuscular blocking drug if necessary.

The respiratory depressant effect of narcotics persists longer than their measured analgesic effect. When used with Droleptan injection, the total dose of all narcotic analgesics administered should be considered by the practitioner before ordering narcotic analgesics during recovery from anaesthesia. It is recommended that narcotics, when required, be used initially in reduced doses as low as 1/4 to 1/3 of those usually recommended.

Caution is advised if Droleptan injection is given concomitantly with strong CYP1A2 and CYP3A4 inhibitors.

Use in psychiatry

In psychiatry, the dosage should be determined on an individual basis and is best initiated and titrated under close clinical supervision. To determine the initial dose, the patient's age, the symptom severity, and the previous response to other neuroleptics should be taken into account.

Use in anaesthesia

Certain forms of conduction anaesthesia, such as spinal anaesthesia and some peridural anaesthetics, can cause peripheral vasodilatation and hypotension because of sympathetic blockade. Through other mechanisms (see Section 5.1 Pharmacodynamic Properties), Droleptan injection can also alter circulation. Therefore, when Droleptan injection is used to supplement these forms of anaesthesia, the anaesthetist should be familiar with the physiological alterations involved, and be prepared to manage them in patients selected for this form of anaesthesia.

If hypotension occurs, the possibility of hypovolaemia should be considered and managed with appropriate parenteral fluid therapy. Repositioning the patient to improve venous return to the heart should also be considered when operative conditions permit. It should be noted that in spinal and peridural anaesthesia, tilting the patient into a head-down position may result in a higher level of anaesthesia than is desirable, as well as impair venous return to the heart. Care should be exercised in moving and positioning of patients because of the possibility of orthostatic hypotension. If volume expansion with fluids together with other countermeasures does not correct the hypotension, then administration of pressor agents other than adrenaline should be considered. Adrenaline may paradoxically decrease the blood pressure in patients treated with Droleptan injection because of the alpha-adrenergic blocking action of droperidol. An adequate circulation volume should be ensured.

Since Droleptan injection is frequently used with the narcotic analgesic fentanyl, it should be noted that fentanyl may produce bradycardia which may be treated with atropine; however, fentanyl should be used with caution in patients with cardiac bradyarrhythmias.

Uses in patients with the following states

In patients with diagnosed / suspected phaeochromocytoma, severe hypertension and tachycardia have been observed after the administration of Droleptan injection. (see Section 4.3 Contraindications) Therefore, the use of Droleptan injection should be avoided in such patients.

Since Droleptan injection may decrease pulmonary arterial pressure, this fact should be considered by those who conduct diagnostic or surgical procedures where interpretation of pulmonary arterial pressure measurements might determine final management of the patient. Vital signs should be monitored routinely.

Other CNS depressant drugs, e.g. barbiturates, tranquillisers, narcotics and general anaesthetics, have additive or potentiating effects with Droleptan injection. When patients have received such drugs, the dose of Droleptan injection required will be less than usual. Likewise, following the administration of Droleptan injection the dose of other CNS depressant drugs should be reduced.

When the EEG is used for postoperative monitoring, it may be found that the EEG pattern returns to normal slowly.

Use with caution in patients with epilepsy (or a history of epilepsy) and conditions predisposing to epilepsy or convulsions.

Sleep apnoea

Sleep apnoea and related disorders have been reported in patients treated with atypical antipsychotics, with or without prior history of sleep apnoea, and with or without concomitant weight-gain. In patients who have a history of or are at risk for sleep apnoea, or who are concomitantly using central nervous system depressants, droperidol should be used with caution.

Use in hepatic impairment

Droleptan injection should be administered with caution to patients with liver dysfunction because of the importance of these organs in the metabolism and excretion of drugs.

Use in renal impairment

Droleptan injection should be administered with caution to patients with kidney dysfunction because of the importance of these organs in the metabolism and excretion of drugs.

Use in the elderly

The initial dose of Droleptan injection should be appropriately reduced in the elderly, debilitated and other poor-risk patients. The effect of the initial dose should be considered in determining incremental doses.

Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of increased risk is not known.

Droperidol is not indicated for the treatment of dementia-related behavioural disturbances.

Paediatric use

The safety of Droleptan injection in children younger than two years of age has not been established. Therefore, this drug is not recommended in this age group.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Drugs known to prolong the QT interval are contraindicated with Droleptan injection. Examples include certain antiarrhythmics, such as those of Class IA (such as quinidine, disopyramide and procainamide) and Class III (such as amiodarone and sotalol); tricyclic antidepressants (such as amitriptyline); certain tetracyclic antidepressants (such as maprotiline); certain antipsychotic medications (such as phenothiazines, pimozide and sertindole); certain antihistamines (such as astemizole and terfenadine); cisapride, bepridil, halofantrine and sparfloxacin.

Droperidol may potentiate the action of sedative drugs (barbiturates, benzodiazepines, morphinomimetics). The same applies to antihypertensive agents, so that orthostatic hypotension may ensue.

Like other sedative drugs, droperidol may potentiate respiratory depression caused by opioids. Since droperidol blocks dopamine receptors, it may inhibit the action of dopamine agonists, such as bromocriptine, lisuride, and L-dopa.

Theoretically, certain agents (e.g. phenobarbitone, carbamazepine, phenytoin), as well as smoking and alcohol consumption, which stimulate metabolising enzymes in the liver, may enhance the metabolic breakdown of neuroleptics, possibly necessitating adjustment of the dose.

Concomitant use of Droleptan injection with CYP1A2 inhibitors and/or CYP3A4 inhibitors could decrease the rate of Droleptan metabolism and prolong its pharmacological action.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

Droleptan injection is pregnancy Category C - Drugs which, owing to their pharmacological effects, have caused, or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.

Non-teratogenic class effect:

Neonates exposed to antipsychotic drugs (including Droleptan injection) during the third trimester of pregnancy are at risk of extrapyramidal neurological disturbances and/or withdrawal symptoms following delivery. There have been post market reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required medical treatment or monitoring.

Droperidol should be used during pregnancy only if the anticipated benefit outweighs the risk and the administered dose and duration of treatment should be as low and as short as possible.

Use in lactation

Butyrophenones are excreted in breast milk. If the use of Droleptan injection is essential, breast-feeding should be avoided.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Droleptan injection may impair mental and / or physical abilities for operating machinery or driving a motor vehicle. Patients should only drive or operate a machine if sufficient time has elapsed after the administration of droperidol, i.e. about 10 hours after a dose of up to 5 mg and 24 hours after higher doses.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Central nervous system

Extrapyramidal reactions - A low incidence of neuromuscular (extrapyramidal) reactions has been reported during the administration of Droleptan injection. The incidence and severity of these symptoms are related to the dose and occur at relatively high doses, but may disappear or become less severe when the dose is reduced. The reactions may be of the Parkinson type, motor restlessness, dystonia, akathisia, hyper-reflexia, opisthotonos or oculogyric crises. They are reversible by the administration of anti-parkinson drugs, such as benzatropine mesilate or diphenhydramine hydrochloride.

Tardive dyskinesia may develop in patients on antipsychotic drugs. The disorder consists of repetitive involuntary movements of the tongue, face, mouth, or jaw (e.g. protrusion of the tongue, puffing the cheeks, puckering of the mouth, chewing movements). The trunk and limbs are less frequently involved. It has been reported that fine vermicular movements of the tongue may be an early sign of the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of the drug increases. Less commonly, the syndrome can develop after relatively brief treatment periods at low doses. The risk seems to be greater in elderly patients, especially females. The

syndrome may become clinically recognizable either during treatment, upon dosage reduction or upon withdrawal of treatment.

The dosage of antipsychotic drugs should be reduced periodically (if clinically possible) and the patient observed for signs of the disorder, since the syndrome may be masked by a higher dose. In patients requiring long-term treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought.

Tardive dyskinesia may be masked when treatment is reinstituted, when the dosage is increased or when a switch is made to a different antipsychotic drug. Such masking is temporary. There is no known effective treatment for tardive dyskinesia. Anti-Parkinsonian agents usually do not alleviate symptoms. It is suggested that anti-psychotic agents be discontinued if symptoms of tardive dyskinesia appear.

Neuroleptic malignant syndrome - A potentially fatal syndrome called neuroleptic malignant syndrome has been reported in association with anti-psychotic drugs including droperidol. The syndrome is characterised by muscular rigidity, fever, hyperthermia, altered consciousness and autonomic instability (eg tachycardia, labile blood pressure, profuse sweating, dyspnoea).

The management of neuroleptic malignant syndrome should include immediate discontinuation of anti-psychotic drugs, intensive monitoring and treatment of symptoms, and treatment of any associated medical problems.

Other central nervous system effects

Drowsiness is frequently reported. Dizziness, chills and/or shivering, restlessness, isolated cases of anxiety, agitation, confusional states, and post-operative hallucinatory episodes (sometimes associated with transient periods of mental depression) may occur.

Cardiovascular

The most frequent adverse reactions reported to occur are mild to moderate hypotension and occasionally tachycardia, but these effects usually subside without treatment. However, should hypotension persist, the possibility of hypovolaemia should be considered and appropriate fluid replacement administered.

Cases of QT-interval prolongation, ventricular arrhythmias and sudden death have been reported rarely. They may occur more frequently with high doses and in predisposed patients.

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs – frequency not known.

General

When Droleptan injection is used with a narcotic analgesic, respiratory depression, apnoea and muscular rigidity can occur. If these remain untreated, respiratory arrest could occur.

In rare cases, body temperature dysregulation has been reported. Hypersensitivity reactions such as rash or angio-oedema and anaphylactic reactions have been reported rarely.

The following adverse reactions have been noted with related compounds, although a causal relationship has not been established. The physician, however, should be aware of their possible occurrence.

Haematological

Leucopenia and leucocytosis, minimal decreases in red blood cell counts, anaemia or a tendency towards lymphocytosis.

Hepatic

Impaired liver function and/or jaundice.

Skin and appendages

Maculopapular and acneform skin rashes. Isolated cases of photosensitivity and loss of hair.

Respiratory

Laryngospasm, bronchospasm and increased depth of respiration.

Endocrine

Hormonal effects of antipsychotic neuroleptic drugs include cases of hyperprolactinaemia, which may cause galactorrhoea, gynaecomastia, mastalgia and menstrual irregularities including amenorrhoea, oligomenorrhoea. Neonatal drug withdrawal syndrome have been associated with prolonged exposure in psychiatric indications. Other endocrine adverse effects include impotence, increased libido, hyperglycaemia and hypoglycaemia. Very rare cases of Syndrome of Inappropriate ADH Secretion (SIADH) have been reported.

Gastrointestinal

Anorexia, jaundice, constipation, diarrhoea, hypersalivation, dyspepsia, nausea and vomiting.

Autonomic nervous system

Dry mouth, blurred vision, urinary retention and diaphoresis.

Reporting suspected adverse effects

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

4.9 OVERDOSE

Acute toxicity - The toxic dose in man is not known.

Symptoms of overdosage

In general, the symptoms of overdosage would be an exaggeration of known pharmacological effects and adverse reactions, the most prominent of which would be:

1. Severe extrapyramidal reactions
2. Hypotension
3. Sedation (over-tranquillisation).

The patient would appear comatose with respiratory depression and hypotension that could be severe enough to produce a shock-like state. The extrapyramidal reaction would be manifested by muscular weakness or rigidity,

and a generalised or localised tremor, as demonstrated by the akinetic or agitans types respectively. Convulsions may occur at toxic doses.

Cases of QT-interval prolongation, ventricular arrhythmias and sudden death have been reported rarely.

Treatment of overdosage

Since there is no specific antidote, treatment is primarily supportive.

Immediate cardiac monitoring by ECG is recommended for any patient who has received an overdose of Droleptan injection. The ECG should be evaluated for possible QT-prolongation and the patient should be evaluated for factors that could predispose to the occurrence of torsade de pointes, such as electrolyte disturbances (especially hypokalaemia or hypomagnesaemia) and bradycardia.

In the presence of hypoventilation or apnoea, oxygen should be administered and respiration should be assisted or controlled as indicated. ECG monitoring should be instituted. A patent airway must be maintained, e.g. by use of oropharyngeal airway or endotracheal tube, or in prolonged cases of coma, by tracheostomy. Hypotension and circulatory collapse may be counteracted by use of intravenous fluids, plasma or concentrated albumin and vasopressor agents such as ephedrine or metaraminol. In case of severe extrapyramidal reactions, anti-Parkinson medication should be administered.

If Droleptan injection is ingested, gastric aspiration or introduction of emesis should be carried out immediately.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Pharmacology in animals

Droperidol is a neuroleptic drug of the butyrophenone group that also includes haloperidol.

It produces general quiescence and a reduced responsiveness to environmental stimuli in several animal species. There is little or no effect in respiration or myocardial contractile force, heart rate, and cardiac output in dogs.

The blood pressure is lowered, in part as a direct vasodilator effect and in part because of adrenergic blockade. Droperidol markedly reduces the ability of apomorphine to produce emesis in dogs. It is effective in protecting rats against experimentally induced traumatic shock and in protecting dogs against adrenaline-induced ventricular arrhythmias.

Pharmacology in humans

Droperidol produces marked tranquillisation and sedation. It also produces an antiemetic effect as evidenced by the antagonism of the emetic effect of apomorphine in dogs. It potentiates other CNS depressants, eg. pentobarbitone and narcotic analgesics such as fentanyl. It also produces mild alpha-adrenergic blockade, peripheral vascular dilatation and reduction of the pressor effect of adrenaline.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

The absorption, metabolism and excretion of tritiated droperidol following intramuscular and intravenous administration have been studied in humans.

Total radioactivity levels were measured in plasma, urine, and faeces.

Absorption

Droperidol was very rapidly absorbed following intramuscular administration.

Distribution

The distribution phase half-life for plasma was calculated as ten minutes.

Metabolism

No data available.

Excretion

The terminal plasma elimination phase half-life was 134 minutes (SD = 13 minutes). Urinary excretion accounted for approximately 75% of the radioactive dose, less than 1% being unchanged droperidol. Faecal recovery accounted for approximately 22% of the dose of radioactivity given intramuscularly, of which 50% was unchanged droperidol. These results suggest that droperidol is partly excreted in the bile.

Droperidol can produce hypotension and decrease peripheral vascular resistance. It may decrease pulmonary arterial pressure, particularly if it is abnormally high. It may reduce the incidence of adrenaline-induced arrhythmias but it does not prevent other cardiac arrhythmias. The onset of action is from three to ten minutes following intravenous or intramuscular administration. The full effect, however, may not be apparent for 30 minutes. The duration of the sedative and tranquillising effects of droperidol generally is two to four hours. Alteration of consciousness may persist as long as 12 hours.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The excipients are water for injections, mannitol and tartaric acid.

6.2 INCOMPATIBILITIES

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

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG)[1]. The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C and protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Droleptan injection is presented as a 1 mL ampoule in a carton of 10.

Phebra product code: INJ080

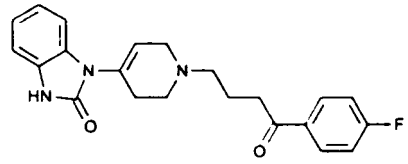
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical name: 1-[1-[4-(4-fluorophenyl)-4-oxobutyl]- 1,2,3,6-tetrahydropyridin-4-yl]- 1,3-dihydro-2H-benzimidazol-2-one. Molecular formula: $C_{22}H_{22}FN_3O_2$. The molecular weight of the compound is 379.42.

Chemical structure



CAS number
548-73-2

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine

8 SPONSOR

Phebra[2] Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia
Telephone: 1800 720 020

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[1] AUST R 46841

[2] Droleptan, Phebra and the Phi symbol are registered trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia

9 DATE OF FIRST APPROVAL

1 November 1993

10 DATE OF REVISION

5 September 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	PI reformatted to align with new form
4.4	Safety update to include Precaution for use in sleep apnoea