

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

DBL™ Hyoscine Injection 0.4 mg/mL Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DBL Hyoscine Injection BP is a sterile solution of Hyoscine hydrobromide trihydrate in Water for Injections. Each mL contains 0.4 mg of Hyoscine hydrobromide trihydrate in Water for Injections.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

DBL Hyoscine Injection BP is a clear, colourless to straw coloured, sterile solution.

The pH of the solution is between 3.8 and 4.2.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DBL Hyoscine Injection BP is indicated as a preoperative medication to produce sedation and amnesia. It is also used preoperatively to inhibit salivation and excessive secretions of the respiratory tract.

Hyoscine hydrobromide is also indicated for the treatment of selected cases of nausea and vomiting resulting from motion sickness, although oral or transdermal administration is more frequently used for this indication.

4.2 Dose and method of administration

Adult dose: The usual adult dose is 0.3 - 0.6 mg given i.m., s.c., or i.v. This dose may be repeated 3 - 4 times a day. When used as an antiemetic doses up to 1 mg have been administered. A reduced dosage may be required in elderly or debilitated patients or those with hepatic or renal insufficiency.

Paediatric dose: The usual paediatric dose is 6 mcg/kg body weight, or 200 mcg/m² surface area, i.m., s.c., or i.v.

Method of Administration

DBL Hyoscine Injection BP is administered by the intramuscular, subcutaneous or intravenous injection. When given intravenously, the drug should be diluted with sterile water for injection and injected slowly with caution.

When used for preoperative medication, hyoscine hydrobromide should be administered 30 to 60 minutes prior to induction of anaesthesia.

4.3 Contraindications

DBL Hyoscine Injection BP is contraindicated in patients hypersensitive to hyoscine hydrobromide.

Hyoscine hydrobromide is also contraindicated in patients with glaucoma or a predisposition to glaucoma, since its effects on the eye can precipitate this condition.

Hyoscine hydrobromide is also contraindicated in patients with pyloric obstruction, paralytic ileus, and in patients with prostatic hypertrophy or urinary bladder neck obstruction, since it may lead to urinary retention in these patients.

Hyoscine hydrobromide is also contraindicated in patients with tachycardia secondary to thyrotoxicosis or cardiac insufficiency, since hyoscine hydrobromide may exacerbate the tachycardia.

4.4 Special warnings and precautions for use

Potentially alarming idiosyncratic reactions may develop following the use of therapeutic doses of hyoscine hydrobromide.

Hyoscine hydrobromide should also be administered with caution in patients with impaired metabolic, hepatic or renal function, since adverse CNS effects are more likely to occur in these groups.

Hyoscine hydrobromide should be administered with caution in patients with fever, since reduction in sweating may inhibit heat loss and lead to hyperpyrexia.

Hyoscine hydrobromide should be administered with caution in patients undergoing cardiac surgery, and in patients with cardiac disease, since the transient increase in heart rate which may be caused by hyoscine hydrobromide may be undesirable in these circumstances.

Use in the elderly

Hyoscine hydrobromide should be administered with caution in elderly patients, since CNS effects are more likely to occur.

Paediatric use

Care should be taken in titrating the dose of hyoscine hydrobromide in children as they are more likely than adults to experience adverse events.

Interference with laboratory tests

Gastric acid secretion test

Administration of cholinergics including hyoscine hydrobromide is not recommended in the 24 hours prior to the test since anticholinergics may antagonize the effects of the drugs used in the evaluation of gastric acid secretory function.

Neuroradiological tests

Mydriasis and cycloplegia may affect the results of neuroradiological tests for intracranial neoplasm, subdural haematoma or aneurysm.

4.5 Interaction with other medicines and other forms of interaction

Anticholinergic agents

Concurrent use of hyoscine hydrobromide and anticholinergic agents may result in an intensification of the anticholinergic effect.*Antihistamines*

Concurrent use of hyoscine hydrobromide and antihistamines possessing anticholinergic effects may result in an intensification of the anticholinergic effect.

Concurrent use of hyoscine hydrobromide and antihistamines possessing CNS depression effects may result in a potentiation of the CNS depression and increased sedation.

Belladonna alkaloids

Concurrent use of hyoscine hydrobromide and belladonna alkaloids may result in an intensification of the anticholinergic effect.

CNS depression-producing medications

Concurrent administration of hyoscine hydrobromide and drugs producing CNS depression may result in potentiation of the CNS depression, and increased sedation.

Cyclopropane

Concurrent administration of hyoscine hydrobromide and cyclopropane may result in ventricular arrhythmias.

Monoamine Oxidase (MAO) Inhibitors

Concurrent use of hyoscine hydrobromide and MAO inhibitors possessing anticholinergic effects may result in an intensification of the anticholinergic effect.

Concurrent use of hyoscine hydrobromide and MAO inhibitors possessing CNS depression effects may result in a potentiation of the CNS depression and increased sedation.

Oral medications

Since hyoscine hydrobromide decreases gastrointestinal tone and gastric secretions, it may affect the absorption of oral medications.

Phenothiazines

Concurrent use of hyoscine hydrobromide and phenothiazines possessing anticholinergic effects may result in an intensification of the anticholinergic effect.

Concurrent use of hyoscine hydrobromide and phenothiazines possessing CNS depression effects may result in a potentiation of the CNS depression and increased sedation.

Procainamide

Concurrent use of procainamide and hyoscine hydrobromide may result in additive antivagal effects on AV node conduction.

Tricyclic antidepressants

Concurrent use of hyoscine hydrobromide and tricyclic antidepressants possessing anticholinergic effects may result in an intensification of the anticholinergic effect.

Concurrent use of hyoscine hydrobromide and tricyclic antidepressants possessing CNS depression effects may result in a potentiation of the CNS depression and increased sedation.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

Category B2¹

Labour: Parenteral administration of hyoscine hydrobromide before the onset of labour may cause CNS depression in the neonate and may contribute to neonatal haemorrhage due to reduction in Vitamin K-dependent clotting factors in the neonate.

Lactation

Small quantities of hyoscine hydrobromide may be excreted into breast milk. Hyoscine hydrobromide may also inhibit lactation. Therefore hyoscine hydrobromide is not recommended for use during lactation.

¹ *Category B2: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increased frequency of malformations or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.*

4.7 Effects on ability to drive and use machinery

Hyoscine hydrobromide may impair mental alertness, physical coordination or visual acuity. Patients should be warned against activities such as driving a car or operating machinery whilst affected by hyoscine hydrobromide.

4.8 Undesirable effects

Cardiovascular system: bradycardia (at low doses), initial tachycardia followed by bradycardia (at higher doses), hypotension, arrhythmia.

Central Nervous system: sedation, drowsiness, irritability, disorientation, hallucinations, impairment of memory and concentration, dizziness, confusion, tremor, acute toxic psychosis, restlessness, delirium, excitement.

Symptoms of CNS depression predominate at therapeutic doses. Symptoms of CNS stimulation predominate at higher doses, and at therapeutic doses in the presence of pain.

Gastrointestinal system: dry mouth, constipation, nausea, vomiting.

Genito-urinary system: difficulty in urinating.

Ocular: blurred vision, mydriasis, closed angle glaucoma.

Skin and appendages: rashes, erythema, redness or irritation at injection site

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

Clinical features

Symptoms associated with overdosage of hyoscine hydrobromide include CNS stimulation (restlessness, confusion, excitement, incoordination, disorientation, memory disturbances, hallucinations, paranoid and psychotic reactions), tachycardia, hyperpyrexia, blurred vision, mydriasis, rapid respiration or respiratory difficulties.

Severe overdosage may cause coma, respiratory depression, cardiac arrhythmia, and may result in death.

Treatment

Treatment of overdose involves the following measures:

- symptomatic and supportive therapy
- diazepam or other short acting benzodiazepine or barbiturate may be given to control CNS stimulation

- if hyperthermia occurs, dissipation of heat should be undertaken (i.e. by cold baths)

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Hyoscine is a belladonna alkaloid. Hyoscine hydrobromide is a tertiary amine antimuscarinic agent, which competitively antagonizes acetylcholine. The main pharmacologic actions of hyoscine hydrobromide are a decrease in the production of salivary, bronchial and sweat gland secretions, dilated pupils (mydriasis), paralysis of accommodation (cycloplegia), a decrease in micturition, a decrease in gastrointestinal tone and gastric secretion, and bradycardia although transient tachycardia may be observed at higher doses.

The effects of hyoscine hydrobromide differ from those of atropine in that hyoscine hydrobromide has a more potent effect on the iris, ciliary body and some secretory glands than atropine, and a less potent effect on the heart, intestine and bronchial muscle. Its effect on the gastrointestinal tract have led to its use as an antispasmodic in irritable bowel syndrome. Unlike atropine, hyoscine hydrobromide usually produces CNS depression at therapeutic doses, although CNS stimulation occurs at higher doses, and may also occur when hyoscine hydrobromide is used in the presence of pain. Hyoscine hydrobromide does not usually produce the increased respiration rate or blood pressure observed with atropine administration.

Clinical trials

No data available

5.2 Pharmacokinetic properties

Hyoscine hydrobromide is rapidly absorbed after intramuscular or subcutaneous administration. It is reported to cross the placenta, and also crosses the blood brain barrier. After intramuscular administration, the onset of action is approximately 30 minutes and the duration of action is approximately 4 hours. Hyoscine hydrobromide is almost completely metabolized in the liver, and excreted in the urine, although it is reported that small amounts are excreted in the breast milk.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

Reproductive and developmental toxicity

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections.

6.2 Incompatibilities

Hyoscine hydrobromide is reported to be incompatible with alkalies, and with methohexitone sodium.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25°C. Protect from light

6.5 Nature and contents of container

| STRENGTH | PACK SIZE |
|----------|-----------|
|----------|-----------|

| | |
|-----------|----------|
| 0.4 mg/mL | 5 x 1 mL |
|-----------|----------|

6.6 Special precautions for disposal and other Handling

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

Compatibilities

For intravenous injection hyoscine hydrobromide should be diluted in sterile water for injection.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Pfizer New Zealand Limited
P O Box 3998

Auckland, New Zealand, 1140
Toll Free Number: 0800 736 363

9. DATE OF FIRST APPROVAL

19 Mar 1987

10. DATE OF REVISION OF THE TEXT

19 February 2021

Summary table of changes

| Section changed | Summary of new information |
|------------------------|---|
| 4.2 | Relocation of text |
| 4.4 | Relocation of text; addition of subsection Use in the elderly |

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