

AMYL NITRITE INHALANT

Amyl Nitrite 98%w/v (USP) inhalation, volatile liquid

PRESENTATION

Amyl Nitrite Inhalant is a rapidly acting vasodilator administered by inhalation. 0.3mL is supplied in a covered thin glass capsule which is easily crushed between the fingers. **Amyl Nitrite Inhalant** is a clear, yellowish liquid having a peculiar ethereal, fruity odour. It is volatile, even at low temperatures, and is flammable. This product is 98% w/v, stabilized with Epoxol 9.5, 2% w/v. The structural formula of amyl nitrite is $(\text{CH}_3)_2\text{CHCH}_2\text{CH}_2\text{ONO}$.

USES

Actions

Amyl nitrite causes a non-specific relaxation of smooth muscle with the most prominent actions occurring in vascular smooth muscle. This effect on vascular smooth muscle results in coronary vasodilation and decreased systemic vascular resistance and left ventricular preload and afterload. Additionally, amyl nitrite induces the formation of methemoglobin. In cases of cyanide poisoning, the methemoglobin combines with the cyanide to form nontoxic cyanmethemoglobin.

Pharmacokinetics

Amyl nitrite vapours are absorbed rapidly through the pulmonary alveoli, manifesting therapeutic effects within one minute after inhalation. The drug is metabolised rapidly, probably by hydrolytic denitration; approximately one third of the inhaled amyl nitrite is excreted in the urine.

INDICATIONS

Amyl Nitrite Inhalant is indicated for the treatment of cyanide poisoning in the conscious patient.

DOSAGE AND ADMINISTRATION

With the patient in a recumbent or seated position a capsule of **Amyl Nitrite Inhalant** is crushed between the fingers, at the dot located at the center of the inhalant and held under the patient's nose. Inhalations should be administered for up to 30 seconds every 2 minutes, using a fresh capsule each time until signs of recovery occur. Up to 8 capsules may be given if there is a delay in administering intravenous antidotes. Discard inhalant after use. Safety and effectiveness in children have not been established.

CONTRAINDICATIONS

Since it may increase intraocular and intracranial pressures, **Amyl Nitrite Inhalant** is contraindicated or should be used with great caution in patients with glaucoma, recent head trauma or cerebral haemorrhage.

Amyl Nitrite Inhalant can cause harm to the foetus when it is administered to a pregnant woman because it significantly reduces systemic blood pressure and blood flow across the maternal side of the placenta.

WARNINGS AND PRECAUTIONS

Transient episodes of dizziness, weakness, or syncope or other signs of cerebral ischemia due to postural hypotension may develop following inhalation of **Amyl Nitrite Inhalant**, particularly if the patient is standing immobile. To hasten recovery, measures which facilitate venous return such as head-low posture, deep breathing and movement of extremities may be used.

Tolerance to **Amyl Nitrite Inhalant** may develop with repeated use of the drug for prolonged periods of time.

High doses of nitrites may produce methemoglobinaemia, especially in individuals with methemoglobin reductase deficiency or other metabolic abnormality that interferes with the normal conversion of methemoglobin back to haemoglobin.

Amyl Nitrite Inhalant should be taken by the patient when seated or lying down.

Use in Pregnancy

Teratogenic effects: Animal studies have not been conducted with amyl nitrite. It is not known whether amyl nitrite can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Amyl nitrite should be given to a pregnant woman only if clearly needed.

Use in Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when amyl nitrite is administered to a nursing woman.

Drug Abuse and Dependence

Abuse: Volatile nitrites are abused for sexual stimulation, with headache as a common side-effect.

Dependence: Tolerance to nitrites can develop; conditions and duration have not been established.

ADVERSE EFFECTS

Mild, transitory headache, dizziness and flushing of the face are common with the use of **Amyl Nitrite Inhalant**. The following adverse reactions may occur in susceptible patients; syncope, involuntary passing of urine and faeces, hypotension, pallor, cold sweat, tachycardia, restlessness, weakness, vomiting and nausea. Excessively high doses of **Amyl Nitrite Inhalant** administered chronically may cause methemoglobinaemia.

Adequate long term studies to establish adverse carcinogenic potential of this drug have not been reported.

INTERACTIONS

Taking **Amyl Nitrite Inhalant** after drinking alcohol may worsen side effects and may cause severe hypotension and cardiovascular collapse.

OVERDOSAGE

Symptoms

Inhaled doses of 5 to 10 drops of **Amyl Nitrite Inhalant** may cause violent flushing of the face, accompanied by a feeling of imminent bursting of the head and very excessive heart action. The inhalation of larger amounts may produce a feeling of suffocation and muscular weakness. Symptoms comparable to shock may be produced (such as weakness, restlessness, sweating, pallor, nausea, vomiting, syncope and incontinence) attributable to pooling of blood in the postarteriolar vessels and failure of the venous blood to return to the heart.

Treatment

Measures which facilitate venous return such as head-low posture, deep breathing and movement of extremities may be used. The use of epinephrine aggravates the shock-like reaction. Methylene blue should be injected for treatment of severe methemoglobinaemia with dyspnea. When treating cyanide poisoning, methylene blue is contraindicated where nitrites cause iatrogenic methemoglobinaemia.

For information on the management of overdose, contact 0800 764 766 (0800 POISON) in New Zealand or the Poisons Information Centre on 12 11 26 in Australia.

PHARMACEUTICAL PRECAUTIONS

Amyl Nitrite Inhalant is very flammable. Keep away from heat and open flame. Do not use where it might become ignited. The capsule contents should be protected from light.

Storage should be in a cold place (2°C - 8°C for 36 months or 8°C - 15°C for 24 months).

MEDICINE CLASSIFICATION

Prescription Medicine;

- except when sold to a person who holds Controlled Substances Licence (issued under section 95B of the Hazardous Substances and New Organisms Act 1996) authorizing the person to possess cyanide;
- except when sold to an exempt laboratory covered by a Hazardous Substances and New Organisms Act 1996 approved code of practice.

PACKAGE QUANTITIES

Amyl Nitrite Inhalant is furnished in covered glass capsules. Each capsule contains 0.3mL of 98% w/v amyl nitrite. It is supplied in boxes of 12.

NAME AND ADDRESS

Distributed in New Zealand by

Baxter Healthcare Limited
33 Vestey Drive
Mt Wellington
Auckland.

PO Box 14-062
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DATE OF PREPARATION

2 April 2014

Based on JamesAlexander Corp Amyl Nitrite Inhalant USP.

Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.