Astrowan Injection
(Atropine Sulfate)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Astrowan Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Atropine Sulfate... 1mg
(USP Specification)

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Horses, Cattle, Dogs and Cats

4.2 Indications for use, specifying the target species

As a parasympatholytic for use in horses, cattle dogs and cats. As a partial antidote to organophosphorus poisoning.

4.3 Contraindications

Should not be used in patients with a known hypersensitivity (allergy) to atropine, in patients with jaundice or internal obstruction.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i. Special precautions for use in animals Atropinisation of the patient should be carefully monitored by clinical observation.

ii Special precautions for the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the doctor the label.

Wash hands after use. iii

Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Anticholinergic effects may be expected to continue into the recovery phase from anaesthesia.

4.7 Use during pregnancy, lactation or lay

Animal teratology and reproductive studies have demonstrated no adverse effects. Caution is recommended when used during early pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

There has been a literature report that the co-administration of anticholinergics (atropine) with alpha 2 receptor agonists such as medetomidine or xylazine as sedatives/pre-medication in dogs can result in tachycardia and continuing hypertension. No adverse clinical reports have been received relating to this possible effect.

4.9 Amount(s) to be administered and administration route

As a parasympatholytic by subcutaneous injection:

e.g. Horses	400kg	20-40 ml	(30-60 µg/kg)
e.g. Dogs	10kg	0.5-0.8 ml	(30-50 µg/kg)
e.g. Cats	4 kg	0.2-0.3 ml	(30-50 µg/kg)
e.g Cattle	400kg	20-40ml	(30-60 µg/kg)

As a partial antidote to organophosphorous poisoning:

Severe cases:
A partial dose (a quarter) may be given by intramuscular or slow intravenous injection and the remainder given by subcutaneous injection.
Less severe cases:
The whole dose is given by subcutaneous injection.
All species:
25 to 200 µg/kg body weight repeated until clinical signs of poisoning are relieved. Several sequential injections may be required, depending on the severity of the poisoning. The frequency of the dose administered should be such that the recurrence of moderate or severe signs of poisoning are
treated, typically at 3 to 4 hour intervals.
Atropine is only effective several minutes after administration and maximum effect may be delayed to some 5 to 10 minutes after injection.
Atropinisation of the patient should be carefully monitored by clinical observation.
Other antidotes may also be employed.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Symptoms: Signs are a combination of central and peripheral effects of atropinisation. Early signs are characterised by marked excitement. (Therapeutic overdose is relatively uncommon).
Treatment: Excitement may be relieved by a suitable sedative. Peripheral effects may be relieved by a physiological antidote, such as pilocarpine. In later stages of overdosage or poisoning, a medullary stimulant and artificial respiration may be required.

4.11 Withdrawal period(s)

Nil.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Belladonna alkaloids, tertiary amines

ATC Vet Code:

QA03BA01

5.1 Pharmacodynamic properties

Atropine is a tertiary amine alkaloid which has peripheral and central antimuscarinic effects.
It first stimulates and then depresses the CNS, and has anti-spasmodic effects on smooth muscle. Atropine depresses the vagus, thereby increasing the heart rate, and is used in anaesthesia pre-medication regimens to diminish the risk of vagal inhibition and to reduce salivary and bronchial secretions. It is used in the treatment or management of bradycardia and asystole. Atropine and other antimuscarinic drugs prevent the muscarinic side-effects of anticholinesterases, which are used to reverse the effects of non-depolarising neuromuscular blocking agents. Atropine reduces tremor and muscular rigidity, for example in Parkinsonism. Atropine has cyclopegic and mydriatic properties.
Atropine is a partial antidote to organophosphorus poisoning.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Acepromazine maleate, chlorpromazine hydrochloride, heparin sodium.
Alkalis, tannic acid, and salts of mercury.

6.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.3 Special precautions for storage

Store below above 25ºC. Protect from light. Keep out of reach of children.
This product does not contain any anti-microbial preservative. Any solution remaining in the vial after withdrawal of the required dose should be discarded.

6.4 Nature and composition of immediate packaging

100ml glass vial, with a rubber stopper and aluminium flip off-seals.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 119877

9. DATE OF FIRST AUTHORISATION DATE:

Date of Reg.: 23-01-2024

10. DATE OF REVISION OF THE

30-07-2024

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
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