LAVOISIER ATROPINE Sulfate 0.25mg/1ml - 0.50mg/1ml - 1mg/1ml

QUALITATIVE AND QUANTITATIVE COMPOSITION

SPECIALTY DOSE	***0.25mg/1ml***	***0.50mg/1ml***	***1mg/1ml***
ATROPINE SULFATE	0.25 mg	0.50 mg	1.00 mg
Sodium chloride	8.90 mg	8.80 mg	8.50 mg
Hydrochloric acid... ……..s.q.…	pH 3.3 à 5.0	pH 3.3 à 5.0	pH 3.3 à 5.0
Water for injectable preparations ……..s.q…	1 ml	1 ml	1 ml

PHARMACEUTICAL FORM

Injectable solution

THERAPEUTIC INDICATIONS

- Preanesthesia: protection against vagal manifestations (bradycardia following induction).
- Auriculoventricular block (AVB) or atrioventricular Block.
- Infarctus: prevention and treatment of auriculoventricular blocks and sinusal bradycardias.
- Symptomatic treatment of acute painful episodes of functional disorders related to digestive tract and bile ducts.
- Symptomatic treatment of spasmodic and painful episodes of urinary tract.

Dose 1 mg/1 ml: specific additional indication

- Specific antidote in acute intoxication with anticholinesterasic (organo-phosphorated insecticides and carbamates) or with parasympathomimetic or cholinomimetic drugs.

POSOLOGY AND ADMINISTRATION

Subcutaneous, slow intravenous, or intramuscular routes according to indications.
Administration of this product under strict medical supervision.

- *Antispasmodic (SC route):*
  . Adults: 0.25 to 1 mg every 6 hours, maximal dose: 2 mg/24 hours.
  . Pediatric patients (children over 6 years old): 0.50 mg in a single dose.
  . Pediatric patients (children aged 2 to 6 years): 0.25 mg in a single dose.

- *Preanesthesic medication (SC injection):*
  . Adults: 1 mg.
  . Pediatric patients (children aged 30 months to 15 years): 0.1 mg to 0.5 mg.
  . Pediatric patients (infants aged 4 weeks to 30 months): 0.1 mg to 0.3 mg.

- *Cardiology (slow IV injection):*
  . Adults: 0.5 to 1 mg.

Only for LAVOISIER ATROPINE (SULFATE) 1 mg/1 ml, injectable solution:

- *Poisoning by anticholinesterasic (IM injection):*
  1 mg, repeated every 5 to 10 minutes in order to obtain pupillary dilatation, salivary secretions and transpiration pause.

CONTRA-INDICATIONS

This drug is not recommended for use in patients with:

- Hypersensitivity to any of the components
- Risk of angle closure glaucoma,
- Risk of urinary obstruction caused by prostatic hyperplasia
- Use in lactation (see pregnancy and lactation section).

This drug is not generally recommended for use in pregnancy during the third trimester (see pregnancy and lactation section).

WARNINGS AND PRECAUTIONS FOR USE

Use with caution in patients with:

- Prostatic hypertrophy,
- Renal and/or hepatic failure,
- Coronary insufficiency, arrhythmias, hyperthyroidy,
- Chronic bronchitis (caused by increased viscosity of bronchial secretions),
- Paralytic ileum, intestinal atony in elderly patients, toxic megacolon.

Do not perform any drug admixtures prior to use.

INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

Coadministrations to be considered:

- **(Other atropinic substances:** imipraminic antidepressants, sedative antihistaminics H1, anticholinergic antiparkinsonism drugs, disopyramide (class 1a antiarrythmic), mequitazine, phenothiazinic neuroleptics: Additive atropinic adverse reactions like urinary obstruction, constipation, dryness of the mouth.

PREGNANCY AND LACTATION

Use in Pregnancy

Studies in animals showed a teratogenic effect of atropine only in one species and at very high doses.
In clinical trials, use of atropine in pregnancy on a small number of women have not shown any malformative or foetoxic effects.
However, confirmatory experimental evidence is needed to evaluate the implications of an exposure during pregnancy.
As safety measure, atropine is not then recommended for use in pregnancy.

Use in lactation

As atropine passes into the breast milk, overdosage in neonates may occur with signs of neurological toxicity principally. Furthermore, atropine inhibits lactation. Therefore, if the drug must be used, lactation is contra-indicated.

Effects on ability to drive vehicles and use machines

Vehicle drivers and machine users should be warned of the risks related to accommodation disorders.

ADVERSE REACTION

- Mouth dryness,
- Thickening of bronchial secretions,
- Decrease of lachrymal secretion,
- Accommodation disorders,
- Tachycardia, palpitations,
- Constipation,
- Urine retention,
- Agitation,
- Irritability, mental confusion in elderly patients.

Posology adjustment may help these effects subside or disappear.

OVERDOSAGE

Clinical signs: dryness of the mouth, mydriasis, accommodation paralysis, drying up of secretions, and principally tachycardia, agitation, confusion and hallucinations including delirious tremens, respiratory depression.

Symptomatic treatment with cardiac and respiratory monitoring in hospital setting.

CLINICAL PHARMACOLOGY

Pharmacodynamics

ANTISPASMODIC ANTICHOLINERGIC/PREMEDICATION IN ANAESTHESIA/ANTIARYTHMIC
(A: Digestive system and metabolism)
(C: Cardiovascular system)

ANTIDOTE (V: MISCELLANEOUS) (ATROPINE SULFATE 1MG/1ML)

Pharmacokinetics

- Plasma half-life is from 2 to 2 hours 30.
  Metabolism occurs through hydrolysis and glucuroconjugation.
- Excretion path is through kidney, 1 /3 unchanged and 2 /3 glucuroconjugated form.
- Atropine crosses the placental barrier and is excreted in the maternal milk.

PHARMACEUTICAL DATA

Incompatibilities
No drug admixtures prior to use.

Shelf life
3 years

Nature and contents of container
1 ml ampoule bottle (type I glass) 10 or 100 units pack.

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

Atropine Sulfate 0.25 mg/1 ml
MA 365 317-4: 1 ml (glass) ampoule bottle - 10 units pack - Not Reimbursed by French Health Care Security

Atropine Sulfate 0.50 mg/1 ml
MA 365 319-7: 1 ml (glass) ampoule bottle - 10 units pack - Not Reimbursed by French Health Care Security

Atropine Sulfate 1 mg/1 ml
MA 365 321-1: 1 ml (glass) ampoule bottle - 10 units pack - Not Reimbursed by French Health Care Security

Hospital Packaging:

Atropine Sulfate 0.25 mg/1 ml
MA 365 318-0: 1 ml (glass) ampoule bottle - 100 units pack - Approved for institutions

Atropine Sulfate 0.50 mg/1 ml
MA 365 320-5: 1 ml (glass) ampoule bottle - 100 units pack - Approved for institutions

Atropine Sulfate 1 mg/1 ml
MA 365 322-8: 1 ml (glass) ampoule bottle - 100 units pack - Approved for institutions

HOW SUPPLIED

List I

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