

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADENAME OF THE MEDICINAL PRODUCT
CONTRATHION 2 PER CENT, powder and solvent for injectable solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Powder

PRALIDOXIME METHYLSULPHATE.....3.225 g
(equivalent quantity of PRALIDOXIME2.000 g)

Solvent

Sodium chloride0.900 mg
Water for injections qs 100 ml

Powder and solvent for 100 ml of reconstituted solution

3. PHARMACEUTICAL FORM

Powder and solvent for injectable solution.

4. CLINICAL DATA

4.1 Therapeutic indications

Organophosphate anticholinesterase derivatives poisoning.

4.2 Posology and route of administration

Intravenous route in emergencies.

Intramuscular, subcutaneous or oral route if the poisoning does not constitute an emergency.

* The solution should be prepared extemporaneously by transferring 10 ml of solvent to the powder vial.

Adults:

* Intravenous route (either undiluted in a slow injection at 1 ml/min, or in an infusion following dilution of the solution in either glucose solution or physiological saline), intramuscular route, subcutaneous route:

- at the first injection, the usual dose of 200 to 400 mg of pralidoxime may be increased to 2 g as a function of the efficacy achieved;

- a dose of up to 400 mg/hour should be maintained as necessary.

* Oral route: 1 to 3 g of pralidoxime every 5 hours.

Children:

- at the first injection, the usual dose is 20 to 40 mg/kg of pralidoxime depending on severity of poisoning and response to treatment;

- a dose of up to 10 mg/kg/hour should be maintained as necessary.

Renally impaired patients:

Dosage reduction is required in patients with impaired renal function.

4.3 Contraindications

This medicinal product is contraindicated in the event of:

-hypersensitivity to pralidoxime

4.4 Warnings and special precautions for use

Warnings:

The efficacy of pralidoxime varies according to the different classes of organophosphate insecticides. Poisoning with carbamate anticholinesterase insecticides should not be treated with pralidoxime since non-covalent binding with acetyl cholinesterase is of a low energy and is rapidly reversible.

Precautions for use

* Ingestion of milk or fats enhances absorption of organophosphates.

* The sooner pralidoxime is administered after poisoning, the higher it's efficient.

It has little effect if the time elapsed between poisoning and the start of treatment is greater than 36 hours.

* Dosage reduction is required in patients with impaired renal function.

* Atropine is generally given concurrently with pralidoxime; pupil size and heart rate should be monitored continuously throughout the course of treatment.

4.5 Interactions with other medicaments and other forms of interaction

4.6 Pregnancy and lactation

There are no reliable animal teratogenesis data.

There are no relevant data to allow assessment of malformation or foetal toxicity associated with pralidoxime when given during pregnancy.

However, this medicinal product may be prescribed during pregnancy where necessary.

In the absence of data concerning passage of this medicinal product into breast milk, breast-feeding should be stopped during administration of this medicinal product.

4.7 Effects on ability to drive vehicles and operate machines

The attention of vehicle drivers and machine operators in particular is drawn to the risk of visual disturbance associated with the use of this medicinal product.

4.8 Adverse effects

- Visual disturbance: diplopia, blurred vision,
- Malaise, dizziness, headache, tachycardia.

4.9 Overdose

In extremely high doses, pralidoxime could aggravate neuromuscular blockade resulting from organophosphate poisoning.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ANTIDOTE

(V: various)

Pralidoxime: antidote for organophosphates (poisons acting indirectly on the neurovegetative system by inactivation through phosphorylation of enzymes involved in the regulation of nervous transmission). Pralidoxime binds to alkyl phosphate group in alkyl-phosphorylated cholinesterase detaching it from acetyl cholinesterase, resulting in regeneration of the latter.

5.2 Pharmacokinetic properties

Pralidoxime is weakly absorbed from the gastrointestinal tract.

Diffusion into the central nervous system is weak (action is restricted to regeneration of neuromuscular junction enzymes).

Metabolism is hepatic.

Excretion via the renal tubules results in rapid elimination within a few hours after administration.

5.3 Preclinical safety data

6. PHARMACEUTICAL DATA

6.1 Incompatibilities

Not applicable.

6.2 Shelf-life

3 years.

6.3 Special storage conditions

Store protected from light.

6.4 Nature and contents of container

15-ml neutral type-II glass vial, closed with a chlorobutyl rubber stopper.

10-ml neutral type-I glass ampoule.

6.5 Instructions for use and handling

Not applicable

7. PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

302 525-9: 10 vials of powder (colourless glass) + 10 ampoules (10-ml) of solvent (colourless glass).



8. PRESCRIBING AND DISPENSING CONDITIONS

9. MARKETING AUTHORISATION HOLDER

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53, rue Villiers de l'Isle Adam
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10. DATE OF APPROVAL / REVISION

29 September 1997/ 4 June 2002