

ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SODIUM CALCIUM EDETATE SERB 50 mg / ml, solution for I.V. injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium calcium edetate 50 mg

For 1 ml of solution for injection.

One ampoule of 10 ml contains 500 mg of sodium calcium edetate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for I.V. injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lead poisoning.

4.2 Posology and method of administration

Intravenous route: **slow intravenous infusion**.

Acute situations: 1 to 2 ampoules per day, usually during 5 days.

After a rest period of 7 days, start another treatment course for 5 days, with 1 to 2 ampoules per day.

The content of each ampoule must be administered by slow intravenous infusion, diluted in 250 ml of isotonic saline or glucose solution.

4.3. Contraindications

This medicinal product is contraindicated in case of:

- hypersensitivity to the active substance (sodium calcium edetate), or to any of the excipients mentioned in section 6.1,
- renal impairment,
- combination with digitalis.

4.4 Special warnings and precautions for use

Precautions for use

- The injection must be performed slowly as an infusion (1 hour) due to the irritant effects and the risk of thrombophlebitis.

- Due to the risk of tubular disorders, it is crucial to assess patient's renal function before carrying out the detoxification and to monitor it during the treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated combinations :

+ Digitalis

Risk of serious or fatal cardiac arrhythmias, with calcium salts administered by I.V. injection.

Combinations to be taken into account :

+ Thiazide diuretics :

Risk of hypercalcemia via decreased calcium urinary excretion.

4.6. Pregnancy and lactation

Pregnancy

Animal studies have demonstrated a teratogenic effect.

There are no or limited amount of data to assess possible malformative or foetotoxic effect of sodium calcium edetate when administered during pregnancy.

Despite this, this medicinal product may be prescribed during pregnancy if needed.

Breast-feeding

Due to the lack of data regarding the excretion of this medicinal product in human milk, breast-feeding should be avoided during its use.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

- Renal tubular necrosis,
- Exceptional reactions which may occur during the first hours following the injection: fever with malaise, vomiting and headache, which are observed particularly with too quick injection, and also transient hypotension and nasal congestion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (ANSM) and Regional Pharmacovigilance Centres network (Website: www.ansm.sante.fr).

4.9. Overdose

High doses of sodium calcium edetate may lead to acute tubular necrosis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: ANTIDOTE, code ATC V03AB03

(V: Various)

Sodium calcium edetate is a chelating agent that has the property of combining with heavy metallic ions leading to stable complexes in which the metal is hidden and loses completely its ionic activity and thus its toxicity.

5.2 Pharmacokinetic properties

Sodium calcium edetate is not metabolized in the body. It is excreted by glomerular filtration. In 24 hours, 72% of the injected product is found as chelates form in urines.

5.3 Preclinical safety data

Non clinical data obtained from conventional safety pharmacology studies and from toxicology studies with repeated administrations did not reveal any particular risk for humans.

Several studies have demonstrated that repeated injections of sodium calcium edetate in pregnant rat leads to foetal malformations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special precautions.

6.5. Nature and contents of container

10 ml type I colourless glass ampoule bottle. Box of 10 ampoules.

6.6. Special precautions for disposal and other handling

No special precautions.

7. MARKETING AUTHORISATION HOLDER

SERB

40 avenue George V
75008 Paris
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

301 679-2: 10 ml in an ampoule (colourless glass), Box of 10 ampoules (marketed).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 September 1997 / 29 September 2012

10. DATE OF REVISION OF THE TEXT

30 April 2014 / V2

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND SUPPLY

List II.