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

Posology

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.

Method of administration

Intravenous route: **slow intravenous infusion**.

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

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

4.4 Special warnings and 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.

This medicinal product contains 61.5 mg sodium per ampoule, equivalent to 3% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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 Fertility, 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.

Fertility

No fertility studies have been performed.

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

The most serious reported side effect is renal tubular necrosis.

The table below lists the adverse events reported with Sodium Calcium Edetate.

Frequencies are defined as: Very common (≥ 1/10); Common (≥ 1/100 to <1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to <1/1,000); Very rare (<1/10,000); Frequency not known (cannot be estimated from the available data)

MedDRA System Organe Class	**MedDRA Prefered Term**	**Frequency**
Nervous system disorders	Headache*	Frequency not known
Vascular disorders	Transient hypotension	Frequency not known
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Frequency not known
Gastrointestinal disorders	Vomiting*	Frequency not known
Renal and urinary disorders	Renal tubular necrosis	Frequency not known

General disorders and administration site conditions	Malaise*	Frequency not known
	Pyrexia*	Frequency not known

Except, renal tubular necrosis, these reactions may occur during the first hours following the injection.

* These reactions are observed particularly with too quick injection.

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 Agence nationale de sécurité du médicament et des produits de santé (ANSM) and Regional Pharmacovigilance Centres network Website: www.signalement-sante.gouv.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, ATC code: **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 requirements

7. MARKETING AUTHORISATION HOLDER

SERB
40 avenue George V
75008 Paris
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

34009 301 679 2 2: 10 ml in an ampoule (colourless glass), Box of 10 ampoules (marketed).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 September 1997
Date of latest renewal: 29 September 2012

10. DATE OF REVISION OF THE TEXT

03/08/2020 V1

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND SUPPLY

List II.