SERB
LABORATOIRES
www.serb-labo.com

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SUCCICAPTAL 200 mg, capsule.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	per capsule	*per pack*
Succimer	200 mg	3 g

Excipients: lactose, magnesium stearate, anhydrous colloidal silica
Capsule shell: gelatin, titanium dioxide
Capsule size: n°1

3. PHARMACEUTICAL FORM

Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Treatment of lead and mercury poisoning.

4.2 Posology and method of administration

Adults

The dosage is 10 mg/kg (or 350 mg/m²) to be administered every 8 hours for 5 days (i.e. 30 mg/kg/day), and then 10 mg/kg or 350 mg/m² every 12 hours for 2 weeks (i.e. 20 mg/kg/day).
The dosage must not exceed 1.80 g/day in adults.

Children

The dosage is 10 mg/kg (or 350 mg/m²) to be administered every 8 hours for 5 days (i.e. 30 mg/kg/day), then 10 mg/kg or 350 mg/m² every 12 hours for 2 weeks (i.e. 20 mg/kg/day).

The doses as a function of bodyweight are therefore as follows:

Bodyweight (kg)	Dose * (mg)
8-15	100
16-23	200
24 - 34	300
35-44	400
> 45	500

* administered every 8 hours for 5 days, and then every 12 hours for 2 weeks.

4.3 Contraindications

This medicinal product is generally not recommended for use during pregnancy or lactation (see §Pregnancy and lactation).

4.4 Special warnings and precautions for use

Warning
This medicinal product contains lactose, and is therefore contraindicated in a context of congenital galactosaemia, of glucose or galactose malabsorption syndrome, or of lactase deficiency.

4.5 Interactions with other medicinal products and other forms of interaction

Pregnancy: in the absence of data concerning the passage of succimer across the placental barrier, it is inadvisable to administer this medicinal product during pregnancy.

Breast-feeding: use during lactation is not advisable, due to the fact that succimer has the effect of eliminating heavy metals.

4.7 Undesirable effects

- Nausea, vomiting.
- Diarrhoea or constipation.
- Possible unpleasant odour and loss of appetite.
- Rash on the skin and mucosae.
- Rhinitis and cough.

4.8 Overdose

Given the short follow-up time of the clinical use of succimer, no treatment can currently be recommended for an overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ANTIDOTE/HEAVY METAL CHELATOR
(V: miscellaneous)

5.2 Pharmacokinetic properties

Succimer increases the urinary excretion of heavy metals.

6. PHARMACEUTICAL PARTICULARS

6.1 Special precautions for storage

Protect from light and moisture.

7. PRESCRIPTION AND DISPENSING CONDITIONS

List I. The initial prescription of this medicine is restricted to a hospital setting.

8. PRESENTATION AND ADMINISTRATIVE NUMBER

365 710-8: 15 capsules in a heat-sealed blister (PVC/Aluminium)

9. MARKETING AUTHORISATION HOLDER

Laboratoires SERB
53 Rue Villiers de l'Isle Adam
75020 PARIS. France

9. DATE OF AUTHORISATION/REVISION

2 November 2004