

SUCCICAPTAL[®] 100 mg, capsule

SUCCICAPTAL[®] 200 mg, capsule

Succimer



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SUCCICAPTAL[®], capsule is and what it is used for
2. What you need to know before you take SUCCICAPTAL[®], capsule
3. How to take SUCCICAPTAL[®], capsule
4. Possible side effects
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■ 1. WHAT SUCCICAPTAL[®], capsule IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group - ATC code V03AB

This medicine is an antidote, (also named "counterpoison") and heavy metals chelating agent (*it fixes heavy metals as lead and mercury present in your organism*).

Therapeutic indications

It is used to treat lead and mercury poisoning.

■ 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SUCCICAPTAL[®], capsule

If you have been told by your doctor that you have an intolerance to some sugars, contact him before taking this medicinal product.

Do not take SUCCICAPTAL[®], capsule

- If you are allergic to the active substance (succimer) or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, you must ask your doctor or pharmacist.

Warnings and precautions

In absence of data, this medicine must be taken with precaution if you suffer from renal or hepatic function impairment (*dysfunction of kidney or liver*).

Talk to your doctor or pharmacist before taking SUCCICAPTAL[®], capsule.

Other medicines and SUCCICAPTAL[®], capsule

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

It is not recommended to take this medicine during pregnancy or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No effect on the ability to drive or use machines is awaited with this medicinal product.

SUCCICAPTAL[®], capsule contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

■ 3. HOW TO TAKE SUCCICAPTAL®, capsule

This medicine will initially be prescribed for you at hospital, then your doctor may renew the prescription.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Posology

The recommended dose for adults and children is:

- 10 mg/kg (or 350 mg/m²) every 8 hours for 5 days (i.e. 30 mg/kg/day).
 - Followed by 10 mg/kg (or 350 mg/m²) every 12 hours for 2 weeks (i.e. 20 mg/kg/day).
- For adults, 1.80 g/day must not be exceeded.

Dosage according to the body weight are therefore:

Bodyweight	Dose
8 – 15 kg	100 mg / dose
16 – 23 kg	200 mg / dose
24 – 34 kg	300 mg / dose
35 – 44 kg	400 mg / dose
> 45 kg	500 mg / dose

For example:

For a 20 kg child, you will give, 200mg every 8 hours for 5 days, then 200mg every 12 hours for 2 weeks.

Method of administration

Oral use.

In young children, the capsule content can be mixed in fruit juice or soft food.

Frequency of administration

Take this medicine 3 times per 24 hours (i.e. every 8 hours) for the first 5 days, then every 12 hours for 2 weeks.

Treatment duration

Duration of treatment is 19 days.

At the end of the treatment it is important to monitor the lead and mercury levels in your blood during 10 days, because there is a risk of release of heavy metals (especially accumulated in bones) observed during this period (rebound effect).

In the most severe cases, you may receive several cycles of treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

■ 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the reactions described are of mild to moderate intensity. They resolved after cessation of the therapy.

The most frequently described side effects are:

- Nausea, vomiting.
- Diarrhoea.
- Lost of appetite.
- Cutaneous eruption (*on skin*), sometimes vesicular and possibly involved mucosa membranes.
- Biological abnormalities:
 - Transient elevation of transaminases (*substances produced by the liver*)
 - Increase of zinc and copper amount in urines.

Other possible side effects can happen:

- Unpleasant breath and urine odour.

Rare cases of hypersensitivity reactions (*allergies*) were also reported:

- Urticaria (*itches*), sudden swelling of the face and neck with burning sensation and breath difficulties (Quinke's oedema), tongue and lips swelling.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (ANSM) and Regional Pharmacovigilance Centers network (Website: www.signalement-sante.gouv.fr). By reporting side effects, you can help provide more information on the safety of this medicine.

■ 5. HOW TO STORE SUCCICAPTAL[®], capsule

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box after {EXP}.
The expiry date refers to the last day of that month.

This medicine must be stored below 25°C and protected from light and humidity.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

■ 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SUCCICAPTAL[®], capsule contains

The active substance is succimer

One capsule of SUCCICAPTAL[®] 100 mg, capsule, contains 100 mg

One capsule of SUCCICAPTAL[®] 200 mg, capsule, contains 200 mg

The other ingredients are:

Lactose monohydrate (see section 2), magnesium stearate, anhydrous colloidal silica.

What SUCCICAPTAL[®], capsule looks like and contents of the pack

This medicine appears in the form of capsule.

One box of SUCCICAPTAL[®] 100 mg, capsule, contains 15 ivory capsules.

One box of SUCCICAPTAL[®] 200 mg, capsule, contains 15 white capsules.

Marketing Authorization Holder / Exploitant / Manufacturer

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This leaflet was last revised in March 2020.

Should you have any questions, please contact SERB at +33 (0) 805 626 997.

Detailed information on this medicine is available on the website of ANSM (France)

ansm.sante.fr.