

# CARA

## SCANDINIBSA 3% Mepivacaine Hydrochloride

Scandinibsa 3% is a local anesthetic of the amide type containing mepivacaine hydrochloride 30 mg/ml as active ingredient. Scandinibsa 3% is suitable for patients to whom addition of epinephrine (adrenaline) as a vasoconstrictor agent is contraindicated. Scandinibsa 3% is especially indicated in the following cases:

- Patients with circulatory problems
- Patients who use tricyclic antidepressants
- Patients with Hyperthyroidism.

### Contraindications

- Known allergy or hypersensitivity to local anesthetics of amide type.
- In children younger than 4 years.
- Severe impairment of the nervous impulses and conduction system of the heart (e.g grade II and III AV block, marked bradycardia).
- Acutely decompensated cardiac insufficiency (acute failure of cardiac output)
- Uncontrolled epilepsy
- Acute intermittent porphyria (a metabolism disorder)

Scandinibsa 3% should be used with particular caution in the event of:

- Severe impairment of the renal or hepatic function
- Severe heart disease
- Inflamed or infected area in the mouth
- Considerably impaired blood coagulation
- Severe untreated hypertension
- Severe anemia

### Pregnancy and lactation:

Not sufficient studies of the use of Scandinibsa 3% during pregnancy are available for evaluating the safety of its application. Especially during the early stage of pregnancy, Scandinibsa 3% should be used only after careful consideration of the benefit-risk ratio.

Relevant transfer of the components to the breast milk is not to be anticipated, as they are rapidly decomposed and eliminated.

### Driving and using machines

Scandinibsa 3% may have a mild effect on mental function and a transient effect on mobility and coordination.

### Interaction

If Ib-class antiarrhythmic drugs and Scandinibsa 3% are taken at the same time, addition of the side effects is possible.

Toxic synergism is described for central analgesics Chloroform, Ether and Thiopental.

Long treatments with antiarrhythmic drugs (used to control heart rhythm), psychopharmacologic drugs or anticonvulsants (used to control seizures) may decrease your sensitivity to anesthetics.

The use of certain disinfectants together with SCANDINIBSA 3% may cause local irritation, swelling, or oedema.

Blood coagulation inhibitors (drugs that prevent blood clotting) and anti-inflammatory drugs may increase the risk of bleeding.

### Posology and method of administration:

The smallest dose which will cause the desired anaesthetic effect should be used. The dosage should be adjusted individually according to each patient's age, weight, and general health condition.

### Posology:

Each cartridge of Scandinibsa 3% contains 54 mg of mepivacaine hydrochloride.

The recommended doses as well as the maximum doses for adults and children are detailed in the following table:

		ADULTS	CHILDREN	
			20-kg child	40-kg child
Recommended dose	in cartridge of 1.8 ml	1 cartridge	1/4 cartridge	1/2 cartridge
	in ml of solution	1.8	0.45	0.9
	in mg of mepivacaine hydrochloride	54	13.5	27
Maximum dose	in cartridge of 1.8 ml	5.5 cartridge	1.5 cartridge	3 cartridge
	in mg/kg	5	5	5
	in mg of mepivacaine hydrochloride	300 mg	88 mg	176 mg

### Administration:

Local injection (block or infiltration).  
For use in dental anaesthesia only.

To avoid a rapid accidental intravascular injection that may cause toxic reactions, injections must always be given slowly and after prior aspiration.

### Therapy of Overdose

#### General basic measures

Treatment must aim to maintain oxygenation, stop the seizures, and also maintain circulation.

Usually, the administration of oxygen is enough to deal with the symptoms of the seizures. Assisted ventilation should be given if required.

#### Special measures

If the seizures do not stop spontaneously in 15-20 seconds, an intravenous anticonvulsant agent should be used (diazepam IV or thiopental IV).

If cardiovascular depression is evident (hypotension, bradycardia), a vasopressor agent should be used (ephedrine IV or epinephrine IM or cortisone IV).

In case of circulatory failure, cardiopulmonary resuscitation must be performed immediately and contact an emergency physician.

### Precautionary Note

Undesirable Effects can arise from overdose, particularly as a result of inadvertent intravascular injection or abnormal absorption conditions e.g. in the inflamed or severely vascularised tissue, and manifest themselves as central nervous and/or vascular symptoms. The measures which should be taken in the event of the occurrence of the symptoms described below are summarized in the section "Therapy of overdose".

Due to the local anesthetic ingredient mepivacaine, the following side effects can occur due to the use of Scandinibsa 3%:

Milder central nervous symptoms involve metallic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, initial increase in respiratory rate.

Severe cardiovascular episodes are shown in the form of the drop in blood pressure, a seizure, bradycardia, cardiovascular arrest. Allergic reactions to mepivacaine are rare.

### STORAGE INFORMATION

Do not use the preparation after the expiry date.

### PACKAGE SIZE

50 cartridges of 1.8 ml.

Keep out of the reach of children.

### Marketing authorisation holder and manufacturer

**Manufacturer:**  
**Laboratorios Inibsa, S.A.**  
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