PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ampres 20 mg/ml solution for injection
chloroprocaine hydrochloride

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ampres is and what it is used for
2. What you need to know before you are given Ampres
3. How Ampres is used
4. Possible side effects
5. How to store Ampres
6. Contents of the pack and other information

1. What Ampres is and what it is used for

Ampres contains the active substance chloroprocaine hydrochloride. It is a type of medicine called local anaesthetic, belonging to the category of the esters of aminobenzoic acid.

Ampres is used to anaesthetise (numb) specific parts of the body and prevent pain during surgery by injecting the solution in proximity to the selected nerves.

Ampres is indicated in adults only.

2. What you need to know before you are given Ampres

Do not use Ampres:

- if you are allergic to chloroprocaine hydrochloride, medicinal products of the PABA (para-aminobenzoic acid) ester group, other ester-type local anaesthetics or any of the other ingredients of this medicine (listed in section 6),
- if there are general and specific contra-indications to regional anaesthesia regardless of the local anaesthetic used,
- if you have been told that you have decreased volume of blood (hypovolemia),
- if you have serious problems with cardiac conduction.

Warnings and precautions

If you suffer of any of these, you should discuss it with your doctor **before** being given this medicine.

- if you have ever had a bad reaction to an anaesthetic in the past
- if you have signs of skin infection or inflammation at or near the proposed site of the injection
- if you are suffering from any of the following:
    - liver disease or kidney problems
    - very low blood pressure
    - problems with clotting of your blood
    - fluid in your lungs
    - septicaemia (blood poisoning)
- if you have a heart condition (e.g. total or partial heart block, cardiac decompensation, arrhythmia)
- if you are in reduced general condition.

Other medicines and Ampres
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. In particular if you are taking any medicines for an irregular heartbeat (class III antiarrhythmics agents), for the treatment of low blood pressure (vasopressors) and for pain relief.

Also tell your doctor if you are taking any of the following medicines:
- cholinesterase inhibitors (such as antimyasthenics, cyclophosphamide)

This is because your body takes longer to get rid of Ampres if you are taking these medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice, before you are given this medicine. Ampres is not recommended for local or regional anaesthesia during pregnancy and it should be given in pregnancy only if absolutely necessary.

It is not known whether chloroprocaine passes into breast milk. If you are breast-feeding you should inform your doctor who will decide whether or not you should be given Ampres.

Driving and using machines
Ampres has a major influence on the ability to drive and use machines.

Your doctor is responsible for deciding in each case if you can drive or use machines.

Ampres contains sodium
This medicine contains 37 mg sodium (main component of cooking/table salt) in each 20 ml vial.
This is equivalent to 1.85% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ampres is used

This medicine will be given to you by your doctor.
Regional anaesthesia must only be administered by a doctor with the necessary knowledge and experience. The doctor in charge is responsible for taking the measures needed to avoid injection in a blood vessel and to know how to recognize and treat undesirable effects.

Equipment, medicines and personnel capable of dealing with an emergency, must be immediately available.

Your doctor will decide what dose is right for you. The dose will depend by your state of health, the part of the body that the medicine is injected into and what the medicine is being used for.

The maximum dose for healthy adults should not exceed 800 mg.

For patients in a compromised general condition and patients with established concomitant disorders (e.g. vascular occlusion, arteriosclerosis, diabetic polyneuropathy), a reduced dose is indicated.

Use in children and adolescents
The safety and efficacy of Ampres in children have not been established. No data are available.

Ampres may be used to produce local anaesthesia by injection of the solution around a peripheral nerve or network of nerves (Perineural use) where the planned surgical procedure should not exceed 60 minutes.

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

4. Possible side effects

Like all medicines, Ampres can cause side effects, although not everybody gets them.

Important side effects to look out for:
Sudden life-threatening allergic reactions (such as anaphylaxis) are rare, affecting up to 1 user in 1,000. Possible symptoms include sudden onset of itching, erythema (redness of skin), edema (swelling), sneezing, vomiting, dizziness, excessive sweating, elevated temperature; and shortness of breath, wheezing or difficult breathing. **If you think that Ampres is causing an allergic reaction, tell your doctor immediately.**

Other possible side effects:

Very common: may affect more than 1 in 10 people

Lowered blood pressure, feeling sick (nausea)

Common: may affect up to 1 in 10 people

Anxiety, restlessness, paresthesia, feeling dizzy, vomiting, failure of the block, difficult in passing urine.

Uncommon: may affect up to 1 in 100 people

Drop in arterial blood pressure (with high doses), high blood pressure (hypertension), slow heart beat, shaking, convulsions, numbness of the tongue, hearing problems, visual problems, speech problems, loss of consciousness.

Rare: may affect up to 1 in 1,000 people

Neuropathy, drowsiness, merging into unconsciousness and respiratory arrest, loss of bladder and bowels control, loss of perineal sensation and sexual function and permanent neurological injury.

Double vision, Uneven heartbeat (arrhythmias).

Depression of myocardium, cardiac arrest (the risk is increased by high doses or unintended intravascular injection).

Shortness of breath, wheezing and difficult breathing.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ampres

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vials and the outer carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze. Keep the vial in the outer carton, in order to protect from light.

Use immediately after first opening. For single use only.

Ampres should not be administered if noticed that the solution is not clear and free from particles.

As this medicine is limited to hospital use the disposal is carried out directly by the hospital. Medicines should not be thrown away via wastewater. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ampres contains

The active substance is chloroprocaine hydrochloride.

1 ml of solution for injection contains 20 mg of chloroprocaine hydrochloride.

1 vial with 20 ml solution, contains 400 mg of chloroprocaine hydrochloride.

The other ingredients are hydrochloric acid 3.7% (for pH adjustment), sodium chloride, water for injections.

What Ampres looks like and contents of the pack

This medicine is presented as a solution for injection. The solution for injection is a clear, colourless solution.

It comes in Type I clear colourless glass 20 ml vial.

Vials closures are bromobutyl stoppers and seals used are aluminium flip-off caps.

Box of 1 vial containing 20 ml of solution for injection.

Marketing Authorisation Holder
B. Braun Melsungen AG
Carl-Braun-Strasse 1
D-34212 Melsungen
Germany

Manufacturer
Sirton Pharmaceuticals S.P.A.
Piazza XX Settembre 2
22079 Villa Guardia
Italy

Sintetica GmbH
Albersloher Weg 11 – 48155 Münster
Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdon (Northern Ireland) under the following names:

Member State	***Product Name***
Austria	Ampres 20 mg/ml Injektionslosung

Belgium	Ampres 20 mg/ml Solution for injection - Oplossing voor injectie - Solution injectable - Injektionslösung
France	Clorotekal 20 mg/ml solution pour injection
Germany	Ampres 20 mg/ml Injektionslosung
Ireland	Ampres 20 mg/ml solution for injection
Italy	Decelex
Poland	Ampres
Spain	Ampres 20 mg/ml solución inyectable
United Kingdom (Northern Ireland)	Ampres 20 mg/ml solution for injection

This leaflet was last revised in September 2021.

The following information is intended for medical or healthcare professionals only:

The SmPC is added at the end of the printed PL as a tear-off section.