

PATIENT INFORMATION LEAFLET

PRICAİN 2% solution for i.v. injection

Administered by injection.

Sterile

- **Active ingredient:** Each 20 ml vial contains 400 mg (20 mg/mL) of prilocaine hydrochloride.
- **Excipients:** Methyl parahydroxybenzoate (as preservative) (E218), sodium chloride, sodium hydroxide or hydrochloric acid, water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this leaflet:

1. *What PRICAİN is and what it is used for?*
2. *Before you are given PRICAİN*
3. *How you will be given PRICAİN?*
4. *Possible side effects*
5. *How to store PRICAİN?*

headlines are included.

1. What PRICAİN is and what it is used for?

PRICAİN is a type of medicine used local anaesthetic.

Box of 1 vial contains 20 ml of PRICAİN.

PRICAİN is used to anaesthetise (numb) specific parts of the body and prevent pain during surgery in adults.

2. Before you are given PRĪCAĪN

DO NOT USE PRĪCAĪN in the following cases

- If you are allergic (hypersensitive) to prilocaine hydrochloride or to any of the other ingredients of PRĪCAĪN.
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine or bupivacaine).
- If you are anaemic (a blood problem which means, you have too few red blood cells).
- If you have a problem with blood pigment levels called ‘methaemoglobinaemia’.

USE CAREFULLY PRĪCAĪN in following cases:

- You have high blood pressure or heart problems.
- You have liver or kidney problems.
- You have difficulty breathing.
- You have epilepsy.
- You have an infection or inflammation at the site where the injection is to be given.
- You have ever been told that you have a rare disease of the blood pigment called ‘porphyria’ or anyone in your family has it.

If these are valid for you now or at any time in the past, please consult your doctor.

Taking PRĪCAĪN with food and drinks

It is not required any warning due to the administration route.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

If you are pregnant or think you may be pregnant or are planning to have a baby, inform your doctor before taking PRĪCAĪN.

PRĪCAĪN is not recommended in pregnant women.

Please consult your doctor or pharmacist if you notice that you are pregnant during treatment.

Lactation

Ask your doctor or pharmacist for advice before taking the medicine.

If you are breast-feeding inform your doctor before taking PRĪCAĪN.

PRĪCAĪN use during the period of breastfeeding is thought to have not a detrimental effect on children.

Driving and using machines

PRICAİN may temporarily affect your ability to physically move, you have given the PRICAİN and surgery that day, do not use any tool or machine.

Important information about some of the ingredients of PRICAİN

- PRICAİN contains 0.105 mmol of sodium. Your doctor will take this into account if you are on a sodium controlled diet.
- PRICAİN contains methyl parahydroxybenzoate (E218). Methylparahydroxybenzoate can cause allergic reactions (possibly delayed) and exceptionally bronchospasm (temporary narrowing of the lung lower respiratory tract).
- This situation may occur some time after the application of PRICAİN. In rare cases, a sudden developing skin rash and inability to breathe may occur.

Taking with other medicines

Tell your doctor if you are taking or you took recently any of the following medicines:

- Nitrate medicines
- Medicines to treat depression
- Medicines to treat migraine
- Medicines to use antipsychotic treatment (it is effective in treating psychiatric disorders such as schizophrenia, psychotic depression)
- Medicines to use against high blood pressure
- Medicines may cause increase methemoglobine amount in blood such as anti-malarial medicines (used to prevent or treat malaria), sulphonamides, nitric derivatives.
- Other local anaesthetics or medicines to treat an uneven heart beat may cause effect to normal dose of PRICAİN.

Your doctor will need to information about drugs that you take to calculate the correct dose to be given carefully.

If you are currently using or have recently used any prescription or non-prescription medication, please give information to your doctor or pharmacist about these.

3. How PRICAİN will be given?

Instructions for use and dose/ frequency of administration:

PRICAİN will be given to you by a doctor. It will be given to you as an injection. The dose that your doctor gives you will depend on the type of pain relief that you need. It will also depend on your body size, age, and physical condition and the part of your body that the medicine is being injected into. You will be given the smallest dose possible to produce the required effect.

PRICAİN will usually be given near the part of the body to be operated on. It stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain. It will start to

work a few minutes after being injected and will slowly wear off when the medical procedure is over.

PRÍCAÏN is not recommended for use in children under 6 months old.

If you have the impression that the effect of PRÍCAÏN is too strong or too weak, talk to your doctor or pharmacist.

If you use more PRÍCAÏN than you should:

Serious side effects from getting too much PRÍCAÏN need special treatment and the doctor treating you is trained to deal with these situations.

The first signs of being given too much PRÍCAÏN are usually as follows:

- Feeling dizzy or light-headed.
- Numbness of the lips and around the mouth.
- Numbness of the tongue.
- Hearing problems.
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you PRÍCAÏN as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much PRÍCAÏN, tell your doctor IMMEDIATELY.

More serious side effects from being given too much PRÍCAÏN include problems with your speech, twitching of your muscles, tremors, trembling, fits (seizures), and loss of consciousness, low blood pressure, erratic heartbeat, slowing or stopping of your heart.

Severe cases of overdose or wrong injection may cause severe tremors, seizures or unconsciousness.

If you use more than you need to use PRÍCAÏN there is a risk of acute methemoglobinemia seen.

Methemoglobinemia is a disease characterized by bruising of the lips and nail beds.

When methemoglobinemia is seen methylene blue solution can administer into a vein (intravenously) to treat effectively.

If PRÍCAÏN injection is stopped when the first symptoms, due to an overdose, appear; risk of serious adverse effects rapidly decreases.

If you use more PRÍCAÏN than you should, talk to a doctor or pharmacist.

If you forget to use PRÍCAÏN:

Not applicable.

If PRICAİN treatment stopped, effects may occur:

No data.

4. Possible side effects

Like all other medicines, PRICAİN may cause side effects in patients with hypersensitivity to any component content.

Very common : in more than 1 in 10 patients

Common : in more than 1 in 100 patients, but less than 1 in 10 patients

Uncommon : in more than 1 in 1,000 patients, but less than 1 in 100 patients

Rare : in more than 1 in 10,000 patients, but less than 1 in 1,000 patients

Unknown : Cannot be estimated with the available data

If you have any of the following side effects, stop using PRICAİN and inform your doctor IMMEDIATELY or consult the nearest emergency room:

Severe allergic reactions (Rare, less than one in 1,000 patients, but more than one in 10,000 patients):

Symptoms can include the sudden onset of the following conditions:

- Swelling of the face, lips, tongue, or throat. This may cause difficulty in swallowing
- Severe or sudden swelling of the hand, foot and wrist,
- Difficulty in breathing,
- Severe itching (with puffiness)

These are all very serious side effects. If you have one of these, you have a serious allergy to PRICAİN. You may need an emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

Very common: Low blood pressure*, feeling sick/ nausea.

Common: Vomiting*, feeling dizzy, pins and needles, slow heartbeat, high blood pressure.

Uncommon: Signs of intoxication (convulsion, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, visual problems, shakiness, tinnitus, difficulty in speaking, loss of consciousness

Rare: Heart attack, uneven heartbeat, allergic reactions (e.g. swelling on face), nervous system disorders, nerve damage, excessive increase in the amount of methemoglobin in the blood, a bluish discoloration of the nail and lip colour, inflammation of the arachnoid, difficulty breathing, double vision.

* These side effects occur more often after epidural block.

If you encounter with any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store PRİCAİN

Keep PRİCAİN out of the reach and sight of children and store in the original container.

Use in accordance with the expiration date.

Store below 25°C. Do not freeze.

Your doctor or the hospital will normally store PRİCAİN and they are responsible for the quality of the product when it has been opened if it is not used immediately. They are also responsible for disposing of any unused PRİCAİN correctly.

Do not use PRİCAİN after the expiration date which is stated on the package.

Marketing Authorisation Holder: POLİFARMA İLAÇ SANAYİ VE TİC. A.Ş.
Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1
Ergene/Tekirdağ/TURKEY

Manufacturing Site: AROMA İLAÇ SANAYİ LTD. ŞTİ.
Vakıflar OSB Mahallesi, Sanayi Caddesi, No:22/1, Kat:2
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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS.

Preservative-free solutions should be used immediately after opening the package. Remaining solution should be discarded.

Microbial contamination risk of multi-dose vials are more than disposable vial. Therefore, single-dose vials to be used wherever possible. When multi-dose vials used, appropriate control actions must be made including below to avoid contamination.

- The use of disposable sterile injection equipment
- A sterile needle and syringe be used for each entry
- Fluid or contaminated substance has been preventing entry into a multiple-dose vial containing

The multiple vials containing doses should not be used by more than 3 days after opening the vial.

PRICAIN is not recommended to re-sterilization.