PRILOTEKAL

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given PRILOTEKAL?

PRILOTEKAL contains the active ingredient prilocaine hydrochloride. PRILOTEKAL is used to anaesthetise (numb) specific parts of the body and prevent pain during surgery in adults.

For more information, see Section 1. Why am I being given PRILOTEKAL? in the full CMI.

2. What should I know before being given PRILOTEKAL?

You must not be given PRILOTEKAL if you have ever had an allergic reaction to prilocaine hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before being given PRILOTEKAL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRILOTEKAL and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is PRILOTEKAL given?

This medicine will be given to you by your doctor who will decide what dose is right for you.

The usual dose in adults is 40-60 mg of prilocaine hydrochloride (2-3 mL of PRILOTEKAL); the maximal dose is 80 mg of prilocaine hydrochloride (4 mL of PRILOTEKAL).

More instructions can be found in Section 4. How is PRILOTEKAL given? in the full CMI.

5. What should I know while being given PRILOTEKAL?

Things you should do	• Remind any doctor, pharmacist or any health professionals you visit that you were given PRILOTEKAL. • Monitor your condition and tell your doctor if your condition worsens or experience any side effects.
Things you should not do	• Do not take any other medicines, including any medicines, vitamins or supplements without checking with your doctor first.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how PRILOTEKAL affects you. • PRILOTEKAL may temporarily interfere with your reactions and muscular coordination.
Drinking alcohol	• Tell your doctor if you drink alcohol. • Do not drink alcohol while you are being given PRILOTEKAL as your blood pressure may drop making you feel dizzy and faint.
Looking after your medicine	• PRILOTEKAL will be stored by your doctor or pharmacist under the recommended conditions. • It should be kept in a cool dry place where the temperature stays below 25°C. • Do not refrigerate or freeze. • It should be kept in original package to protect from light and used immediately after first opening.

For more information, see Section 5. What should I know while being given PRILOTEKAL? in the full CMI.

6. Are there any side effects?

You may feel sick, have lowered blood pressure or a slow heart beat. Other possible effects are headache after surgery, vomiting and difficulty in passing urine. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

PRILOTEKAL

Active ingredient: *prilocaine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about PRILOTEKAL. **You should also speak to your doctor or healthcare professional if you would like further information or if you have any concerns or questions about being given PRILOTEKAL.**

Where to find information in this leaflet:

1. Why am I being given PRILOTEKAL?

PRILOTEKAL contains the active ingredient *prilocaine hydrochloride*. PRILOTEKAL is a local anaesthetic.

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

PRILOTEKAL is injected into the lower part of your spine. This quickly stops pain from your waist down for a limited period of time (short-term surgical procedures).

2. What should I know before being given PRILOTEKAL?

Warnings

You must not be given PRILOTEKAL if:

- you are allergic to prilocaine hydrochloride, other amide-type local anaesthetics or any of the ingredients listed at the end of this leaflet (always check the ingredients to make sure you can use this medicine),
- you have serious problems with cardiac conduction,
- you suffer from severe anaemia,
- you have a decompensated cardiac insufficiency,
- you have cardiogenic and hypovolemic shock,
- you have a problem with your blood called methemoglobinemia,
- you have general or specific contraindications for the technique of subarachnoid (spinal) anaesthesia.

You must not be given PRILOTEKAL into a blood vessel. PRILOTEKAL must not be used in children.

Check with your doctor if you:

- have any other medical conditions such as:
  - diseases of the central nervous system such as meningitis, polio and problems with your spinal cord due to anaemia
  - a severe headache
  - brain, spine or any other tumours
  - tuberculosis of the spine
  - recent trauma to your spine
  - very low blood pressure or low blood volume
  - problems with clotting of your blood
  - acute porphyria
  - fluid in your lungs
  - septicaemia (blood poisoning)
- take any medicines for any other condition
- have ever had a bad reaction to an anaesthetic in the past
- have a skin infection at or near the proposed site of the injection
- have a heart condition (e.g. total or partial heart block, cardiac decompensation, arrhythmia)
- have any liver or kidney problems
- suffer from neurological disorder, such as multiple sclerosis, hemiplegia, paraplegia or neuromuscular disorders
- are in reduced general condition.

Spinal 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 into a blood vessel and to know how to recognize and treat undesirable effects.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether prilocaine hydrochloride passes into breast milk. Breast-feeding can be resumed approximately 24 hours after treatment.

Children and adolescents

- PRILOTEKAL is not recommended for the use in children and adolescents. The safety and efficacy of PRILOTEKAL in paediatric population have not been established. No data are available.
- The use of PRILOTEKAL in children younger than 6 months is contraindicated due to a higher risk of developing methemoglobinemia.

PRILOTEKAL contains sodium

- This medicine contains less than 1 mmol sodium (23 mg) per dose (maximum dose equal to 4 mL of PRILOTEKAL solution for injection).

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, if you are taking any medicines for irregular heartbeat (class III antiarrhythmics agents) and for pain relief.

Tell your doctor if you are taking blood thinning tablets e.g. aspirin, warfarin.

Some medicines may interfere with PRILOTEKAL and affect how it works.

Some medicines may interfere with PRILOTEKAL and increase the risk of methemoglobinemia (a blood disorder in which too little oxygen is delivered to your cells). Types of medicines are antibiotics (sulfonamides) and some drugs for treating malaria, blood pressure (sodium nitroprusside) and heart conditions (nitroglycerine).

Medicines that may <u>increase</u> the effect of PRILOTEKAL include:

- other anesthetics
- those for irregular heartbeat (antiarrhythmics), such as lidocaine and mexiletine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PRILOTEKAL.

4. How is PRILOTEKAL given?

How much is given

- This medicine will be given to you by your doctor who will decide what dose is right for you.
- The usual dose in adults is 40-60 mg of prilocaine hydrochloride (2-3 mL of PRILOTEKAL); the maximal dose is 80 mg of prilocaine hydrochloride (4 mL of PRILOTEKAL).

When is PRILOTEKAL used

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

How is PRILOTEKAL given

- The doctor will give you PRILOTEKAL into the lower part of your spine while you are in a seated position or lying down.
- PRILOTEKAL is not recommended for the use in children and adolescents. The safety and efficacy of PRILOTEKAL in the paediatric population have not been established. The use of PRILOTEKAL in children younger than 6 months is contraindicated due to a higher risk of developing methemoglobinemia.
- For patients in a compromised general condition and with established concomitant disorders (e.g. vascular occlusion, arteriosclerosis, diabetic polyneuropathy), a reduced dose is indicated.
- In the case of compromised liver or kidney function a lower dosage range is recommended.
- PRILOTEKAL is injected via spinal route.
- Equipment, drugs and personnel capable of dealing with an emergency, must be immediately available. Rare cases of severe reactions have been reported after using local anaesthetics, even in the absence individual hypersensitivity in the patient's case history.

If you have been given too much PRILOTEKAL

If you are given too much PRILOTEKAL, you may need urgent medical attention.

The doctor giving you PRILOTEKAL will be experienced in the use of spinal local anaesthetics, so it is unlikely that you will be given an overdose. However, if the dose is accidently injected directly into the blood, you may develop problems for a short time with your sight or hearing, twitching of your muscles, tremors, trembling, fits (seizures), and loss of consciousness. Whenever you are given PRILOTEKAL, equipment will be available to care for you if an overdose happens.

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given PRILOTEKAL?

Remind any doctor, nurse or pharmacist you visit that you were given PRILOTEKAL.

Things you should not do

- Do not drink alcohol while you are being given PRILOTEKAL.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PRILOTEKAL affects you.

PRILOTEKAL may temporarily interfere with your reactions and muscular coordination.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are being given PRILOTEKAL.

If you drink alcohol while you are being given PRILOTEKAL your blood pressure may drop making you feel dizzy and faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

How to store PRILOTEKAL

- Store PRILOTEKAL below 25°C.
- Do not refrigerate or freeze.
- Use immediately after first opening.

Follow the instructions in the carton on how to take care of the medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight.

Keep it where young children cannot reach it.

When to discard PRILOTEKAL

Do not use PRILOTEKAL after the expiry date which is stated on the ampoules and the outer carton.

Getting rid of any unwanted medicine

Any remaining product must be disposed of. As it is limited to hospital use the waste drug elimination is carried out directly by the hospital. These measures will help to protect the environment.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

As with all local anaesthetics, a drop in arterial pressure may occur and cardiac frequency may decrease. You may feel sick, have lowered blood pressure or a slow heartbeat. Other possible effects are headache after surgery, vomiting and difficulty in passing urine.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders • Nausea, vomiting **Musculoskeletal and connective tissue disorders** • Back pain, temporary muscle weakness **Vascular disorders** • Lowered blood pressure, elevated blood pressure **Central Nervous System disorders** • Circumoral paresthesia, shaking, feeling of numbness affecting the tongue, hearing problems, tinnitus, visual problems **Blood and lymphatic system disorders** • Methemoglobinemia, Cyanosis	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Central Nervous System disorders • Restlessness, speech problems, disorientation, dizziness, muscle contractions, cramps, vomiting, loss of consciousness, respiratory arrest, convulsions, loss of consciousness, arachnoiditis, neuropathy, lesions of peripheral nerves **Cardiovascular system disorders** • Raised arterial pressure and pulse frequency, slow heartbeat, irregular heartbeat, drop in arterial pressure, asystole, inhibition or block of the cardiac conduction system, cardiac frequency may slow down, myocardial depression, cardiac arrest **Immune system disorders** • Anaphylactic shock, anaphylactic reactions, allergic reactions, itching **Eye disorders** • Diplopia, mydriasis **Respiratory disorders** • Respiratory depression	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

PRILOTEKAL solution for injection is unlikely to cause serious side effects unless it is accidentally injected in the wrong way or used together with other local anaesthetics. If this happens, numbness of the tongue, light-headedness, dizziness, shakiness and fits may occur. In extremely rare cases, prilocaine has been associated with heart attack, breathing difficulties, loss of feeling in your lower body and allergic reactions, which may cause rashes, swelling or very low blood pressure.

A rare, but serious undesirable effect of spinal anaesthesia is a high or total spinal block, with consequent cardiovascular and respiratory depression.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PRILOTEKAL contains

Active ingredient (main ingredient)	prilocaine hydrochloride 1 ampoule with 5 mL solution contains 100 mg of prilocaine hydrochloride.
Other ingredients (inactive ingredients)	Glucose Sodium hydroxide Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What PRILOTEKAL looks like

PRILOTEKAL is a clear, colourless solution for injection.

PRILOTEKAL comes in Type I clear colourless glass ampoules.

Box of 10 ampoules each containing 5 mL of solution for injection.

AUST R 376271

Who distributes PRILOTEKAL

B. Braun Australia Pty Ltd

Level 5, 7-9 Irvine Place

Bella Vista NSW 2153

Australia

Toll free number: 1800 251 705

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