

**PATIENT INFORMATION LEAFLET FOR THE USER**  
**Citanest® with Octapressin DENTAL**  
**Solution for Injection**  
**Prilocaine Hydrochloride 3% w/v**  
**Felypressin 0.54 µg/ml**

**WHAT YOU SHOULD KNOW ABOUT YOUR MEDICINE**

**Please read all of this leaflet before you are given this medicine.**

- The full name of your medicine is Citanest® with Octapressin DENTAL but will be referred to as Citanest Dental from now on in this leaflet.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist or doctor.
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- Normally a dentist or dental hygienist will use this product on you in the dental surgery. It is unlikely that you will be permitted to take this medicine home.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your dentist or doctor.

**In this leaflet:**

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**1. What Citanest Dental is and what it is used for**

The name of your medicine is Citanest Dental and it is a solution for injection. It contains prilocaine hydrochloride and Octapressin (which contains felypressin).

Prilocaine hydrochloride is a type of medicine called a local anaesthetic. These are medicines which numb an area of the body. Octapressin is a type of medicine called a vasoconstrictor. These are medicines which make the blood vessels at the site of injection narrower which means that you will bleed less and the effects of the medicine will last longer.

**What this medicine is used for**

It is used to stop the pain during dental procedures.

## **2. Before being given Citanest Dental**

### **Do not use Citanest Dental**

- in infants
- if you are allergic (hypersensitive) to any of the ingredients of Citanest Dental (see Section 6, Further information)
- If your doctor has told you that you have congenital or acquired methaemoglobinaemia (a condition where too much haemoglobin has changed into methaemoglobin in your blood. If too much methaemoglobin is formed, it becomes more difficult for the blood to provide the tissues with oxygen)
- If your doctor has told you that you have anaemia
- if you have ever had an allergic reaction to another local anaesthetic
- This product contains less than 1 mmol sodium (23 mg) per 1 ml, i.e. essentially 'sodium free'. This should be taken into consideration in patients who are following a reduced-salt diet.
- as an injection directly into the vein.

### **Tell your dentist or doctor if you:**

- are pregnant, think you might be pregnant, or considering becoming pregnant
- are breast feeding
- have had high blood pressure or any heart problems
- have any liver or kidney problems
- have any breathing difficulties
- have any other blood disorders including anaemia
- are a child
- are an elderly person
- are in poor general condition
- have epilepsy
- have an infection at the site where the injection is to be given
- have received any other local anaesthetics very recently

### **Using other medicines**

Make sure your dentist or doctor knows if you are taking any of the medicines listed here:

- sulfonamides, e.g. co-trimoxazole, which are antibiotics used to treat bacterial infections
- anti-malarials used to treat malaria
- nitric compounds used to treat patients with heart problems
- anti-arrhythmic drugs used to treat patients with irregular heartbeat problems
- any other anaesthetics

Tell your dentist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Pregnancy and breast-feeding**

If you are pregnant, think you might be pregnant, are considering becoming pregnant or are breastfeeding, ask your dentist or doctor for advice before being given Citanest Dental.

## **Driving and using machines**

Citanest Dental has no known effect that should affect your ability to drive or use machines.

## **3. How Citanest Dental will be given**

Citanest Dental will be given to you as an injection by your dentist or doctor, who will decide what dose is right for you. This will normally be between 1 and 2 ml for healthy adults and about 1 ml for children under 10 years of age.

People who are unwell and elderly people should be given smaller doses. Children will be given smaller doses in relation to their body weight. The maximum dose in healthy adults is 20 ml (600 mg of prilocaine hydrochloride).

In all cases, the smallest dose that is needed should be used.

You may receive an injection of Citanest Dental inside your mouth before receiving dental treatment. Your dentist or doctor will wait a few minutes for the area to go numb before starting the treatment, so that you will feel less pain. The numbness will last until the treatment is finished and for a while afterwards.

**Take care** not to accidentally bite your tongue or cheek. Also, avoid drinking very hot drinks and eating very hot food until the feeling fully returns. The numbness will slowly go away.

If you feel that you have been given too much or too little Citanest Dental, talk to your dentist or doctor **immediately**.

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

## **4. Possible side effects of Citanest Dental**

Like all medicines, Citanest Dental may sometimes cause side effects as well as the effects that are needed. These side effects are rare and usually only occur with high doses.

**If you have any of the following rare side effects while taking your medicine, tell your dentist or doctor immediately, or go straight to the emergency department of your nearest hospital if you have left the dental surgery when these occur.**

Severe allergic reactions may include:

- a red and lumpy skin rash
- difficulty in breathing
- lowered blood pressure
- raised blood pressure
- bruising
- mouth ulceration

- injection site hardness
- swelling of the face, mouth, lips, or eyelids

### **Rare side effects (affecting fewer than 1 in 1,000 people)**

- Feelings of nervousness, dizziness, blurred vision, shakiness, sounds/ringing in the ears, and occasionally drowsiness and loss of consciousness
- Fits
- Lowered blood pressure
- Nausea, headache, or a faster heart beat
- A slow heart beat or cardiac arrest (heart attack)
- Slow breathing or respiratory arrest (when breathing stops completely)
- Methaemoglobinaemia, which can cause headache, breathlessness and blue-tinged skin (more commonly in infants). (Methaemoglobinaemia is a condition where too much haemoglobin has changed into methaemoglobin in your blood. If too much methaemoglobin is formed, it becomes more difficult for the blood to provide the tissue with oxygen.)

If any of these side effects become serious, or if you get any side effects not listed in this leaflet, tell your dentist or dental hygienist while still in the dental surgery or tell your doctor if you have already returned home when these occur.

## **5. How to store Citanest Dental**

You will not normally be asked to store your medicine as it will be given to you by a healthcare professional.

Keep Citanest Dental out of the reach and sight of children.

Do not use Citanest Dental after the expiry date which is printed on the container after Exp. The expiry date refers to the last day of the month.

Do not store above 25°C.

Do not use if there is any appearance of cloudiness or color.

## **6. Further information**

### **What Citanest Dental contains**

Each ml contains Prilocaine Hydrochloride 30mg (66 mg/2.2 ml cartridge) and Felypressin 0.54 µg/ml (1.19 µg/2.2 ml cartridge).

The other ingredients are: hydrochloric acid, sodium chloride, sodium hydroxide and water for injection.

### **What Citanest Dental looks like and contents of the pack**

A clear, colourless, sterile solution.

Solution for injection for dental use.

Each glass cartridge contains 2.2 ml of Citanest Dental.

Each pack contains 50 or 100 cartridges.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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DENTSPLY Pharmaceutical