Prilocaine Hydrochloride with Felypressin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Citanest DENTAL with Octapressin.

It does not contain all the available information. It does not take the place of talking to your dental practitioner or dental nurse.

All medicines have risks and benefits. Your dental practitioner has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your dental practitioner.

Keep this leaflet.

You may need to read it again.

What Citanest DENTAL with Octapressin is used for

Citanest DENTAL with Octapressin is used to prevent or relieve pain during dental procedures, but it will not put you to sleep. This medicine belongs to a group of medicines called local anaesthetics.

It is injected into the gums and works by making the nerves unable to pass pain messages to the brain.

Depending on the amount used, it will either totally stop pain or will cause a partial loss of feeling.

The felypressin makes the blood vessels at the site of injection narrower, which means you bleed less. It is then easier for your dental practitioner to see what is happening.

Ask your dental practitioner if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

Before you are given Citanest DENTAL with Octapressin

When you must not be given it Do not take Citanest DENTAL with Octapressin if you have an allergy to:

• any medicine containing prilocaine

- any of the ingredients listed at the end of this leaflet
- any other similar medicines, such as other local anaesthetics e.g. Xylocaine.

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Citanest DENTAL with Octapressin if you have any of these medical conditions:

• a problem with abnormal blood pigment levels (methaemoglobinaemia).

It may not be safe for you to be given this medicine if you have any of these conditions. This medicine will only be used if the solution is clear, the package is undamaged and the use by (expiry) date printed on the pack has not been passed.

Before you are given it

Tell your dental practitioner if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your dental practitioner if you have or have had any of the following medical conditions:

- problems with your heart beat rhythm or a very slow heart beat
- anaemia (a decreased number of red blood cells)
- diabetes
- nerve problems
- liver problems
- kidney problems
- heart problems
- malignant hyperthermia.

Tell your dental practitioner if you are pregnant or plan to become pregnant or are breast-feeding.

Your dental practitioner can discuss with you the risks and benefits involved.

This medicine has been widely used for dental procedures during pregnancy with no reports of ill effects to the mother or baby.

This medicine may enter breast milk, but in such small amounts that there is generally no risk of affecting the baby.

If you have not told your dental practitioner about any of the above, tell him/her before you are given Citanest DENTAL with Octapressin.

Taking other medicines

Tell your dental practitioner if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Citanest DENTAL with Octapressin may interfere with each other. These include:

- medicines used to maintain the normal rhythm of your heart, such as mexilitene
- a type of antibiotic medicine, known as sulphonamides, such as sulfamethoxozole
- medicines used to treat malaria, such as quinine
- medicines called nitric compounds such as nitroglycerin which is used to treat angina.

These medicines may be affected by Citanest DENTAL with Octapressin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your dental practitioner and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Citanest DENTAL with Octapressin is given

Follow all directions given to you by your dental practitioner carefully. They may differ from the information contained in this leaflet.

How much you are given

The dosage you will be given will depend on your body size, age and the type of dental work you will be having done.

Your dental practitioner will choose the best dose for you. They will be willing to discuss this decision with you.

How it is given

Citanest DENTAL with Octapressin will be injected by your dental practitioner into your gum near a single nerve, or into an area which contains a large number of nerves. This will result in an area of numbness at the

site or near the site of injection. Citanest DENTAL with Octapressin should not be injected directly into the blood.

If you are given too much (overdose)

The dental practitioner giving you this medicine will be experienced in the use of local anaesthetics, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to it, or the dose is accidentally injected directly into your blood, you may develop problems for a short time.

Symptoms of an overdose may include:

- a numb feeling in or around the mouth
- feeling dizzy or stiff
- muscle twitching.

Whenever you are given the medicine, equipment will be available to care for you if an overdose happens.

While you are being given Citanest DENTAL with Octapressin

Things you must not do

Do not eat or drink anything until the feeling has completely returned to your mouth.

You may burn or bite yourself.

Things to be careful of

Be careful driving or operating machinery until you know how Citanest DENTAL with Octapressin affects you.

This medicine may cause dizziness, nervousness, drowsiness, blurred vision or feeling strange/disoriented in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your dental practitioner as soon as possible if you do not feel well while you are being given Citanest DENTAL with Octapressin.

This medicine helps most people have painfree visits to the dental practitioner but it may have unwanted side effects in a few people, although these are rare. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your dental practitioner to answer any questions you may have. Tell your dental practitioner if you notice

nervousness

- nervousness
- dizziness
- blurred vision
- drowsiness
- ringing in the ears
- numbness
- feeling strange (disoriented)
- nausea
- vomiting
- shakes (tremor)
- headache.

The above list includes side effects that are usually mild and short lived.

If Citanest DENTAL with Octapressin is given wrongly or you are very sensitive to it, any of the following may happen. Tell your dental practitioner immediately or go to Accident and Emergency at your nearest hospital:

- fits
- unconsciousness
- breathing problems
- dizziness
- slow heart beat
- collapse.

The above list includes very serious side effects. If you have them, you may have had a serious (allergic) reaction to the medicine. You may need urgent medical attention or hospitalisation.

Tell your dental practitioner if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After using Citanest DENTAL with Octapressin

Storage

Citanest DENTAL with Octapressin will be stored by your dental practitioner under the recommended conditions.

It should be kept in a cool dry place where the temperature stays below 25°C. Protect from light.

Disposal

Any medicine from a single dose which is not used will be disposed of in a safe manner by your dental practitioner.

Product Description

What it looks like

Citanest DENTAL with Octapressin is a clear, colourless solutions in 2.2 mL and 1.8 mL dental cartridges. Each cartridge is distinctly colour banded for ease of identification with green and gold. *Ingredients*

Citanest DENTAL with Octapressin

contains 30 mg/mL of prilocaine hydrochloride and 0.54 μ g/mL of felypressin as the active ingredients. It also contains:

- Sodium chloride
- Sodium hydroxide and/or

- Hydrochloric acid
- Water for Injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier/Sponsor

Citanest DENTAL with Octapressin is supplied in Australia by: Dentsply Sirona Pty Ltd 11-21 Gilby Rd Mount Waverley Victoria, 3149 Australia Tel: 1300 55 29 29 Citanest DENTAL with Octapressin is supplied in New Zealand by: Dentsply Sirona (N.Z.) Limited c/o- Lowndes Jordan Level 15, PWC Tower 188 Quay Street Auckland 1010 New Zealand Tel: 0800 33 68 77 This leaflet was prepared on 14 December 2018. Australian Register numbers: 3% Citanest® DENTAL with Octapressin® 2.2 mL injection cartridge AUST R 220320 3% Citanest® DENTAL with

Octapressin® 1.8 mL injection cartridge AUST R 220319

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