

## **1.3.2 Proposed Consumer Medicine Information**

# Cleviprex™

*cleviprex butyrate*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Cleviprex™.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you being given this medicine against the benefits this medicine is expected to have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet, you may need to read it again.**

Cleviprex™ will only be given to you by specially trained personnel in a hospital environment.

### What Cleviprex™ is used for

This medicine is used to treat

- patients with raised blood pressure (also called hypertension)
- patients who are having surgery and need to have their blood pressure lowered for the procedure

Cleviprex™ belongs to a group of medicines called calcium channel blockers. Calcium channel blockers are medicines which lower blood pressure.

**Your doctor may have prescribed Cleviprex™ for another reason. Ask your**

**doctor if you have any questions about why Cleviprex™ has been prescribed for you.**

Cleviprex™ is not addictive.

Cleviprex™ is not recommended for use in children.

### Before you are given Cleviprex™

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

**When you must not be given this medicine:**

**You must not be given this medicine if you have had an allergic reaction to:**

- any medicine containing cleviprex butyrate
- any of the ingredients listed at the end of this leaflet
- Soybeans, soy products, eggs or egg products
- any other similar medicines

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin

- dizziness or light-headedness
- back pain

**You must not be given this medicine if the packaging is torn or shows signs of tampering.**

**You must not be given this medicine after the expiry date printed on the pack.**

**Before you are given this medicine**

**Tell your doctor if you have allergies to:**

- any other medicines
- any other substances such as foods, preservatives or dyes

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- difficulties processing fats (or lipids) such as hyperlipaemia (increased fat in the bloodstream), lipoid nephrosis (a disorder of the blood filtering structure of the kidneys), or acute pancreatitis (inflammation of the pancreas) if it is accompanied by hyperlipidaemia (high levels of lipids in the blood such as high cholesterol)
- critical aortic stenosis (narrowing of one of the valves in the heart)

**Tell your doctor if you are pregnant or intend to become pregnant.**

Cleviprex™ should not be used during pregnancy unless clearly necessary. Your doctor will decide whether or not this

treatment is appropriate for you.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is recommended that you do not breast-feed while you are receiving this medicine, as it is not known whether it passes into breast milk.

**If you are not sure whether any of these apply to you, check with your doctor or pharmacist.**

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

Some medicines may be affected by Cleviprex™ or may affect how it works.

You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

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

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**How Cleviprex™ is given**

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***How it is given***

Cleviprex is given as a slow infusion (drip) into a vein.

Your doctor or nurse will inject the medicine for you.

**Never inject this medicine yourself. Always let your doctor or nurse do this.**

**Ask your doctor or pharmacist if you have any questions on Cleviprex™**

***How much is given***

Your doctor will decide what dose you will receive. This depends on your condition and

the reduction in blood pressure which is required.

The usual dose of Cleviprex™ should be started at 2 mg/hour and increased as tolerated in doubling amounts (i.e. 2 to 4, 4 to 8, 8 to 16, 16 to 32 mg/hour) every 90 seconds.

Most patients will achieve the desired therapeutic response at doses up to 16 mg/hour.

Some patients may require a dose up to 32 mg/hour.

**Ask your doctor if you want to know more about the dose of Cleviprex™ you receive.**

***How often it will be given***

Your doctor will decide how often Cleviprex™ will be given to you.

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**In Case of Overdose**

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**As Cleviprex™ is given to you under the supervision of your doctor, it is unlikely that you will receive too much. However, if you experience any side effects after being given Cleviprex™, tell your doctor immediately.**

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken or been given too much Cleviprex™. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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**While you are being given Cleviprex™**

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***Things you MUST do:***

**Tell all doctors and health care professionals who are treating you that you are being given Cleviprex™.**

**If you are about to be started on any new medicine, tell your doctor or health care professional that you are being given Cleviprex™.**

**Tell your doctor if you become pregnant while you are being given Cleviprex™.**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

You may feel light-headed or dizzy after you are given Cleviprex™. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

**Be careful driving or operating machinery until you know how Cleviprex™ affects you.**

As with other medicines, Cleviprex™ may cause dizziness, lightheadedness or tiredness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous if you are tired, dizzy or lightheaded.

**Tell any other doctors, dentists, and pharmacists who are treating you that you are being given Cleviprex™.**

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**Side Effects**

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**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Cleviprex™.**

Like all medicines, Cleviprex™ can cause side effects. If they occur, most are likely to be minor and temporary.

However, some may be serious and need medical attention.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

**Tell your doctor, nurse or pharmacist if you notice any of the following side effects and they worry you:**

- dizziness
- headache
- nausea
- flushing

These are the more common side effects of Cleviprex™.

**Tell your doctor, nurse or pharmacist as soon as possible if you notice any of the following:**

- anxiety
- confusion
- inability to sleep
- chest pain
- swelling of body parts or build-up of fluid in the lungs
- fast or rapid heart beat
- changes in blood test results related to liver or kidney function

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

**Tell your doctor, nurse or pharmacist immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:**

- Sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

**Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.**

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

**Even after you have finished your treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.**

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### After using Cleviprex™

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#### **Storage**

Cleviprex™ will be stored appropriately at the pharmacy or on the ward. The vial is kept in a refrigerator where the temperature stays between 2 – 8°C.

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### Product Description

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#### **What it looks like**

Cleviprex is a milky-white opaque emulsion in a glass vial.

#### **Ingredients**

Cleviprex™ contains the active ingredient clevipidine butyrate 0.5mg/mL

Other ingredients:

Cleviprex also contains soya oil, glycerol, lecithin – egg and sodium hydroxide.

Cleviprex™ can be identified by an Australian Register Number, which is found on the packaging:

AUST R XXXXX Cleviprex™  
25mg/50mL.

AUST R XXXXX Cleviprex™  
50mg/100mL.

#### **Manufactured for**

Cleviprex™ is manufactured for:

The Medicines Company  
Parsippany, NJ 07054

#### **Sponsor**

##### Australia

Kendle R & D Pty Limited  
156-158 Drummond Street  
Oakleigh  
Victoria Australia 3166

##### New Zealand

Debra Wyber  
32 Quigley Street  
Newlands  
Wellington 6037  
New Zealand

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