

CLEVIPREX[®]

Consumer Medicine Information (CMI) summary

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

1. Why am I being given CLEVIPREX?

CLEVIPREX contains the active ingredient clevidipine. CLEVIPREX belongs to a group of medicines called calcium channel blockers. CLEVIPREX is given to adults to reduce high blood pressure.

For more information, see Section [1. Why am I being given CLEVIPREX?](#) in the full CMI.

2. What should I know before I am given CLEVIPREX?

You must **not** be given CLEVIPREX if you have ever had an allergic reaction to clevidipine, soybeans, soy products, eggs or egg products or any of the ingredients listed at the end of the CMI.

Talk to your doctor if:

- your body cannot process lipids (fats, including cholesterol) properly
- you have narrowing of a heart valve, heart failure or phaeochromocytoma.
- you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.

For more information, see Section [2. What should I know before I am given CLEVIPREX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLEVIPREX and affect how it works. Tell your doctor about any other medicines you are taking.

More information is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is CLEVIPREX given?

CLEVIPREX will be given to you by a doctor or nurse as a slow infusion (drip) into a vein. Your doctor will decide what dose you will receive.

More information can be found in Section [4. How is CLEVIPREX given?](#) in the full CMI.

5. What should I know while being given CLEVIPREX?

Things you should do	<ul style="list-style-type: none">• Tell your doctor or nurse straight away if you develop a fluttering or rapid heart rate and/or feel very dizzy or light-headed while having CLEVIPREX. They may adjust your dose.• Because your blood pressure has been lowered, get up slowly out of a chair or from your bed in case you are dizzy or light-headed.• Stay in hospital for as long as your doctor says so they can make sure your blood pressure does not suddenly go up again.• Keep your follow-up appointments with your doctor, as they will want to monitor your blood pressure.
Driving or using machines	CLEVIPREX may make you dizzy, light-headed or tired, so do not drive or operate machines or do anything else that requires you to be alert.
Storage	CLEVIPREX will be stored in the hospital pharmacy or on the ward, away from light in a refrigerator where the temperature stays between 2°C and 8°C. Once opened, any left-over liquid will be thrown away.

For more information, see Section [5. What should I know while I am being given CLEVIPREX?](#) in the full CMI.

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. Less serious side effects include dizziness, headache, nausea, flushing, feeling anxious, confused, unable to sleep. More serious side effects include racing or fluttering heartbeat, chest pain, wheezing or problems breathing and serious allergic reactions (swollen nose, lips, face, eye or throat).

For more details about side effects, and what to do, see Section [6. Are there any side effects?](#) in the full CMI.

CLEVIPREX[®]

Active ingredient: *Clevidipine*

Consumer Medicine Information (CMI)

This leaflet provides important information about being given CLEVIPREX.

Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given CLEVIPREX.

Where to find information in this leaflet:

- [1. Why am I being given CLEVIPREX?](#)
- [2. What should I know before I am given CLEVIPREX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is CLEVIPREX given?](#)
- [5. What should I know while I am given CLEVIPREX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given CLEVIPREX?

CLEVIPREX contains the active ingredient clevidipine. CLEVIPREX belongs to a group of medicines called calcium channel blockers.

CLEVIPREX 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.

2. What should I know before I am given CLEVIPREX?

Warnings

You must not be given CLEVIPREX if:

- you have ever had an allergic reaction to clevidipine or any of the ingredients listed at the end of this leaflet
- you have ever had an allergic reaction to soybeans, soy products, eggs or egg products
- your body cannot process lipids (fats, including cholesterol) properly- this can happen if you have hyperlipidaemia (high lipid levels), lipoid nephrosis (a kidney disorder) or acute pancreatitis with hyperlipidaemia
- you have narrowing of a heart valve (critical aortic stenosis)

Always check the ingredients to make sure you can have this medicine.

Check with your doctor if you:

- have any other medical conditions
- are allergic to any other medicines or foods, preservatives or dyes
- take any medicines for anything else, for example, beta-blockers for heart conditions or medicines where your lipids need to be restricted

While being given CLEVIPREX, you may be at risk of getting certain side effects. It is important you understand these risks and how to watch for them. See extra information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant. CLEVIPREX should not be given during pregnancy unless clearly necessary.

Talk to your doctor if you are breastfeeding. It is not known if CLEVIPREX passes into breast milk, so it is recommended that you do not breastfeed while being given it.

Your doctor will look at whether the benefits of having CLEVIPREX outweigh any possible effects on unborn or newborn babies.

Children

CLEVIPREX is not recommended for use in children or adolescents. There is not enough information to recommend the use of this medicine for children or adolescents under the age of 18 years.

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.

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

4. How is CLEVIPREX given?

How it is given

- CLEVIPREX is given as a slow infusion (drip) into the vein.
- Your doctor or nurse will inject this medicine for you.
- Never inject this medicine yourself. Always let your doctor or nurse do this.

How much is given

- Your doctor will decide what dose you will have, depending on your condition and what your blood pressure level needs to be. They will start you with a lower dose and increase it until your blood pressure reaches the target level.
- Ask your doctor if you want to know more about the dose they are giving you.

If you have too much CLEVIPREX

It is unlikely that you will receive too much CLEVIPREX, however if you think you have received too much, tell your doctor or nurse straight away. Your doctor or nurse will treat and monitor your side effects.

You can also contact the Poisons Information Centre (by calling 13 11 26) if you have any concerns.

5. What should I know while being given CLEVIPREX?

Things you should do

- Tell your doctor or nurse straight away if you develop a fluttering or rapid heart rate and/or feel very dizzy or light-headed while having CLEVIPREX. They may adjust your dose.
- Because your blood pressure has been lowered, get up slowly out of a chair or from your bed in case you are dizzy or light-headed.
- Tell your doctor or nurse if the dizziness or light-headedness gets worse or does not improve.
- Stay in hospital for as long as your doctor says so they can make sure that your blood pressure does not suddenly go up again.
- Keep your follow-up appointments with your doctor, so they can monitor your blood pressure.
- Remind any doctor, dentist or pharmacist you visit that you have been given CLEVIPREX.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CLEVIPREX affects you. CLEVIPREX may make you dizzy, light-headed or tired.

Looking after CLEVIPREX

CLEVIPREX will be stored in the hospital pharmacy or on the ward, away from light in a refrigerator where the temperature stays between 2°C and 8°C.

When your medicine will be discarded

- Once opened, any left-over liquid will be thrown away after 12 hours.
- The medicine will also be thrown away if the expiry date has passed

6. Are there any side effects?

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

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
General body <ul style="list-style-type: none">• feeling hot or cold, having a fever• flushing• feeling pain Gut <ul style="list-style-type: none">• stomach pain• feeling or being sick• constipation Kidney <ul style="list-style-type: none">• frequent urination Mental health <ul style="list-style-type: none">• feeling anxious or confused• unable to sleep Nervous system <ul style="list-style-type: none">• headache• dizziness Skin <ul style="list-style-type: none">• rash• hives (itchy raised red bumps)	Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<p>General body</p> <ul style="list-style-type: none"> blue lips pain radiating to arms, shoulders, jaw, neck or back indigestion fainting, fatigue swelling of body parts <p>Heart</p> <ul style="list-style-type: none"> racing, slowed or irregular heartbeat chest pain <p>Lungs</p> <ul style="list-style-type: none"> problems breathing feeling of having fluid in the lungs wheezing or shortness of breath fast breathing coughing <p>Nervous system</p> <ul style="list-style-type: none"> sudden loss of balance, vision or ability to speak facial drooping and/or muscle weakness on one side <p>Hypersensitivity (allergic) reaction:</p> <ul style="list-style-type: none"> sudden rash, itching, hives on the skin swollen face, tongue or other parts of the body shortness of breath, wheezing or problems breathing 	<p>Tell your doctor or nurse straight away or (if you have finished your treatment and are not in hospital) go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

Other side effects not listed may occur in some people.

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

Reporting side effects

After you have spoken to your doctor, nurse or pharmacist about any side effects you have, 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.

7. Product details

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

What CLEVIPREX contains

Active ingredient (main ingredient)	Clevidipine
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Soya oil Glycerol Egg lecithin Oleic acid Disodium edetate Water for injections Sodium hydroxide
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Do not have this medicine if you are allergic to any of these ingredients.

What CLEVIPREX looks like

CLEVIPREX is a white, milky liquid (emulsion) with a reflective surface and no particles, in a sterile, clear glass vial.

Each vial contains 0.5 mg clevidipine per mL of liquid.

There are two sizes:

CLEVIPREX 25 mg/ 50 mL; Aust R 203313

CLEVIPREX 50 mg/ 100 mL; Aust R 203314

Not all pack sizes may be available.

Who supplies CLEVIPREX

Chiesi Australia Pty Ltd
 Level 7, Suite 1, 500 Bourke Street,
 Melbourne, VIC 3000
 Email: medinfo.au@chiesi.com
 Website: www.chiesi.com.au

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