

Cafnea[®] Injection and Cafnea[®] Oral Solution

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 is Cafnea Injection or Cafnea Oral Solution being given?

Cafnea Injection and Cafnea Oral Solution contains the active ingredient caffeine citrate. Cafnea Injection and Cafnea Oral Solution are used to help improve the breathing of premature infants suffering from apnoea of prematurity who have been born between 28 and less than 33 weeks gestation. For more information, see Section [1. Why is Cafnea Injection or Cafnea Oral Solution being given?](#) in the full CMI.

2. What should I know before Cafnea Injection or Cafnea Oral Solution is given?

Your baby should not be given Cafnea Injection or Cafnea Oral Solution if they have ever had an allergic reaction to caffeine or citrate or any of the ingredients listed at the end of the CMI. For more information, see Section [2. What should I know before Cafnea Injection or Cafnea Oral Solution is given?](#) in the full CMI.

3. What if I am using other medicines?

Some medicines may interfere with Cafnea Injection or Cafnea Oral Solution and affect how it works.

A list of these medicines is in Section [3. What if I am using other medicines?](#) in the full CMI.

4. How is Cafnea Injection or Cafnea Oral Solution given?

- Cafnea Injection or Cafnea Oral solution must only be given by a doctor or nurse.
- Cafnea Injection is infused into a vein slowly using a syringe infusion pump.
- Cafnea Oral Solution is given in a measured dose by mouth through a dropper or feeding tube.

More instructions can be found in Section [4. How is Cafnea Injection or Cafnea Oral Solution given?](#) in the full CMI.

5. What should I know while using Cafnea Injection or Cafnea Oral Solution?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that Cafnea Injection or Cafnea Oral solution is being used. • Check with your doctor if your baby's breathing problems are caused by other medical conditions. • Check with your doctor if the baby has any of the following medical conditions: seizure disorders, heart problems, kidney problems and liver problems.
Things you should not do	<ul style="list-style-type: none"> • Do not give your baby Cafnea Injection or Cafnea Oral Solution if the solution is discoloured, cloudy, turbid, or a precipitate or particles are present. The solutions are normally clear, and colourless. • Your baby should not be given either medicine if, when mixed with another solution, it causes the solution to become discoloured, cloudy, turbid, precipitate or form particles.
Looking after the medicine	<ul style="list-style-type: none"> • Cafnea Injection and Cafnea Oral Solution will be stored in the surgery, pharmacy or ward of a hospital in a cool dry place where the temperature stays below 30°C. • The medicine will be opened for use on your baby. It will be used only once and then it will be discarded. It will never be stored after it is opened or used for more than one baby.

For more information, see Section [5. What should I know while using Cafnea Injection or Cafnea Oral Solution?](#) in the full CMI.

6. Are there any side effects?

The serious side effects include irritability, jitteriness, restlessness, fast heartbeat, stomach upset or vomiting, reflux, passing large amounts of urine, excessive thirst, dry mouth and skin, sweating, weakness, dizziness, trembling, flushing or paleness, symptoms of necrotising enterocolitis a serious stomach condition which include lack of energy, severe vomiting, stomach/abdominal bloating (distension) and bloody stools. 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.

Cafnea[®] Injection and Cafnea[®] Oral Solution

Active ingredient: *caffeine citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cafnea Injection and Cafnea Oral Solution. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cafnea Injection and Cafnea Oral Solution.**

Where to find information in this leaflet:

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

1. Why is Cafnea Injection or Cafnea Oral Solution being given?

Cafnea Injection and Cafnea Oral Solution contain the active ingredient caffeine citrate.

Cafnea Injection and Cafnea Oral Solution are used to help improve the breathing of premature infants suffering from apnoea of prematurity who have been born between 28 and less than 33 weeks gestation.

Apnoea of prematurity is a condition where a baby stops breathing for short periods of time.

Cafnea Injection and Cafnea Oral Solution work by stimulating breathing in premature babies.

Ask your doctor if you have any questions about why Cafnea Injection or Cafnea Oral Solution has been prescribed for your baby.

Your doctor may have prescribed it for another reason.

2. What should I know before Cafnea Injection or Cafnea Oral Solution is given?

Warnings

You should not be given Cafnea Injection or Cafnea Oral Solution if:

- you are allergic to caffeine or citrate, or any other similar medicine.
- Always check the ingredients to make sure you can use this medicine.

Your baby should not be given Cafnea Injection or Cafnea Oral Solution if the solution is discoloured, cloudy, turbid, or a precipitate or particles are present. The solutions are normally clear, and colourless.

Your baby should not be given either medicine if, when mixed with another solution it causes the solution, to become discoloured, cloudy, turbid, precipitate or form particles.

The solutions are normally clear, and colourless.

The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

If you are not sure whether your baby should be given either medicine talk to your doctor.

Check with your doctor if:

- your baby has allergies to any other medicines, foods, preservatives, or dyes.
- your baby's breathing problems are caused by other medical conditions. If the breathing problems are caused by another medical condition. Cafnea Injection or Cafnea Oral Solution may not be used until the other condition is treated.
- your baby has any of the following medical conditions:
 - seizure disorders
 - heart problems
 - kidney problems
 - liver problems.

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?](#)

3. What if I am using 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.

Some medicines can be passed onto your baby through the placenta before birth or in breast milk.

Some medicines may interfere with Cafnea Injection and Cafnea Oral Solution. These include:

- methylxanthines such as theophylline and aminophylline, medicines used to control asthma
- antibiotics used to treat bacterial infections such as ciprofloxacin, enoxacin, norfloxacin
- any medicine containing caffeine
- medicines used to treat heart problems such as Mexiletine and Verapamil
- Cimetidine a medicine used to treat reflux and ulcers
- Fluvoxamine a medicine used to treat depression
- Idrocilamide a medicine used to relax muscle
- Methoxsalen a medicine used to treat skin problems
- Tiabendazole used to treat certain worm infections
- Artemisinin a medicine used to treat malaria
- medicines used to treat fungal infections such as Fluconazole and Terbinafine
- Phenytoin a medicine used to treat epilepsy
- benzodiazepines a group of medicines used as a sedative or to treat anxiety
- Clozapine a medicine used to treat schizophrenia.

These medicines may be affected by Cafnea Injection and Cafnea Oral Solution or may affect how well they work. Your doctor and pharmacist have more information on medicines to be careful with or avoid while your baby is being given Cafnea Injection or Cafnea Oral Solution.

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

4. How is Cafnea Injection or Cafnea Oral Solution given?

How much to be given

- Your doctor will decide what dose of Cafnea Injection or Cafnea Oral solution your baby will receive and for how long they will receive it. This depends on their medical condition and other factors, such as weight.
- It will also depend on what medicines and fluids the mother has consumed prior to delivery as these may have crossed the placenta and been passed onto the baby.

How is Cafnea Injection or Cafnea Oral Solution given

- Cafnea Injection or Cafnea Oral Solution must only be given by a doctor or nurse.
- Cafnea Injection is usually infused into a vein slowly using a syringe infusion pump.
- Cafnea Oral Solution is usually given in a measured dose by mouth through a dropper or feeding tube.

If too much Cafnea Injection or Cafnea Oral Solution is given

Both Cafnea Injection and Cafnea Oral Solution must only be given by a doctor or nurse, so an overdose is not likely to occur.

Contact your doctor or nurse immediately if you notice any symptoms of an overdose in your baby:

- jitteriness
- loss in weight
- fever
- irritability, sleeplessness
- poor feeding
- rapid shallow breathing, difficulty breathing
- muscle spasms or contractions including tremors in the hands or feet and arching of the back
- muscle spasm in which the head and the heels are bent backward and the body bowed forward
- muscle stiffness causing poor control of movement
- unusual jaw and lip movement
- vomiting
- passing large amounts of urine
- excessive thirst, dry mouth and skin
- seizures, fits or convulsions
- increased heart rate
- stomach bloating
- pain or redness at the injection site.

If you think that your baby had too much Cafnea Injection or Cafnea Oral Solution, your baby may need urgent medical attention.

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 using Cafnea Injection or Cafnea Oral Solution?

Your doctor may do tests on your baby from time to time to make sure the medicine is working and to prevent unwanted side effects.

Looking after your medicine

Cafnea Injection and Cafnea Oral Solution will be stored in the surgery, pharmacy or ward of a hospital in a cool dry place where the temperature stays below 30°C.

Cafnea Injection or Cafnea Oral Solution will be opened for use on your baby. It will be used only once and then it will be discarded. It will never be stored after it is opened or used for more than one baby.

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.

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

Tell your doctor or nurse as soon as possible if your baby does not appear well while receiving Cafnea Injection or Cafnea Oral Solution.

Do not be alarmed by the following list of side effects. Your baby may not experience any of them.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> irritability, jitteriness, restlessness fast heartbeat stomach upset or vomiting reflux passing large amounts of urine excessive thirst, dry mouth and skin sweating weakness, dizziness, trembling flushing or paleness symptoms of necrotising enterocolitis a serious stomach condition. These include: <ul style="list-style-type: none"> lack of energy (lethargy) severe vomiting stomach/abdominal bloating (distension) bloody stools. 	<p>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.</p>

Tell your doctor or nurse if you notice anything that is making your baby feel unwell.

Other side effects not listed above may also occur in some babies.

Some side effects can only be found when your doctor does tests from time to time to check your baby's progress.

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 Cafnea Injection and Cafnea Oral Solution contains

Active ingredient (main ingredient)	caffeine
Other ingredients (inactive ingredients)	citric acid monohydrate sodium citrate dihydrate water for injections

These medicines do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes, alcohol or preservatives.

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

What Cafnea Injection and Cafnea Oral Solution looks like

Cafnea Injection and Cafnea Oral Solution are clear, colourless solutions in a clear glass vial with a grey rubber stopper, aluminum seal and a plastic top.

Cafnea Injection

Cafnea Injection contains caffeine citrate 40 mg in 2 mL (equivalent to 20 mg of caffeine) is presented in 2 mL clear vial available as pack of 10 vials (AUST R 153873).

Cafnea Oral Solution

Cafnea Oral Solution contains caffeine citrate 25 mg in 5 mL (equivalent to 12.5 mg of caffeine) is available in 7 mL clear vial available as pack of 10 vials (AUST R 153874).

Who distributes Cafnea Injection and Cafnea Oral Solution

Cafnea Injection and Cafnea Oral solution is made and supplied in Australia by:

Phebra Pty Ltd
17-19 Orion Road
Lane Cove West, NSW 2066
Australia
Telephone: 1800 720 020

This leaflet was prepared in December 2025.

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