

Cafnea® Injection and Cafnea® Oral Solution

Caffeine Citrate Injection and Oral Solution

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cafnea Injection and Cafnea Oral Solution. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of your baby being given Cafnea Injection or Cafnea Oral Solution against the benefits this medicine is expected to have for your baby.

If you have any concerns about either medicine being given to your baby, ask your doctor.

Keep this leaflet in a safe place.

You may need to read it again.

What Cafnea Injection and Cafnea Oral Solution are used for

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.

Before Cafnea Injection or Cafnea Oral Solution is given

When they should not be given

Your baby should not be given Cafnea Injection or Cafnea Oral Solution if they have an allergy to:

- caffeine or citrate
- any other similar 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.

Before either is given

Tell your doctor if your baby has allergies to any other medicines, foods, preservatives, or dyes.

Your doctor will check if 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 doctor will check if your baby has any of the following medical conditions:

- seizure disorders
- heart problems
- kidney problems
- liver problems.

Taking other medicines

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

How Cafnea Injection and Cafnea Oral Solution are given

Cafnea Injection must only be given by a doctor or nurse.

How it is given

Cafnea Injection is usually infused into a vein slowly using a syringe infusion pump.

How much is given

Your doctor will decide what dose of Cafnea Injection 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.

Cafnea Oral Solution must only be given by a doctor or nurse.

How it is given

Cafnea Oral Solution is usually given in a measured dose by mouth through a dropper or feeding tube.

How much is given

Your doctor will decide what dose of 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.

If too much is given (overdose)

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.

Contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

While Cafnea Injection or Cafnea Oral Solution is being given

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.

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.

Cafnea Injection and Cafnea Oral Solution may have unwanted side effects in a few babies. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some side effects may require medical treatment.

Do not be alarmed by the following list of side effects.

Your baby may not experience any of them.

Ask your doctor to answer any questions you may have.

If any of the following happen, tell your doctor or nurse immediately:

- irritability, jitteriness, restlessness
- fast heart beat
- 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:
 - lack of energy (lethargy)
 - severe vomiting
 - stomach/abdominal bloating (distension)
 - bloody stools.

The above list includes very serious side effects. Your baby may need urgent medical attention.

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.

After Cafnea Injection or Cafnea Oral Solution is given

Storage

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.

Product description

What it looks like

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

Cafnea Injection is available in a 2 mL vial.

Cafnea Oral Solution is available in a 7 mL vial.

Ingredients

Cafnea Injection contains 40 mg of caffeine citrate injection in 2 mL equivalent to 20 mg of caffeine base as the active ingredient.

It also contains:

- citric acid monohydrate
- sodium citrate dihydrate
- water for injections.

Cafnea Oral Solution contains 25 mg of caffeine citrate in 5 mL equivalent to 12.5 mg of caffeine base as the active ingredient.

It also contains:

- 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.

Manufacturer

Cafnea Injection and Cafnea Oral Solution are made in Australia by:

Phebra Pty Ltd
19 Orion Road
Lane Cove West, NSW 2066
Australia

Cafnea Injection
(caffeine citrate 40 mg in 2 mL)
2 mL vial,
AUST R 153873
Phebra product code INJ101

Cafnea Oral Solution
(caffeine citrate 25 mg in 5 mL)
5 mL of solution in a 7 mL vial.
AUST R 153874
Phebra product code SOL026

This leaflet was last updated on 05 May 2021.

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