

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

CAFCIT

Caffeine citrate 10 mg/ml equivalent to 5 mg caffeine

Solution

Sugar free

Read all of this leaflet carefully before CAFCIT is administered to your newborn

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What CAFCIT is and what it is used for
2. What you need to know before CAFCIT is administered to your newborn
3. How to use CAFCIT
4. Possible side effects
5. How to store CAFCIT
6. Contents of the pack and other information

1. What CAFCIT is and what it is used for

Caffeine belongs to a group of medicines known as methylxanthines. It is used in the treatment of interrupted breathing in premature babies (primary apnoea of premature newborns). These short periods when premature babies stop breathing are due to the baby's breathing centres not being fully developed. This medicine has been shown to reduce the number of episodes of interrupted breathing in premature newborns.

2. What you need to know before CAFCIT is administered to your newborn

Your newborn should not be given CAFCIT

- if hypersensitive (allergic) to caffeine citrate or any of the other ingredients of CAFCIT (listed in section 6).

Warnings and precautions

Talk to your baby's doctor before your newborn is given CAFCIT if your baby:

- has liver or kidney disease
- has had any unusual heart rhythms detected or heart disease
- suffers from seizures
- has frequent regurgitation
- produces more urine than usual
- has a reduced weight gain or food intake
- If you (the mother) consumed caffeine prior to delivery

Other medicines and CAFCIT

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your baby's doctor if your newborn is taking, have recently taken or might take any other medicines.

- CAFCIT may interact with other medicines given at the same time. A premature baby may need many medicines, and any problems with caffeine are likely to be minor but tell the doctor about any other medication they may not know about, particularly any other medicine (for example theophylline) given to your baby to help it breathe.
- Medications containing phenobarbitone or phenytoin, taken by the mother herself to treat epilepsy, may also have an effect on the way the baby reacts to caffeine therapy. If you have been taking treatment for epilepsy during pregnancy, please tell your baby's doctor about it.
- Doxapram (used to treat breathing difficulties)
- Cimetidine (used to treat gastric disease)
- Ketoconazole (used to treat fungal infections)

- This medicine may increase the risk for serious intestinal disease with bloody stools (necrotising enterocolitis) when administered with medicines used to treat gastric disease (such as antihistamine H2 receptor blockers or proton-pump inhibitors that reduces gastric acid secretion).

Pregnancy and breastfeeding

If you (the mother) are breastfeeding while your newborn is treated with CAFCIT, you should not drink coffee or take any other high caffeine product as caffeine passes into breast milk.

Driving and using machines

Not applicable.

CAFCIT contains sodium

CAFCIT contains 3,04 mg sodium per 1 ml of the solution, which the doctor will need to consider if your baby is on a controlled sodium diet.

3. How CAFCIT is used

You will not be expected to give your baby CAFCIT. It will be given to your baby by a person who is qualified to do so.

The doctor or nurse will administer CAFCIT Solution for Injection into a venous infusion (drip). It can also be equally effective when given by mouth, and all or some of the doses may be given this way when possible. CAFCIT should not be given by intramuscular injection.

The exact dose, to be determined by the doctor, depends on each baby's needs and response to the treatment, but will usually be:

- A starting dose of 20 mg/kg of the baby's body weight calculated as caffeine citrate (equivalent to caffeine 10 mg/kg or 2 ml/kg of this solution) if by injection then infused over 30 minutes

- Followed after 24 hours by a lower daily maintenance dose of 5 mg/kg of the baby's body weight calculated as caffeine citrate (equivalent to caffeine 2,5 mg/kg or 0,5 ml/kg of this solution) if by injection then infused over 10 minutes or oral administration.

If your baby fails to respond to the starting dose (after 24 hours), the doctor or nurse may give one more additional starter dose, before continuing to the lower maintenance doses.

If your newborn is given more CAFCIT than they should

Since a healthcare provider will administer CAFCIT, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

CAFCIT can have side effects.

Not all side effects reported for CAFCIT are included in this leaflet. Should your newborn's general health worsen or if you notice any untoward effects while your newborn is being treated with CAFCIT, please consult your healthcare provider for advice.

Tell your doctor immediately if you notice any of the following with your newborn:

Less frequent side effects

- allergic reactions

Frequency unknown

- serious intestinal disease with bloody stools (necrotising enterocolitis)
- seizures (convulsions)
- bloodstream infection (sepsis)

These are all serious side effects. Your newborn may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- inflammation of a vein at the injection site (phlebitis)
- pain and swelling at the injection site

Frequency unknown

- cardiac disorders such as fast heart beat (tachycardia) or irregular heart beat (dysrhythmia)
- reduced sugar in blood or serum (hypoglycaemia)
- increased sugar in blood or serum (hyperglycaemia)
- failure to grow
- feeding intolerance
- irritability, nervousness and restlessness, brain injury
- deafness
- regurgitation
- increase in stomach aspirate
- increase of urine flow
- increase of certain urine components (sodium and calcium)
- changes in blood tests (reduced levels of haemoglobin after prolonged treatment, reduced thyroid hormone at the start of treatment)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you notice side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CAFCIT.

5. How to store CAFCIT

Store all medicines out of reach of children.

Store at or below 30 °C.

After opening the ampoule, the medicinal product should be used immediately.

Do not use this medicine after the expiry date, which is stated on the label, or if there are any signs of discolouration or clouding of the solution

6. Contents of the pack and other information

What CAFCIT contains

- The active substance is caffeine citrate 10 mg/ml equivalent to 5 mg caffeine
- The other ingredients are citric acid, sodium chloride and water for injection.

CAFCIT can be either used without dilution or diluted in sterile solutions for infusion such as 5 % glucose or 0,9 % sodium chloride or glucose 4 % with saline 0,18 % immediately after withdrawal from the ampoule.

What CAFCIT looks like and contents of the pack

A clear, colourless solution.

Type I clear, glass ampoule containing 1 ml in packs of 1 or 10 ampoules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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An electronic copy of the Professional Information (PI) is available on the Equity website

<http://www.equitypharmaceuticals.co.za> or <http://www.sahpra.org.za>