

Caffeine Citrate 10mg/ml Oral Solution

Equivalent to Caffeine 5mg/ml

Please read all of this leaflet carefully before your baby is given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask the hospital doctor who is looking after your baby.

If your newborn gets any side effects, talk to your baby's doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Caffeine Citrate 10mg/ml Oral Solution is and what it is used for
2. What you need to know before your baby is given Caffeine Citrate 10mg/ml Oral Solution
3. How Caffeine Citrate 10mg/ml Oral Solution is used
4. Possible side effects
5. How to store Caffeine Citrate 10mg/ml Oral Solution
6. Contents of the pack and other information

1. What Caffeine Citrate 10mg/ml Oral Solution 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 your baby is given Caffeine Citrate 10mg/ml Oral Solution

Your baby should not be given Caffeine Citrate 10mg/ml Oral Solution

- if allergic to caffeine citrate or to any of the other ingredients of this medicine listed in section 6.

Warnings and precautions

Talk to your baby's doctor before your newborn is given Caffeine Citrate 10mg/ml Oral Solution 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 Caffeine Citrate 10mg/ml Oral Solution

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

As with most medicines, Caffeine Citrate 10mg/ml Oral Solution 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 breast-feeding

If you (the mother) are breast-feeding while your infant is treated with Caffeine Citrate 10mg/ml Oral Solution, you should not drink coffee or take any other high caffeine product as caffeine passes into breast milk.

Caffeine Citrate 10mg/ml Oral Solution contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How Caffeine Citrate 10mg/ml Oral Solution is used

Caffeine Citrate 10mg/ml Oral Solution should only be used in a neonatal intensive care unit in which adequate facilities are available for patient surveillance and monitoring. Treatment should be initiated under supervision of a physician experienced in neonatal intensive care.

The doctor or nurse will administer Caffeine Citrate 10mg/ml Oral Solution by mouth or via a gastric feeding tube. The exact dose depends on each baby's needs and response to the treatment, but will usually be:

- A starting dose of 20mg/kg of the baby's body weight calculated as caffeine citrate (equivalent to caffeine 10mg/kg or 2ml/kg of this solution).
- Followed after 24 hours by a lower daily maintenance dose of 5 to 10mg/kg of the baby's body weight calculated as caffeine citrate (equivalent to caffeine 2.5 to 5mg/kg or 0.5 to 1ml/kg of this solution).

If your baby fails to respond to the starting dose (after at least 4 hours), the

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doctor or nurse may give one more higher dose, before continuing to the lower maintenance doses.

Duration of treatment

Your baby's doctor will decide exactly how long your newborn must continue therapy with Caffeine Citrate 10mg/ml Oral Solution. If your baby has 5 to 7 days without apnoea attacks, the doctor will stop treatment.

The doctor may decide to check the levels of caffeine in a blood sample as a precaution, or if your baby is not responding to treatment as expected.

If your baby is given more Caffeine Citrate 10mg/ml Oral Solution than they should

If too much caffeine solution is accidentally given to your baby, the side effects described above may become more noticeable. In cases of very high overdosage, fits can also occur. If signs of over-dosage are noticed, please tell the baby's doctor immediately.

Treatment with Caffeine Citrate 10mg/ml Oral Solution should be stopped immediately and your baby's doctor should treat the overdose.

If you have any further questions on the use of this medicinal product, ask your baby's doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. However, it is difficult to distinguish them from frequent complications occurring in premature babies and complications due to the disease. While under treatment with Caffeine Citrate 10 mg/ml Oral Solution, your newborn may experience some of the following reactions:

- Serious side effects**
- serious intestinal disease with bloody stools (necrotising enterocolitis)
 - convulsion
 - allergic reactions
 - bloodstream infection (sepsis)

Other side effects

Common (may affect up to 1 in 10 people)

- cardiac disorders such as fast heart beat (tachycardia)
- increased sugar in blood or serum (hyperglycaemia)

Uncommon (may affect up to 1 in 100 people)

- cardiac disorders such as irregular heart beat (arrhythmia)

Not known (frequency cannot be estimated from the available data)

- reduced sugar in blood or serum (hypoglycaemia)
- failure to grow
- feeding intolerance
- stimulation of central nervous system such as irritability,nervousness, restlessness and 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

Reporting of side effects

If your newborn gets any side effects, talk to your baby's doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Caffeine Citrate 10mg/ml Oral Solution

Keep this medicine out of the sight and reach of children.

There are no other special conditions of storage.

Do not use this medicine after the expiry date which is stated on the label.

The expiry date refers to the last day of that month

Do not use if there are any signs of discolouration or clouding of the solution. Use once only and discard bottle and any remaining solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Caffeine Citrate 10mg/ml Oral Solution contains

The active ingredient is caffeine citrate 10mg/ml.

The other ingredients are:

- water for injections
- citric acid
- sodium chloride
- sodium hydroxide
- dilute hydrochloric acid

What Caffeine Citrate 10mg/ml Oral Solution looks like and contents of the pack

- Caffeine Citrate 10mg/ml Oral Solution is available in clear glass bottles with a rubber stopper and screw cap containing 5ml. Each 1ml of the solution contains 10mg caffeine citrate, equivalent to 5mg caffeine.

Marketing authorisation holder

Macarthy's Laboratories Limited
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Manufacturer

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