

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.

In this leaflet:

1. What Caffeine Citrate 10mg/ml Oral Solution is and what it is used for
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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 stimulates breathing, and is used to treat apnoea of prematurity (breathing difficulties as a result of being born prematurely).

2. Before your baby takes Caffeine Citrate 10mg/ml Oral Solution

Your baby should not be given Caffeine Citrate 10mg/ml Oral Solution if there is known hypersensitivity (allergy) to any of the ingredients listed in paragraph 6 overleaf.

Special care is needed with Caffeine Citrate 10mg/ml Oral Solution when your baby:

- has liver or kidney disease
- has had any unusual heart rhythms detected.

Please tell the doctor looking after your baby of any of such problems.

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.

If you, as the mother, drank a lot of coffee, or took any other high caffeine-containing product just before your baby was born, some caffeine may still be present in your baby's circulation. Tell the doctor about this.

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.

Caffeine Citrate 10mg/ml Oral Solution contains 3.04mg sodium per 1ml of the solution, which the doctor will need to consider if your baby is on a controlled sodium diet.

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

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).

Continued overleaf

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

4. Possible side effects

Caffeine acts as a stimulant to the nervous system. Side effects from this action may include restlessness or jitteriness. Caffeine may also aggravate any tendency to vomiting.

If you think your baby is showing any of these side effects, or you notice any other effects after caffeine treatment, please tell the doctor immediately.

Other side-effects are not visible, but will be detected by the monitoring equipment used in the special care baby unit:

- your baby may produce more urine than usual, and as a consequence blood levels of certain chemicals (sodium, calcium and glucose) may be affected.
- Increased blood pressure or heart rate

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.

Accidental overdose: 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 overdose, fits can also occur. If signs of over-dosage are noticed, please tell the baby's doctor immediately.

5. Storing Caffeine Citrate 10mg/ml Oral Solution

Caffeine Citrate 10mg/ml Oral Solution needs to be kept out of the reach and sight of children. There are no other special conditions of storage.

Use by date: Do not use Caffeine Citrate 10mg/ml Oral Solution after the expiry date on the label, or if there are any signs of discolouration or clouding of the solution.

6. Further Information

The active ingredient is caffeine.

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

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Manufacturer

Martindale Pharmaceuticals, Bampton Road, Harold Hill, Romford, Essex RM3 8UG

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