

## Caffeine Citrate 10mg/ml Solution for Injection

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 Solution for Injection is and what it is used for
2. Before your baby is given Caffeine Citrate 10mg/ml Solution for Injection
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5. Storing Caffeine Citrate 10mg/ml Solution for Injection
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### 1. What Caffeine Citrate 10mg/ml Solution for Injection 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 is given Caffeine Citrate 10mg/ml Solution for Injection

**Your baby should not be given Caffeine Citrate 10mg/ml Solution for Injection** if there is known hypersensitivity (allergy) to any of the ingredients listed in section 6 below.

**Special care is needed with Caffeine Citrate 10mg/ml Solution for Injection 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 Solution for Injection 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 Solution for Injection contains 3.04mg sodium per 1 ml of the solution, which the doctor will need to consider if your baby is on a controlled sodium diet.
- Opening the ampoules may introduce glass particles into this solution. It is recommended that Caffeine Citrate 10mg/ml Solution for Injection be filtered before administration. Filters should **not** then be used to administer the dose from the syringe.

### 3. How Caffeine Citrate 10mg/ml Solution for Injection is used

The doctor or nurse will administer Caffeine Citrate 10mg/ml 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. **This medicine 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 20mg/kg of the baby's body weight calculated as caffeine citrate (equivalent to caffeine 10mg/kg or 2ml/kg of this solution) if by injection then infused over 30 minutes
- 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 by injection then infused over 10 minutes

If your baby fails to respond to the starting dose (after at least 4 hours), the doctor or nurse may give one more additional starter dose, before continuing to the lower maintenance doses.

*Continued overleaf*

#### 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 Solution for Injection

Caffeine Citrate 10mg/ml Solution for Injection 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 Solution for Injection after the expiry date on the label, or if there are any signs of discolouration or clouding of the solution.

#### 6. Further Information

##### What Caffeine Citrate 10mg/ml Solution for Injection contains

The active ingredient is caffeine citrate 10mg/ml, equivalent to caffeine 5mg/ml.

Other ingredients are:

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

Caffeine Citrate 10mg/ml Solution for Injection contains 3.04mg sodium per 1ml of the solution.

##### What Caffeine Citrate 10mg/ml Solution for Injection looks like and contents of the pack

- Each 1ml ampoule of Caffeine Citrate 10mg/ml Solution for Injection contains 10mg of caffeine citrate, equivalent to 5mg caffeine.
- Each 2ml ampoule of Caffeine Citrate 10mg/ml Solution for Injection contains 20mg of caffeine citrate, equivalent to 10mg caffeine.
- Caffeine Citrate 10mg/ml Solution for Injection is available in ampoules of 1ml or 2ml, in packs of 10 ampoules

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