

PACKAGE LEAFLET

Package leaflet: Information for the user
Caffeine citrate 20mg/mL solution for infusion and oral solution (equivalent to 10 mg/mL of caffeine base)

Read all of this leaflet carefully before treatment with this medicine because it contains important information for your new born

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your baby's doctor.
- 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 20mg/mL solution for infusion and oral solution is and what it is used for
2. What you need to know before your baby is given Caffeine citrate 20mg/mL solution for infusion and oral solution
3. How to use Caffeine citrate 20mg/mL solution for infusion and oral solution
4. Possible side effects
5. How to store Caffeine citrate 20mg/mL solution for infusion and oral solution
6. Contents of the pack and other information

1. WHAT CAFFEINE CITRATE 20MG/ML SOLUTION FOR INFUSION AND ORAL SOLUTION IS AND WHAT IT IS USED FOR

Caffeine citrate 20mg/mL solution for infusion and oral solution contains the active substance caffeine citrate, which is a stimulant of the central nervous system, belonging to a group of medicines called methylxanthines.

Caffeine citrate 20mg/mL solution for infusion and oral solution 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 20MG/ML SOLUTION FOR INFUSION AND ORAL SOLUTION

Do not use Caffeine citrate 20mg/mL solution for infusion and oral solution:

- If your newborn is allergic to caffeine citrate or 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 20mg/mL solution for infusion and oral solution.

Prior to starting treatment for apnoea of prematurity with Caffeine citrate 20mg/mL solution for infusion and oral solution other causes of apnoea should have been excluded or properly treated by your baby's doctor.

Caffeine citrate 20mg/mL solution for infusion and oral solution should be used with caution. Please inform your baby's doctor:

- If your newborn suffers from seizures
- If your newborn suffers from any heart disease

- If your newborn has kidney or liver problems
- If your newborn has frequent regurgitation
- If your newborn produces more urine than usual
- If your newborn has a reduced weight gain or food intake
- If you (the mother) consumed caffeine prior to delivery

Other medicines and Caffeine citrate 20mg/mL solution for infusion and oral solution

Tell your baby's doctor if your newborn is taking, have recently taken or might take any other medicines. Please inform your baby's doctor if your newborn has been previously treated with theophylline.

Do not use the following medicines during the treatment with Caffeine citrate 20mg/mL solution for infusion and oral solution without talking to your

baby's doctor. The doctor may need to adjust the dose or change one of the medicines to something else:

- theophylline (used to treat breathing difficulties)
- doxapram (used to treat breathing difficulties)
- cimetidine (used to treat gastric disease)
- ketoconazole (used to treat fungine infections)
- phenobarbital (used to treat epilepsy)
- phenytoin (used to treat epilepsy)

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 20mg/mL solution for infusion and oral solution, you should not

drink coffee or take any other high caffeine product as caffeine passes into breast milk.

Caffeine citrate 20mg/mL solution for infusion and oral solution contains sodium

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

3. HOW TO USE CAFFEINE CITRATE 20MG/ML SOLUTION FOR INFUSION AND ORAL SOLUTION

Caffeine citrate 20mg/mL solution for infusion and 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.

Dose

Your baby's doctor will prescribe the right amount of Caffeine citrate 20mg/mL solution for infusion and oral solution based on your baby's weight.

The starting dose is 20 mg per kg body weight (equivalent to 1 mL per kg body weight).

The maintenance dose is 5 mg per kg body weight (equivalent to 0.25 mL per kg body weight) every 24 hours.

Route and method of administration

Caffeine citrate 20mg/mL solution for infusion and oral solution will be infused by controlled intravenous infusion, using a syringe infusion pump or other metered infusion device.

This method is also known as "a drip".

Some of the doses (maintenance doses) may be given by mouth.

It may be needed that your baby's doctor decides to check the levels of caffeine in a blood test periodically throughout treatment to avoid toxicity.

Duration of treatment

Your baby's doctor will decide exactly how long your newborn must continue therapy with Caffeine citrate 20mg/mL solution for infusion and oral solution.

If your baby has 5 to 7 days without apnoea attacks, the doctor will stop the treatment.

If your newborn receives more Caffeine citrate 20mg/mL solution for infusion and oral solution than he/she should

Your newborn may experience fever, rapid breathing (tachypnoea), jitteriness, muscular tremor, vomiting, high blood levels of sugar (hyperglycemia), low blood levels of potassium (hypokalaemia), high blood levels of certain chemicals (urea), elevated number of certain cells (leukocyte) in blood and seizures if he/she receives more caffeine citrate than he/she should.

In the event of this happening treatment with Caffeine citrate 20mg/mL solution for infusion and 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 20mg/mL solution for infusion and oral solution, your newborn may experience some of the following reactions:

Serious side effects

Side effects where the frequency cannot be estimated from the available data

- serious intestinal disease with bloody stools (necrotising enterocolitis)

The following other side effects may also be considered serious by your baby's doctor in the context of the global clinical evaluation.

Other side effects

Common reported side effects (may affect up to 1 in 10 people)

- local inflammatory reactions at the infusion site
- cardiac disorders such as fast heart beat (tachycardia)
- changes of sugar in blood or serum (hyperglycaemia)

Uncommon reported side effects (may affect up to 1 in 100 people)

- stimulation of central nervous system such as convulsion
- cardiac disorders such as irregular heart beat (arrhythmia)

Rare reported side effects (may affect up to 1 in 1,000 people)

- allergic reactions

Side effects where the frequency cannot be estimated from the available data

- bloodstream infection (sepsis)
- changes of sugar in blood or serum (hypoglycaemia), failure to grow, feeding intolerance
- stimulation of central nervous system such as 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 and 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:

United Kingdom: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google

Play or Apple App Store

Ireland: HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CAFFEINE CITRATE 20MG/ML SOLUTION FOR INFUSION AND ORAL SOLUTION

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

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.

The medicinal product does not require any special storage conditions.

Vials of all parenteral solutions must be inspected visually for particulate matter prior to administration.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Caffeine citrate 20mg/mL solution for infusion and oral solution contains

The active substance is caffeine citrate.

Each mL contains 20 mg caffeine citrate (equivalent to 10 mg/mL of caffeine base).

Each 3 mL fill in 5mL vial contains 60 mg caffeine citrate (equivalent to 30 mg of caffeine base).

The other ingredients are citric acid monohydrate, sodium citrate dihydrate and water for injections.

What Caffeine citrate 20mg/mL solution for infusion and oral solution looks like and content of the pack

Caffeine citrate 20mg/mL solution for infusion and oral solution is a solution for infusion and oral solution. Caffeine citrate 20mg/mL solution for infusion and oral solution is a clear, colourless solution, supplied in glass vial.

It comes in an individual pack of each carton containing 1 vial or in a multipack comprising 5 or 10 individual cartons each containing 1 vial or multipack carton comprising 5 or 10 vials packed using a partition.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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