PACKAGE LEAFLET: INFORMATION FOR THE USER

Peyona 20 mg/ml solution for infusion and oral solution caffeine citrate

Read all of this leaflet carefully before treatment with this medicine because it contains important information for your newborn
- Keep this leaflet. You may need to read it again.
- If you have 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 PEYONA IS AND WHAT IT IS USED FOR

Peyona contains the active substance caffeine citrate, which is a stimulant of the central nervous system, belonging to a group of medicines called methylxanthines.

Peyona 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 PEYONA

Do not use Peyona:
- 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 Peyona.
Prior to starting treatment for apnoea of prematurity with Peyona other causes of apnoea should have been excluded or properly treated by your baby's doctor.

Peyona 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 Peyona
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 Peyona 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 Peyona, you should not drink coffee or take any other high caffeine product as caffeine passes into breast milk.

Peyona contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. is essentially 'sodium-free'.

3. HOW TO USE PEYONA

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

If your newborn receives more Peyona 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 Peyona 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 Peyona, 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.

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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 UK: Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
ROI: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PEYONA

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.
Ampoules of all parenteral solutions must be inspected visually for particulate matter prior to administration.
After opening the ampoules, the medicinal product should be used immediately.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Peyona contains
The active substance is caffeine citrate.
Each ml contains 20 mg caffeine citrate (equivalent to 10 mg/ml of caffeine base).
Each 1 ml ampoule contains 20 mg caffeine citrate (equivalent to 10 mg of caffeine base).
Each 3 ml ampoule contains 60 mg caffeine citrate (equivalent to 30 mg of caffeine base).
The other ingredients are citric acid, sodium citrate and water for injections.

What Peyona looks like and content of the pack
Peyona is a solution for infusion and oral solution.
Peyona is a clear, colourless solution, supplied in glass ampoules. Each carton contains 10 ampoules.

Marketing Authorisation Holder
Chiesi Farmaceutici S.p.A,
Via Palermo 26/A,
43122 Parma,
Italy

Manufacturer (Batch release)
Alfasigma S.p.A,
Via Enrico Fermi 1,
Alanno (PE)
Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the website of the European Medicines Agency
http://www.ema.europa.eu

The following information is intended for medical or healthcare professionals only:
For detailed information refer to the enclosed Summary of Product Characteristics of PEYONA.

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