LAMINATED CARD

Peyona (caffeine citrate) 20 mg/ml Solution for Infusion and Oral Solution

Before using Peyona (caffeine citrate) 20 mg/ml either intravenously or orally, in addition to reading the Summary of Product Characteristics, please check the following points:

Indication for use

- The indication is for the treatment of primary apnoea of premature newborns.
- Treatment must be provided on neonatal intensive care units only.
- Treatment must be initiated and supervised by a physician experienced in neonatal intensive care.
- Measurement of baseline caffeine levels, monitoring of plasma concentrations as well as dose adjustments during therapy is advisable.
- Special attention should be paid to dosage recommendations, contraindications, warnings and precautions for use. *Refer to the Summary of Product Characteristics for further information on safe use.*

There are two authorised presentations which differ in the fill-volume: **3 ml** (equivalent to **60mg** of caffeine citrate) and **1 ml** (equivalent to **20mg** of caffeine citrate).
1ml ampoule will allow administration of small volumes of solution in accordance with the recommended loading and maintenance dose, which is of importance for very premature infants with a small weight.

Recommended dosage

	Dose of caffeine citrate (Volume)	Dose of caffeine citrate (mg/kg body weight)	Route	Frequency
Loading dose	**1.0 ml/kg** body weight	**20 mg/kg** body weight	Intravenous infusion (over 30 minutes)	Once
Maintenance dose *	**0.25 ml/kg** body weight	**5 mg/kg** body weight	Intravenous infusion (over 10 minutes) or by oral administration	Every 24 hours*

*** Beginning 24 hours after the loading dose**

A second loading dose of 10-20 mg/kg may be given in preterm infants with insufficient clinical response to the recommended loading dose after 24 hours.
Higher maintenance doses of 10 mg/kg body weight could be considered in case of insufficient response, taking into account the potential for accumulation of caffeine in premature neonates and the progressively increasing capacity to metabolise caffeine in relation to post-menstrual age (where clinically indicated, caffeine plasma levels should be monitored).

The diagnosis of apnoea of prematurity may need to be reconsidered if patients do not respond adequately to a second loading dose or maintenance dose of 10 mg/kg/day.
The diagnosis of apnoea of prematurity may need to be reconsidered in patients who do not respond adequately to a second loading dose or higher maintenance dose.

Key warnings

- Specify the dose to be administered clearly as caffeine *citrate, as the dose expressed as caffeine base is one-half the dose expressed as caffeine citrate (e.g. 20 mg caffeine citrate is equivalent to 10 mg caffeine base).*
- **Each ampoule is for single and immediate use only: any unused portion left in the ampoule must be discarded.**
- It is advisable to measure baseline caffeine levels in infants whose mothers have ingested large quantities of caffeine prior to delivery or breastfeeding, or infants who previously have been treated with theophylline (caffeine citrate should not be used together with theophylline).
- If caffeine and doxapram are used concurrently, the patient should be closely monitored.
- Plasma concentrations of caffeine may need to be monitored and doses be adjusted
  - since caffeine may accumulate in premature neonates because of it's long half-life
  - in case of insufficient clinical response or signs of toxic effects
  - in patients with underlying conditions increasing the risk for elevated plasma concentrations (e.g. very premature infants less than 28 weeks gestational age and/or body weight < 1000g particularly when receiving parenteral nutrition, infants with hepatic or renal impairment, co-medication known to interfere with caffeine metabolism)
  - in clinical conditions with increased risk for adverse reactions (e.g. clinically significant cardiac disease, seizure disorders).

Once administered, please be alert to the following risks:

- Toxicity due to maternal caffeine ingestion, whilst breast-feeding, in mothers who consume large amounts of caffeine.
- Symptoms arising from increased caffeine plasma levels in premature infants with cholestatic hepatitis or significant renal impairment.
- Cardiac disorders (including arrhythmias) in neonates with pre-existing cardiac disease.
- If you see any evidence suggestive of a link between caffeine citrate administration and convulsions, seizures, necrotising enterocolitis, symptoms and signs of caffeine withdrawal, medically abnormal slow increase in infantile weight gain or drug interactions with other medicines please report this as a suspected adverse reaction to Chiesi Limited using the contact details below.
- Report all suspected adverse reactions in accordance with national reporting requirements.

07/2015

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