Information on the safe use of Peyona (caffeine citrate) 20mg/ml solution for infusion and oral solution

Dear Healthcare Professional,

Chiesi Limited in Agreement with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) wishes to provide you with relevant information concerning the safe use of Peyona (caffeine citrate).

Summary

- Peyona (caffeine citrate) is authorised only for the treatment of primary apnoea of premature newborns. Treatment must be initiated under the supervision of a physician experienced in neonatal intensive care. Peyona is for use in Neonatal Intensive Care Units only.
- Measurement of baseline caffeine levels, monitoring of plasma concentrations as well as dose adjustments during therapy is advisable.
- Healthcare professionals should pay special attention to dosage recommendations, contraindications, warnings and precautions for use.

Further information on dosage

- Peyona (caffeine citrate) is available as ampoules containing 20mg/ml of caffeine citrate solution for infusion or oral administration.
- There are two authorised presentations which differ in the fill-volume: **3ml** (equivalent to 60mg of caffeine citrate) and **1ml** (equivalent to 20mg of caffeine citrate).
- Each ampoule is for single and immediate use only. Any unused portions remaining in the ampoule should be discarded.
- Doses specified on prescriptions should always be expressed as caffeine citrate in order to avoid medication errors, as the dose expressed as caffeine base is one-half the dose expressed as caffeine citrate (e.g. 20mg caffeine citrate is equivalent to 10mg caffeine base).

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- A second loading dose of 10-20mg/kg may be given in preterm infants with insufficient clinical response to the recommended loading dose after 24 hours.

- Higher maintenance doses of 10mg/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 in patients who do not respond adequately to a second loading dose or higher maintenance dose.

Further information on monitoring of plasma concentrations

- 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 and theophylline should not be used together!).

- Plasma concentrations of caffeine may need to be monitored and doses be adjusted in cases of insufficient clinical response or signs of toxic effects and in patients with underlying conditions increasing the risk for elevated plasma concentrations (e.g. very premature infants particularly when receiving parenteral nutrition, infants with hepatic or renal impairment, co-medication known to interfere with caffeine metabolism) or clinical conditions with increased risk for adverse reactions (e.g. clinically significant cardiac disease, seizure disorders).

Once administered, please be alert to the risk of cardiac disorders (including arrhythmias) in neonates with pre-existing cardiac disease.

For detailed information on the administration, special warnings and precautions for use of Peyona, please refer to the attached Summary of Product Characteristics.

Call for reporting

Please be alerted to the known risks associated with the administration of Peyona as specified in the Summary of Product Characteristics. In addition please look out for any other suspected adverse drug reactions that might occur during caffeine therapy such as:

- Necrotising Enterocolitis (NEC)
- Symptoms of caffeine withdrawal
- Abnormal slow increase infantile weight gain
- Convulsions and seizures
- Drug interactions with other medicines

Reports on adverse reactions in patients who obtain Peyona should be reported to Chiesi Limited at the following addresses:

Medical Services Chiesi Limited Cheadle Royal Business Park, Highfield, Cheadle SK8 3GY Tel: + 44 161 488 5555	OR	The Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Ireland Tel: +353-1-6764971

Communication information

Should you have any further questions or require additional information regarding the use of Peyona please feel free to contact us under the below address:

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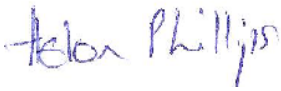
Name Helen Phillips

Signature 

Title Medical Director

Date 4th May 2012

Annexes

Summary of Product Characteristics