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.

- 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).

- Another formulation of caffeine citrate solution for treatment of apnoea in newborns is also available, which contains a different dose strength of caffeine citrate to Peyona. Care should be taken not to confuse the two products, as this may result in medication errors.

- 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 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).

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
- Drug interactions with other medicines

Please report suspected adverse reactions with any medicine or vaccine:

In **UK** to the MHRA via Yellow Card Scheme at www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission of Human Medicines (CHM) free phone line: 0800-731-6789
- Or by electronic download through the MHRA website (http://yellowcard.mhra.gov.uk/downloads/)

In **Ireland** to the HPRA via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Adverse reactions to Peyona may also be reported to Chiesi Limited at the following address:

Medical Services
Chiesi Limited
333 Styal Road
Manchester
M22 5LG
Tel: 0161 488 5555
Fax: 0161 488 5566

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:

Chiesi Limited
333 Styal Road
Manchester
M22 5LG
Tel: 0161 488 5555

Name Shishir Patel

Signature 

Title Head of Medical Affairs
BSc (Hons) DIP COMM Pharm MRPharmS GPhC

Date 10th March 2016

Annex

Summary of Product Characteristics