MARTINDALE PHARMA
An Ethypharm Group Company

Date

Information on the safe use of **Caffeine Citrate 10 mg/ml** Solution for Injection

We, Martindale Pharma, in agreement with JFDA, would like to notify you with the following information related to Caffeine Citrate 10mg/ml solution for injection.

This DHPC (Direct Healthcare Professional Communication) is in line with the reference product Peyona (Chiesi Limited). We wish to provide you with relevant information concerning the safe use of caffeine citrate 10mg/ml Solution for Injection.

Summary

- Caffeine Citrate 10mg/ml Solution for Injection is authorised only for the treatment of apnoea of prematurity. Treatment must be initiated under the supervision of a physician experienced in neonatal intensive care. Caffeine Citrate 10mg/ml Solution for Injection is for use in Neonatal Intensive Care Units (NICUs) 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

Caffeine Citrate 10mg/ml Solution for Injection is available as ampoules containing 10mg/ml Caffeine Citrate for infusion.

- There is one authorised presentation: 1ml of solution that contains 10mg Caffeine Citrate, equivalent to 5mg of caffeine.
- 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., 10mg Caffeine Citratee is equivalent to 5mg caffeine base).
- 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).
- If concurrent use of doxapram is indicated, cardiac rhythm and blood pressure must be carefully monitored.
- 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).

Call for reporting

Please be alerted to the known risks associated with the administration of Caffeine Citrate 10mg/ml Solution for Injection, 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
- Decrease in weight gain/ or abnormal slow increase infantile weight gain
- Drug interactions with the most commonly used drugs in the NICU

Please report suspected adverse reactions (in accordance with national reporting requirements)
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates. Adverse reactions to Caffeine Citrate 10mg/ml Solution for Injection may also be reported to pharmacovigilance department.

Name of the MAH: Macarthys Laboratories T/A Martindale Pharma

Email: ethypharm.ICSRtransmission@vigipharm.fr
(CC: drugsafety@ethypharm.com)
Also you are encouraged to report suspected adverse reaction on JFDA below contacts:

وسائل الإبلاغ عن الآثار الجانبية الخاصة بالمؤسسة العامة للغذاء والدواء	
jpc@jfda.jo	البريد الالكتروني:
https://primaryreporting.who-umc.org/JO	رابط الإبلاغ الالكتروني على موقع المؤسسة www.jfda.com
+962-6-5632000	الهاتف:
	رمز الاستجابة السريعة QR Code:

Communication information

Should you have any further questions or require additional information regarding the use of Caffeine Citrate 10mg/ml Solution for Injection, please feel free to contact us under the below address:

Email: medinfo@ethypharm.com

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