MARTINDALE PHARMA
An Ethypharm Group Company

# 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.

**Before using Caffeine Citrate 10mg/ml either intravenously, in addition to reading the Summary of Product Characteristics, please check the following points:**

### INDICATION FOR USE

- The indication is for the treatment of apnoea of prematurity.
- Treatment should be administered only in a neonatal intensive care unit in which adequate facilities are available for patient surveillance and monitoring.
- Treatment with caffeine citrate should be initiated under the supervision of 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 is one authorised presentation: 1 ml (equivalent to 10mg 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 10 mg/ml Solution for Injection | Dose Expressed as Caffeine Citrate | Dose Expressed as Caffeine Base | Route | Frequency |
|---|---|---|---|---|---|
| **Loading Dose** | 2 ml/kg | 20 mg/kg | 10 mg/kg | Intravenous** (over 30 min) or oral | Once |
| **Maintenance Dose** | 0.5 – 1 ml/kg* | 5 – 10 mg/kg* | 2.5 – 5.0 mg/kg* | Intravenous** (over 10 min) or oral | Every 24 hours*** |

* In some cases maintenance doses higher than 10mg/kg/day (expressed as caffeine citrate) may be required to achieve maximal efficacy (e.g. in continuing apnoeic episodes where plasma levels indicate the dose may be safely increased).
** By intravenous infusion
*** Beginning 24 hours after the loading dose(s)

If there is inadequate clinical response to the first loading dose, a second dose may be given, but if there is continued inadequate response, the plasma levels should be confirmed before further doses are given, as the failure to respond could be an indication of another cause of apnoea. Plasma levels should not normally exceed 50 micrograms/ml (optimally 10-30 micrograms/ml).

## 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. 10 mg Caffeine Citrate is equivalent to 5 mg caffeine base).
- **Each ampoule is for single and immediate infusion use only: any unused portion left in the ampoule must be discarded.**
- **Only clear solution without particulate matter should be used. For single use only. Any unused solution should be discarded.**
- It is advisable to measure baseline caffeine levels in infants whose mothers have ingested large quantities of caffeine prior to delivery or while breastfeeding, or infants who previously have been treated with theophylline (caffeine citrate should not be used together with theophylline).
- If doxapram is used with caffeine citrate the patient must be closely monitored.

Plasma concentrations of caffeine may need to be monitored and doses be adjusted

- 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, decrease in weight gain/failure to thrive or drug interactions with the most commonly used drugs in NICs, and medication error please report this as a suspected adverse reaction to Pharmacovigilance department using the contact details below.

Report all suspected adverse reactions in accordance with national reporting requirements.

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: |

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