ALERT CARD

Gencebok 10 mg/ml

Solution for infusion

Caffeine citrate (equivalent to 5 mg/ml of caffeine base)

Intravenous and Oral use

This alert card is a measure taken to ensure the safe and effective use of Gencebok 10 mg/ml and minimise the risk of caffeine toxicity.

- Gencebok is indicated for treatment of primary apnoea of premature newborns.
- Treatment with Gencebok must be provided in a neonatal intensive care unit and initiated and supervised by a physician experienced in neonatal intensive care.
- Caffeine may accumulate in premature newborn infants because of its long half-life.
- The dose of caffeine expressed as caffeine base is one half the dose of caffeine expressed as caffeine citrate (10 mg caffeine citrate is equivalent to 5 mg caffeine base). Prescriptions should clearly indicate that caffeine citrate is to be administered.
- Gencebok contains 10 mg caffeine citrate, equivalent to 5 mg caffeine base and should be administered according to the following dosing scheme:

	Dose of caffeine citrate (Volume)	Dose of caffeine citrate (mg/kg body weight)	Route	Frequency
Loading dose	**2,0 ml/kg** body weight	20 mg/kg body weight	Intravenous infusion (over 30 minutes)	Once
Maintenance dose*	**0,5 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

- The medicinal product should be used immediately after opening the ampoule and unused portions left in the ampoule should be discarded.
- Baseline plasma levels may need measuring because of an increased risk of toxicity if:
  - The neonate has been previously treated with theophylline
  - The mother has been consuming large amounts of caffeine prior to delivery or breast feeding
- Caffeine and theophylline should not be used concurrently
- If caffeine and doxapram are used concurrently, the patient should be closely monitored
- Additional plasma caffeine monitoring and dosage adjustment may be necessary in at risk situations such as preterm infants:
  - With cholestatic hepatitis
  - With significant renal impairment
  - With seizure disorders
  - With cardiac disease
  - less than 28 weeks gestational age and/or body weight <1000g particularly when receiving parenteral nutrition
  - with co-administration of medicinal products known to interfere with caffeine metabolism
- Cardiac disorders (including arrhythmias) may arise in newborn infants with pre-existing cardiac disease

All suspected adverse reactions should be reported to HPRA Pharmacovigilance on the following website: www.hpra.ie

In particular, if convulsions, seizures, necrotising enterocolitis, symptoms and signs of caffeine withdrawal, medically abnormal decrease in infant weight gain or interactions with other medicines are suspected as being associated with the use of caffeine citrate, these should be reported to

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For more information, please consult the Summary of Product Characteristics (SmPC) and the package leaflet for Gencebok 10 mg/ml. Electronic versions of the SPC and the leaflet are available on the EMA website: https://www.ema.europa.eu/en/documents/product-information/gencebok-epar-product-information_en.pdf

GPM 012 – Approved 02/2021

gennisium PHARMA

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