Fenapin (caffeine citrate): the new cost-effective solution for primary apnoea in premature newborns

Fenapin is indicated for the treatment of primary apnoea of premature newborns.[1] Each 1 ml ampoule contains 20 mg caffeine citrate (equivalent to 10 mg caffeine).[1] Fenapin 20 mg/ml solution can be administered by **IV infusion or orally.**[1]

Pharmaceutical Form

Fenapin is conveniently supplied in glass ampoules with a **shelf life of 3 years** and **does not require any special storage conditions.**[1]

Fenapin is a clear, colourless, aqueous solution with a pH of between 4.2 and 5.21 and osmolality of 153–155 mOsm/l. These levels of pH and osmolarity should **improve IV tolerability compared with some other licenced caffeine citrate preparations.**[1,2]

Ordering Fenapin

Fenapin 20 mg/ml solution orders should be placed with **Alloga UK or Alliance Healthcare UK**.

Fenapin (caffeine citrate) 20 mg/ml Solution for Infusion, 5 x 1 ml ampoules

PIP code: 4256426
EAN code: 5070000854335

Prescribing information can be found on the next page.

Adverse events should be reported. For reporting within the UK, forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Galvany Pharma Lts on Phone: +44(0) 1438310048 or Email: information@galvanypharma.com.

For more information, please call +44 (0) 1438 310048 or email information@galvanypharma.com.

Galvany Pharma

Prescribing Information

Fenapin (caffeine citrate) 20 mg/mL Solution for Infusion PRESCRIBING INFORMATION ACTIVE INGREDIENT(S): Caffeine citrate **Please refer to Summary of Product Characteristics (SmPC) before prescribing. INDICATION(S):** FENAPIN is indicated for the treatment of primary apnoea of premature newborns. **DOSAGE & ADMINISTRATION:** Treatment should be administered in a neonatal intensive care unit in which adequate facilities are available for patient surveillance and monitoring. Infants must be of sufficient respiratory maturity not to require positive pressure ventilation. The recommended dose in previously untreated infants is a loading dose of 20 mg/kg body weight by slow intravenous infusion over 30 minutes. After an interval of 24 hours, maintenance doses of 5 mg/kg body weight may be administered over 10 minutes every 24 hours. Oral administration may be used alternatively for maintenance doses without adjusting the dose. Doses may need to be adjusted according to medical judgment following routine monitoring of caffeine plasma concentrations in at risk situations, incomplete clinical response, or signs of toxicity. The optimal duration of treatment has not been established. In clinical practice, treatment is usually continued until the patient has reached a post-menstrual age of 37 weeks. This duration may be revised according to medical judgment. It is recommended that treatment should be stopped when the patient has 5-7 days without a significant apnoeic attack. If the patient has recurrent apnoea, treatment can restart with a maintenance dose or a half loading dose, depending on the time since treatment stopped. Patient monitoring should continue for approximately one week after stopping treatment. **Patients with hepatic or renal impairment:** There is limited experience in patients with renal and hepatic impairment. Treatment should be administered with caution in preterm newborn infants with impaired renal or hepatic function. Doses should be adjusted by monitoring caffeine plasma concentrations to avoid toxicity in this population. **Refer to SmPC for full details CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **SPECIAL WARNINGS & PRECAUTIONS:** Apnoea: Other causes of apnoea should be ruled out or properly treated prior to initiation of treatment. Failure to respond to treatment could indicate another cause of apnoea. Caffeine consumption: In newborn infants born to mothers who consumed large quantities of caffeine prior to delivery, baseline plasma caffeine concentrations should be measured prior to initiation of treatment. Breast-feeding mothers of newborn infants treated with FENAPIN should not ingest caffeine-containing foods and beverages or medicinal products containing caffeine. Theophylline: In newborns previously treated with theophylline, baseline plasma caffeine concentrations should be measured prior to initiation of treatment. Seizures: Extreme caution must be exercised if FENAPIN is used in newborns with seizure disorders. Cardiovascular reactions: FENAPIN should be used with caution in newborns with known cardiovascular disease. If there have been any unusual rhythm disturbances on a cardiotocograph trace before the baby is born, FENAPIN should be administered with caution. Renal and hepatic impairment: FENAPIN should be administered with caution in preterm newborn infants with impaired renal or hepatic function. Doses should be adjusted by monitoring caffeine plasma concentrations to avoid toxicity in this population. Necrotising enterocolitis: As for all preterm infants, those treated with FENAPIN should be carefully monitored for the development of necrotising enterocolitis. Sodium content: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. Educational Risk Minimisation Materials: Before administering treatment, physicians must ensure they are familiar with the FENAPIN 20 mg/ml Solution for Infusion Card available at https://www.medicines.org.uk/emc/product/15325/rmms. **Refer to SmPC for full details UNDESIRABLE EFFECTS: Common: (≥ 1/100 to <1/10):** Hyperglycaemia, tachycardia, infusion site phlebitis, infusion site inflammation. **Uncommon: (≥ 1/1,000 to <1/100):** Convulsion, arrhythmia. **Rare: (≥ 1/10,000 to <1/1,000):** Hypersensitivity reaction. **Not known (cannot be estimated from the available data):** Sepsis, hypoglycaemia, failure to thrive, feeding intolerance, irritability, jitteriness, restlessness, brain injury, deafness, increased left ventricular output and increased stroke volume, regurgitation, increased gastric aspirate, necrotising enterocolitis, urine output increased, urine sodium and calcium increased, haemoglobin decreased, thyroxine decreased. **Refer to SmPC for full details PREGNANCY:** Caffeine in animal studies, at high doses, was shown to be embryotoxic and teratogenic. These effects are not relevant with regard to short term administration in the preterm infant population. **LACTATION:** In newborn infants born to mothers who consumed large quantities of caffeine prior to delivery, baseline plasma caffeine concentrations should be measured prior to initiation of treatment. Breast-feeding mothers of newborn infants treated with FENAPIN should not ingest caffeine-containing foods and beverages or medicinal products containing caffeine. **INTERACTIONS:** Caffeine and theophylline should not be used concurrently due to inter-conversion. Dose adjustment may be needed when FENAPIN is co-administered with other active substances. Where doubt exists about possible interactions, plasma caffeine concentrations should be measured. Co-administering FENAPIN with medicines that suppress gastric acid could theoretically increase the risk of necrotising enterocolitis due to potential bacterial overgrowth in the gut. Using caffeine and doxapram together might potentiate their stimulatory effects on the cardio-respiratory and central nervous system. If used concurrently, cardiac rhythm and blood pressure must be carefully monitored. **Refer to SmPC for full details**

LEGAL CATEGORY: POM.
PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBERS: Type I clear glass 1 mL ampoule with a yellow ring around the neck. Pack size: 5 ampoules.
PL 56809/0002

FURTHER INFORMATION AVAILABLE FROM THE MARKETING AUTHORISATION HOLDER: Galvany Pharma Ltd., Business & Technology Centre, Bessemer Drive, Stevenage, SG1 2DX, UK. Email: information@galvanypharma.com.

Prescribing information last revised: January 2024

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IV, intravenous.

References

1. Fenapin 20 mg/ml Solution for Infusion Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/15325.
2. Ejiwumi O, et al. Infant. 2016;12(6):219-221.

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