



19 August 2020  
EMA/354319/2020

## Gencebok: potential for dosing errors

Gencebok, a medicine for treating apnoea of prematurity, is a solution that contains the active substance caffeine citrate 10 mg/ml. It can be given either by infusion (drip) into a vein or by mouth. The baby could receive the wrong dose if the full name of the active substance is not used for prescribing the medicine (2 mg caffeine citrate is equivalent to 1 mg caffeine) or if an incorrect strength of the active substance is used for calculating the dose. Another medicine for treating apnoea of prematurity is available that contains a different strength of caffeine citrate.

### Information for healthcare professionals

- Prescribing and dispensing systems, administration protocols and infusion equipment must be aligned to the strength of caffeine citrate medicine used in the neonatal intensive care unit.
- Since caffeine citrate medicines are available in different strengths, the strength of the intended medicine must be ascertained when calculating the dose.
- The dose of the active substance should be calculated in terms of caffeine citrate and prescribed in terms of the amount of caffeine citrate (in mg). There is a potential for error if the active substance is described in any other way.
- The following table shows doses in terms of the amount of caffeine citrate together with the corresponding volume of Gencebok needed:

	Dose as amount of caffeine citrate	Route	Volume of Gencebok solution (10 mg/ml)
Loading dose	20 mg/kg as a single dose	By intravenous infusion (over 30 minutes)	2.0 ml/kg as a single dose
Maintenance doses (starting 24 hours after loading dose)	5 mg/kg every 24 hours	By intravenous infusion (over 10 minutes) or by mouth	0.5 ml/kg every 24 hours

- An information card which includes information, warnings and precautions for the appropriate and safe use of Gencebok is available for display in neonatal intensive care units. It should be consulted when prescribing and administering Gencebok.
- Healthcare professionals should report any suspected adverse reactions with caffeine citrate to their [national regulatory authorities](#).



---

### **More about the medicine**

Gencebok is a medicine for treating apnoea of prematurity. It is available in ampoules as a solution containing caffeine citrate 10 mg/ml for use by intravenous infusion or for giving by mouth (e.g. through a nasogastric tube). The medicine should only be used in a neonatal intensive care unit where appropriate facilities are available for closely monitoring the baby and the effects of the medicine.

More information about the medicine is available on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/gencebok](http://ema.europa.eu/medicines/human/EPAR/gencebok)