

WHO-PQ recommended clinical and preclinical information for the patient

This information reflects the recommendations of current WHO guidelines and the scope of WHO's prequalification programme.

Information for the patient

[AP003 trade name]*
Caffeine citrate

Carers or parents looking after the person who takes this medicine should use this information to give the medicine correctly and take note of the warnings and side effects

1. What [AP003 trade name] is and what it is used for

[AP003 trade name] contains caffeine citrate.

[AP003 trade name] is used for treating and preventing breathing interruption (apnoea) in premature babies. It can also be used to prevent apnoea when removing the tube used for helping the baby breathe. Removal of this tube is called extubation.

Apnoea occurs in premature babies because the part of the brain that controls breathing is not yet fully developed.

How [AP003 trade name] works

Caffeine citrate, the active substance in [AP003 trade name], works on the baby's brain to get it to start controlling the baby's breathing. It does this by blocking the effect of adenosine, a natural substance that slows down the part of the brain that controls breathing.

2. What you need to know before you take [AP003 trade name]

Do not use [AP003 trade name]

Do not use [AP003 trade name] if:

- your baby is allergic (hypersensitive) to caffeine citrate or to any other ingredient in [AP003 trade name] (see section 6, 'What [AP003 trade name] contains').

Warnings and precautions

Your baby's health care provider may need to change how your baby has the medicine or take extra care in some cases. The health care provider will be watching your baby closely but tell the health care provider if your baby:

- has seizures (fits)
- has a heart condition
- has kidney or liver problems
- frequently regurgitates (food returning into the mouth after swallowing)
- is passing more urine than usual
- does not gain weight properly or does not take enough food

Also tell the baby's health care provider if you (the mother) took drinks or food containing caffeine before giving birth.

Speak with your health care provider if you need more information.

Watch out for any digestive or gut problems, particularly if there is blood in the baby's stool because these may be signs of a serious condition called necrotising enterocolitis.

* Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Other medicines and [AP003 trade name]

Tell your baby's health care provider if your baby is taking another medicine. Also tell the health care provider if the baby has recently taken another medicine or if the baby might start taking other medicines.

Tell your baby's health care provider if your baby has been treated with any of the following:

- aminophylline, doxapram or theophylline (for treating breathing difficulties)
- medicines to reduce stomach acid

The health care provider may need to adjust your baby's treatment if the baby has been treated with any of the above medicines.

Breast-feeding

Mothers who are breast-feeding their babies must not take drinks, foods or medicines that contain caffeine. Caffeine can be passed to the baby through breast milk.

3. How to take [AP003 trade name]

Your baby's health care provider will give [AP003 trade name] by mouth to your baby.

The dose of [AP003 trade name] depends on the baby's weight and the baby's condition. The health care provider will work out the right dose for your baby.

The baby will usually get a high starting dose and then, after a day, a continuing dose, which the baby gets once every day.

Usual starting dose: 20 mg/kg given once

Usual continuing dose: 5 mg/kg given every day.

Your baby's health care provider will continue treatment usually for 6 weeks or until the baby can breathe well enough. If the medicine is used to help your baby breathe after removing a breathing tube, treatment may be shorter (about 6 days). The health care provider will decide the best time to stop the medicine.

If your baby receives more [AP003 trade name] than the baby should

Because [AP003 trade name] is given by a health care provider, it is not likely that the baby will receive too much of the medicine. If the baby has received too much medicine the baby may get some of the side effects listed in section 4. Speak with the health care provider if you see any of these side effects.

If you have any questions on this medicine, ask your health care provider.

How the medicine is given

Your baby's health care provider will give [AP003 trade name] to your baby by mouth.

4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

Because premature babies can frequently have health complications, it is not always possible to say which of the ill effects are caused by their medicine and which are caused by being born too early.

Serious side effects

- serious intestinal disease with bloody stools (necrotising enterocolitis) – not known how often this occurs
- convulsions (fits) – an uncommon effect
- allergic reactions – a rare effect
- infection in the bloodstream (sepsis) – not known how often this occurs

All side effects

Common side effects (up to 1 in 10 premature babies can get this side effect)

- raised sugar level in the blood (hyperglycaemia)
- fast heartbeat
- if the medicine is given into the baby's vein, redness, pain and swelling along the vein

Uncommon side effects (up to 1 in 100 premature babies can get this side effect)

- convulsions (fits)
- irregular heart rhythm (arrhythmia)

Rare side effects (up to 1 in 1000 premature babies can get this side effect)

- allergic reactions

Side effects with unknown frequency (not known how often they can occur)

- infection in the bloodstream (sepsis)
- low sugar level in the blood (hypoglycaemia)
- not growing or putting on weight, cannot take food by mouth
- irritability, jitteriness, restlessness
- brain injury
- deafness
- heart pumping more forcefully
- bringing food back up (regurgitation) or bringing stomach content back up
- serious intestinal disease with bloody stools (necrotising enterocolitis)
- passing increased urine
- increased sodium and calcium in urine
- blood test showing decreased haemoglobin (the substance that carries oxygen in blood) or decreased thyroxine (a hormone produced by the body)

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [AP003 trade name]

Product specific information on the storage conditions is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.

6. Contents of the pack and other information

What [AP003 trade name] contains

What [AP003 trade name] looks like and contents of the pack

Supplier and Manufacturer

This leaflet was last revised in July 2026

Product specific information on the composition, visual appearance of the formulation, appearance and size of packs as well as on the supplier, is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.