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# Peyona[1] (*caffeine citrate*)

An overview of Peyona and why it is authorised in the EU

## What is Peyona and what is it used for?

Peyona is a stimulant medicine used for treating apnoea of prematurity, a condition in which babies born prematurely stop breathing for longer than 20 seconds.

Peyona contains the active substance caffeine citrate.

## How is Peyona used?

Peyona can only be obtained with a prescription. A doctor with experience of treating newborn babies on intensive care should supervise the start of treatment with the medicine. Peyona should be given only in an intensive care unit for newborns that is well equipped to closely monitor the baby.

The dose of Peyona is calculated using the baby's weight. The first dose (of 20 mg caffeine citrate per kilogram of bodyweight) is given by infusion (drip) into a vein over 30 minutes, using a device to closely control the rate at which the medicine is given. To continue treatment, Peyona is given in lower doses (5 mg caffeine citrate per kilogram of bodyweight) every 24 hours. These lower doses can be given either by infusion over 10 minutes or by mouth (e.g. through a tube into the stomach). Treatment usually continues until the baby can breathe well enough for at least 5 days.

For more information about using Peyona, see the package leaflet or contact your doctor or pharmacist.

## How does Peyona work?

Apnoea in premature babies occurs because the part of the baby's brain that controls breathing ('breathing centre') is not fully developed.

Caffeine citrate, the active substance in Peyona, blocks the effect of adenosine. Adenosine is a natural substance that slows down the activity of some parts of the brain including the breathing centre. By reducing the effect of adenosine, caffeine citrate stimulates the brain to resume breathing.

[1] Previously known as Nymusa.

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## What benefits of Peyona have been shown in studies?

Because caffeine citrate has been used in premature babies for a long time, the company presented information from published scientific literature.

In a study involving 85 premature babies who had had several episodes of apnoea, caffeine citrate was compared with placebo (a dummy treatment) over 10 days. On 6 out of 10 days, caffeine citrate was more effective than placebo in reducing the number of apnoea episodes by at least a half. In addition, 22% of babies given caffeine citrate had at least 8 days with no apnoea compared with none of babies who received placebo.

A study involving 2,006 premature babies with apnoea found that 46% of babies given placebo died or had neurological disabilities compared with 40% of babies given caffeine citrate.

A review of five studies compared caffeine or theophylline (another stimulant) with placebo in 192 premature babies with apnoea. The review considered a baby to be in treatment failure if there was no halving of the number of apnoea episodes, if the baby required a machine to help with breathing or if the baby died. Fewer babies treated with caffeine or theophylline had treatment failure compared with placebo.

## What are the risks associated with Peyona?

The most common side effects with Peyona (which may affect up to 1 in 10 babies) are hyperglycaemia (high blood glucose levels), tachycardia (rapid heartbeat), and phlebitis (inflammation of a vein) and inflammation at the site of infusion.

For the full list of side effects and restrictions of Peyona, see the package leaflet.

## Why is Peyona authorised in the EU?

The European Medicines Agency decided that Peyona's benefits are greater than its risks and it can be authorised for use in the EU. Published scientific literature has shown that Peyona is effective and its side effects are manageable.

## What measures are being taken to ensure the safe and effective use of Peyona?

The company that markets Peyona will provide a card to display in intensive care units where the medicine will be used. It will include information, warnings and precautions on the appropriate and safe use of Peyona, including how to work out and prescribe the dose.

Recommendations and precautions for the safe and effective use of Peyona have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Peyona are continuously monitored. Side effects reported with Peyona are carefully evaluated and any necessary action taken to protect patients.

## Other information about Peyona

Nymusa received a marketing authorisation valid throughout the EU on 2 July 2009. The name of the medicine was changed to Peyona on 24 November 2010.

Further information on Peyona can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/peyona.

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