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Gencebok (*caffeine citrate*)

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

What is Gencebok and what is it used for?

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

Gencebok contains the active substance caffeine citrate.

Gencebok is a 'hybrid' medicine. This means that it is similar to a 'reference medicine' containing the same active substance, but at a different strength. The reference medicine for Gencebok is Peyona.

How is Gencebok used?

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

The dose of Gencebok 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, Gencebok 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 Gencebok, see the package leaflet or contact your doctor or pharmacist.

How does Gencebok 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 Gencebok, 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 restore breathing.

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How has Gencebok been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Peyona, and do not need to be repeated for Gencebok.

As for every medicine, the company provided studies on the quality of Gencebok. There was no need for 'bioequivalence' studies to investigate whether Gencebok is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Gencebok is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

There was also no need for bioequivalence studies for Gencebok when used by mouth. This is because the composition of Gencebok is very similar to that of the reference medicine, except for the strength, and both are expected to be absorbed in the same way when given by mouth.

What are the benefits and risks of Gencebok?

Because Gencebok is a hybrid medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Gencebok authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Gencebok has been shown to be comparable to Peyona. Therefore, the Agency's view was that, as for Peyona, the benefits of Gencebok outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Gencebok 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 Gencebok, including how to work out and prescribe the dose.

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

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

Other information about Gencebok

Gencebok received a marketing authorisation valid throughout the EU on 19 August 2020.

Further information on Gencebok can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/gencebok. Information on the reference medicine can also be found on the Agency's website.

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