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Sibnayal (*potassium citrate / potassium hydrogen carbonate*)

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

What is Sibnayal and what is it used for?

Sibnayal is a medicine used to treat patients from the age of one year with distal renal tubular acidosis (dRTA), a disease in which the kidneys do not remove acid through the urine well enough. This results in a build-up of acid in the blood, which leads to a range of symptoms including hearing and growth problems, vomiting, kidney stones and lack of alertness. The disease also causes levels of potassium in the blood to fall, which can lead to muscle weakness and paralysis.

Sibnayal contains the active substances potassium citrate and potassium hydrogen carbonate.

How is Sibnayal used?

Sibnayal is available as prolonged-release granules to be taken by mouth, and can only be obtained with a prescription. Prolonged release means that the active substance in Sibnayal is released slowly into the body over a few hours after being taken. The starting dose depends on the age and body weight of the patient, and is gradually increased to obtain the optimal dose that provides adequate control of acid and potassium levels in the blood. Sibnayal is taken twice daily, typically twelve hours apart.

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

How does Sibnayal work?

Sibnayal contains a combination of two salts, potassium citrate and potassium hydrogen carbonate. Because the combination is alkaline and contains potassium, it neutralises excess acid in the blood and restores levels of potassium, thus relieving the symptoms of the disease.

What benefits of Sibnayal have been shown in studies?

One study in 37 patients with dRTA showed that Sibnayal was effective at reducing the level of acid and normalising the level of potassium in the blood.

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Patients were first treated with their usual medicines for neutralising excess acid for 5 days, then switched to Sibnayal. The optimal dose of Sibnayal was reached gradually over 30 days, after which patients were given this dose for at least 5 days.

The large majority (90%) of patients had a reduction in blood acid levels during treatment with Sibnayal, and this effect was generally maintained during 24 months of treatment. In addition, blood potassium levels returned to normal in 83% of patients. The corresponding figures during treatment with other medicines were 45% and 82%, respectively.

What are the risks associated with Sibnayal?

The most common side effects with Sibnayal (which may affect more than 1 in 10 people) is abdominal (belly) pain. Nausea (feeling sick) at start of treatment, stomach pain and gut pain may affect up to 1 in 10 people. For the full list of side effects of Sibnayal, see the package leaflet.

Sibnayal must not be used in patients with moderately or severely impaired kidney function and in patients with hyperkalaemia (high blood potassium levels). For the full list of restrictions, see the package leaflet.

Why is Sibnayal authorised in the EU?

Sibnayal was shown to be effective at reducing the level of acid and normalising the level of potassium in dRTA patients' blood. The safety of Sibnayal was considered acceptable, and its side effects manageable and in line with other treatments for this disease. The European Medicines Agency therefore decided that Sibnayal's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sibnayal have been included in the summary of product characteristics and the package leaflet.

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

Other information about Sibnayal

Sibnayal received a marketing authorisation valid throughout the EU on 30 April 2021.

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

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