EMA/106197/2026
EMEA/H/C/006617

Bopediat (*furosemide*)

A plain-language overview of Bopediat and why it is authorised in the EU

What is Bopediat and what is it used for?

Bopediat is used in babies and children less than 18 years of age to treat:

- oedema (swelling in the body) caused by heart, kidney or liver problems;
- high blood pressure caused by chronic (long-term) kidney disease.

Bopediat contains the active substance furosemide and is a hybrid medicine. This means that it is similar to a reference medicine containing the same active substance, but there are certain differences between the two.

Bopediat is available as orodispersible tablets (tablets that dissolve in the mouth) and at a lower strength than the reference medicine so that it can be given to young children.

The reference medicine for Bopediat is Lasilix Faible.

How is Bopediat used?

Bopediat can only be obtained with a prescription. The medicine is given once or twice a day, and the daily dose depends on the child's weight. The orodispersible tablets are placed in the mouth and allowed to dissolve. They can also be placed in water and given into the mouth with a syringe.

For more information about using Bopediat, see the package leaflet or contact your healthcare provider.

How does Bopediat work?

The active substance in Bopediat, furosemide, works in the kidneys by helping the body remove excess water. It does this by stopping sodium and chloride from being taken back into the blood. The sodium and chloride then draw more water into the urine. By removing excess water, furosemide helps reduce swelling and lower the blood pressure.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Bopediat have been shown in studies?

As for every medicine, the company provided studies on the quality of Bopediat. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

Studies carried out with Bopediat are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Bopediat?

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

The most common side effects with Bopediat (which may affect more than 1 in 10 people) include an imbalance in the levels of salts in the blood, dehydration, hypovolaemia (a low volume of blood and fluids in the body), an increase in levels of creatinine (a sign that the kidneys may not be working properly), high levels of triglycerides (a type of fat) in the blood, and orthostatic hypotension (sudden drop in blood pressure on standing up).

Bopediat must not be used in children who have very low levels of potassium or sodium in the blood, a low volume of blood and body fluids, an obstruction in the urinary tract or brain damage caused by liver problems as well as in children who are dehydrated. It must not be used in children with anuria (when the kidneys cannot produce urine) or those who have acute (sudden) kidney failure with anuria that does not respond to treatment with furosemide. It must also not be used in children with severe liver problems or severe kidney failure.

Why is Bopediat authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Bopediat has been shown to have comparable quality and to be bioequivalent to Lasilix Faible.

Bopediat, which is in a form and strength suitable for young children, will improve the availability of treatment for children.

Therefore, the Agency's view was that, as for Lasilix Faible, the benefits of Bopediat 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 Bopediat?

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

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

Other information about Bopediat

Bopediat received a marketing authorisation valid throughout the EU on <date of issue of the Marketing Authorisation>.

Further information on Bopediat, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/bopediat.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in MM-2026.