

# **Summary Public Assessment Report**

## **Generics**

**Furosemid Xantis 40 mg  
furosemide**

**SK/H/0192/001/DC**

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# Summary Public Assessment Report

## Generics

Furosemid Xantis 40 mg

Furosemide, tablets, 40 mg

This is a summary of the public assessment report (PAR) for Furosemid Xantis 40 mg. It explains how Furosemid Xantis 40 mg was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Furosemid Xantis 40 mg.

For practical information about using Furosemid Xantis 40 mg, patients should read the package leaflet or contact their doctor or pharmacist.

### **What is Furosemid Xantis 40 mg and what is it used for?**

Furosemid Xantis 40 mg is a ‘generic medicine’. This means that Furosemid Xantis 40 mg is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Lasix 40 mg Tabletten.

### **Furosemide Xantis 40 mg can be used in the following cases:**

- Accumulation of fluid (oedema) in the tissues due to heart or liver diseases
- Accumulation of fluid (oedema) in the tissues due to kidney disease. In nephrotic syndrome (loss of protein, lipid disorder, water accumulation) it is essential to treat the underlying disease
- Accumulation of fluid (oedema) in the tissues due to burn injury
- High blood pressure (arterial hypertension)

### **How does Furosemide Xantis 40 mg work?**

Furosemide Xantis 40 mg contains furosemide, which belongs to the group of medicines called diuretics (water tablets). It reduces excess water (fluid retention) in the body by increasing urine production.

### **How is Furosemide Xantis 40 mg used?**

The pharmaceutical form of Furosemide Xantis 40 mg is tablet and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

### **What benefits of Furosemide Xantis 40 mg have been shown in studies?**

Because Furosemide Xantis 40 mg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Lasix 40 mg Tabletten.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

### **What are the possible side effects of Furosemide Xantis 40 mg?**

Because Furosemide Xantis 40 mg is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of restrictions, see the package leaflet.

### **Why is Furosemide Xantis 40 mg approved?**

It was concluded that, in accordance with EU requirements, Furosemide Xantis 40 mg has been shown to have comparable quality and to be bioequivalent to reference medicine. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Lasix 40 mg Tabletten, the benefits are greater than its risk and recommended that it can be approved for use.

### **What measures are being taken to ensure the safe and effective use of Furosemide Xantis 40 mg?**

A risk management plan has been developed to ensure that Furosemide Xantis 40 mg is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Furosemide Xantis 40 mg, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

### **Other information about Furosemide Xantis 40 mg**

The marketing authorisation for Furosemide Xantis 40 mg was granted on 11 December 2018.

The full PAR for Furosemide Xantis 40 mg can be found on the website [https://www.sukl.sk/hlavna-stranka/slovenska-verzia/pomocne-stranky/detail-lieku?page\\_id=386&lie\\_id=9814C](https://www.sukl.sk/hlavna-stranka/slovenska-verzia/pomocne-stranky/detail-lieku?page_id=386&lie_id=9814C)

For more information about treatment with Furosemide Xantis 40 mg, read the package leaflet [https://www.sukl.sk/hlavna-stranka/slovenska-verzia/pomocne-stranky/detail-lieku?page\\_id=386&lie\\_id=9814C](https://www.sukl.sk/hlavna-stranka/slovenska-verzia/pomocne-stranky/detail-lieku?page_id=386&lie_id=9814C)

or contact your doctor or pharmacist.

This summary was last updated in 12-2018.