

Lasix® 20mg/2ml

Furosemide 20mg

SANOPI

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again later.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you.
- Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is Lasix 20 mg solution for injection and what it is used for?

Lasix 20 mg Solution for Injection is a mean to increase urine formation (diuretic). Lasix 20 mg Solution for Injection is indicated when at oral administration of furosemide no adequate urine excretion is achieved or if an oral use is not possible.

Lasix 20 mg Solution for Injection is used:

- in Retention of fluid in the tissues (edema) and/or abdominal dropsy (ascites) as a result of diseases of the heart or liver,
- in Retention of fluid in the tissues (edema) as a result of diseases of the kidneys,
- in Retention of fluid in the tissues (edema) as a result of burns,
- in accumulation of fluid in the lung tissue (pulmonary edema) (e.g. in acute occurring heart muscle weakness [acute cardiac insufficiency]),
- as a supportive measure in fluid accumulation in the brain tissue (cerebral edema),
- in decreased production of urine (oliguria) as a result of pregnancy complications (gestoses), if necessary, after removal of a volume deficiency condition (edema and/or high blood pressure in gestoses are not an indication!),
- in critical rise of blood pressure (hypertensive crisis) along with other therapeutic measures.

2. What you should know before taking Lasix 20 mg solution for injection?

Lasix 20 mg Solution for Injection should not be taken,

- if you are hypersensitive to furosemide, sulfonamides (possible cross-allergy with furosemide) or any of the other ingredients of Lasix 20 mg Solution for Injection,
- in renal failure with absence of urine production (anuria) that does not respond to treatment with Lasix,
- in liver failure with disturbances of consciousness (coma and hepatic precoma),
- in severe potassium deficiency conditions,
- in severe sodium deficiency conditions,
- in reduced circulating blood volume (hypovolemia) or deficiency of body water (dehydration),
- if you are breast-feeding (see also section «Pregnancy and Lactation»).

Taking special care when using Lasix 20 mg Solution for Injection is required,

- if you have a greatly decreased blood pressure (hypotension),
- at already existing or so far not apparent diabetes (manifest or latent diabetes mellitus); a regular check of blood glucose is required,
- if you suffer from gout; a regular check of uric acid in blood is required,
- if you have an obstruction of urine flow (e.g. in prostate enlargement, hydronephrosis, narrowing of the ureter),
- at a reduced protein content in blood (hypoproteinemia), e.g. in nephrotic syndrome (protein loss, fat metabolism disturbance and water retention); a careful adjustment of the dose is then required,
- in a rapidly progressive kidney function disturbance associated with a severe liver disease as e.g. liver cirrhosis (hepatorenal syndrome),
- if you have circulatory disorders of cerebral vessels (cerebrovascular circulatory disorders) or of coronary vessels (coronary heart disease), as you would be particularly at risk at an undesirably severe drop of blood pressure. In patients with voiding disorders (e.g. in prostate enlargement) Lasix 20 mg Solution for Injection can only be used, when free urine flow is provided, as a sudden onset of excessive urination can lead to urinary retention with overstretching of the bladder. During a long-term treatment with Lasix, certain blood levels, particularly potassium, sodium, calcium, bicarbonate, creatinine, urea and uric acid as well as blood sugar should be regularly checked. A particularly dose monitoring is required, if you notoriously have a high risk to develop electrolyte disturbance or in case of a greater fluid loss (e.g. by vomiting, diarrhea or intensive sweating). A decreased circulating blood volume (hypovolemia) or a deficiency of body water (dehydration) and significant electrolyte disturbances or disturbances in acid-base balance must be corrected. This may require the temporary cessation of the treatment with Lasix. The weight loss induced by increased urine excretion should not exceed, regardless the extent of urine excretion, 1 kg/day. In nephrotic syndrome (s. a.) it must be carefully dosed because of the risk of increased occurring side effects. The solution for injection should not be injected together with other medicines in the «mixing syringe». Care should be taken, that the pH value of the ready-to-use solution for injection is in the weakly alkaline to neutral range (pH value not below 7). Acidic solutions cannot be used because a precipitation of the active ingredient may occur.

Concurrent use with risperidone:

In placebo-controlled studies with risperidone in elderly patients with dementia a higher mortality in patients was observed, who were treated simultaneously with furosemide and risperidone, in comparison to patients, who had received risperidone alone or furosemide alone. Therefore, caution is recommended, and the risks and benefits of this combination or concurrent treatment with other strong diuretic medicines are to be weighed by the doctor. It has to be avoided, that a deficiency of body water

the active ingredient furosemide crosses the placenta. Furosemide is excreted in breast milk and inhibits the production of breast milk. You should therefore not be treated with Lasix 20 mg solution for injection, if you are breastfeeding. If possible, you must stop breastfeeding.

Ability to drive and use of machines

This medicine may also, at intended use, change the responsiveness to the extent that the ability of active participation in road traffic, of operating machines or working securely is impaired. This applies to a greater extent at the beginning of treatment, dose increase or when changing preparation as well as in conjunction with alcohol.

Important information about some of the ingredients of Lasix 20 mg Solution for Injection

Lasix 20 mg solution for injection contains sodium, but less than 1 mmol (23 mg) sodium per ampoule, i.e., it is almost «sodium free».

3. How to take Lasix 20 mg solution for injection?

Always use Lasix 20 mg solution for injection exactly according to the doctor's instructions. Please ask your doctor or pharmacist, if you are not completely sure.

Dosage:

The dosage should be individually determined - particularly after the success of treatment. The lowest dose sufficient to achieve the desired effect is to be used. Unless otherwise prescribed, the following dosage guidelines apply to adults:

Retention of fluid in the tissues (edema) and/or «abdominal dropsy» (ascites) due to a heart or liver disease:

At the start of treatment 2-4 ml Lasix 20 mg solution for injection (equivalent to 20-40 mg furosemide) IV. In severe mobilizable edemas, at appropriate time intervals, possibly repeated administration of this dose until onset of diuresis.

Retention of fluid in the tissues (edema) as a result of diseases of the kidneys:

Initial dose 2-4ml Lasix 20 mg solution for injection (equivalent to 20-40 mg furosemide) IV. In severely mobilizable edemas, at appropriate time intervals, possibly repeated administration of this dose until onset of diuresis. In nephrotic syndrome it must be carefully administered due to the increased risk of side effects.

Retention of fluid in the tissues (edema) as a result of burns:

The daily and/or single dose can be between 4 and 10 ml Lasix 20 mg solution for injection (equivalent to 40-100 mg furosemide), in exceptional cases in impaired renal function, up to 25 ml Lasix 20 mg solution for injection (equivalent to 250 mg furosemide) may be administered. Intravascular volume depletion must be compensated before the use of Lasix 20 mg solution for injection.

Retention of fluid in the lung tissues (pulmonary edema) (e.g. in acute occurring heart muscle weakness [acute cardiac insufficiency]): Use in conjunction with other therapeutic measures.

Initial dose 2-4ml Lasix 20 mg solution for injection (equivalent to 20-40 mg furosemide) IV. In absence of increase of urine excretion repeat after 30-60 minutes, possibly with a double dose.

As a supportive measure in case of fluid accumulation in the brain tissue (cerebral edema):

The daily and/or single dose can be between 4 and 10 ml Lasix 20 mg solution for injection (equivalent to 40-100 mg furosemide), in exceptional cases in impaired renal function may be up to 25 ml Lasix 20 mg solution for injection (equivalent to 250 mg furosemide).

Decreased production of urine (oliguria) as a result of pregnancy complications (gestoses):

Strictest indication!

An intravascular volume depletion must be compensated before the use of Lasix 20 mg solution for injection.

The dose can be daily between 1 and 10 ml Lasix 20 mg solution for injection (equivalent to 10-100 mg furosemide).

Edema and/or hypertension in gestoses are not an indication for Lasix 20 mg solution for injection!

Critical rise of blood pressure (hypertensive crisis):

2-4ml Lasix 20 mg solution for injection (equivalent to 20-40 mg furosemide) along with other therapeutic measures.

Use in children:

Unless otherwise prescribed, Lasix 20 mg solution for injection should be given parenterally to infants and children under 15 years old only exceptionally in threatening conditions. The average daily dose is 0.5 mg furosemide/kg body weight. Exceptionally, up to 1 mg of furosemide/kg body weight can be injected IV.

Mode and duration of use:

Usually, Lasix 20 mg solution for injection is injected into a vein (IV). This should be done slowly. The injection rate should not exceed 0.4 ml Lasix 20 mg solution for injection (equivalent to 4 mg furosemide) per minute. In patients with advanced renal insufficiency (serum creatinine > 5 mg/dl) the injection rate should not exceed 0.25 ml Lasix 20 mg solution for injection per minute (corresponding to 2.5 mg furosemide per minute). At increasing the dose to 25 ml (equivalent to 250 mg furosemide) an infuser (dosing apparatus) should be used. When needed, the solution for injection can be diluted with isotonic sodium chloride solution. The intramuscular (IM) use, i.e. injection into a muscle, should take place only in exceptional cases where neither an oral nor an IV administration is considered. It is however not suitable for the treatment of acute conditions (e.g. not in pulmonary edema). The solution for injection should not be injected together with other medicines in the «mixing syringe».

Care should be taken, that the pH value of the ready-to-use solution for injection is in the weakly alkaline to neutral range (pH value not below 7). Acidic solutions cannot be used because a precipitation of the active ingredient may occur. The chemical and physical stability of the ready-to-use preparation has been proved for 24 hours at 25 °C. From a microbiological point of view, the ready-to-use preparation should be used immediately. If the ready-to-use preparation is not used immediately, the user is responsible for the duration and conditions of the storage. To achieve optimal efficacy and suppress counter-regulation, a continuous furosemide infusion is to be preferred to repeated injections. Furosemide is then given intravenously only when oral use is not possible or ineffective (e.g. in poor intestinal absorption) or a rapid action is required. Parenteral use of Lasix should, as soon as the treatment allows it, be switched to oral administration. The duration of use is decided by the treating physician. It depends on the type and severity of the disease.

Please talk to your doctor if you have the impression that the effect of Lasix is too strong or too weak.

If you have used a larger quantity of Lasix 20 mg Solution for Injection than you should:

On suspicion of an overdose with larger quantities of Lasix 20 mg Solution for Injection, a doctor must be notified immediately. He can decide on the appropriate measures required, according to the severity of the overdose. The signs of acute or chronic overdose