PACKAGE LEAFLET: INFORMATION FOR THE USER

Lasix® 20mg solution for injection

furosemide sodium

What is in this leaflet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. WHAT LASIX IS AND WHAT IT IS USED FOR

Lasix is a diuretic (a medicine that promotes urine production).

Lasix is given if your urine output remains insufficient after taking furosemide by mouth or if you cannot take furosemide by mouth.

Lasix is used in the following cases:
- Fluid accumulation in tissue (oedema) and/or in the abdomen (ascites) due to heart or liver disease,
- Fluid accumulation in tissue (oedema) due to renal disorder,
- Fluid accumulation in tissue (oedema) due to burns,
- Fluid accumulation in the lungs (pulmonary oedema), e.g. due to acute heart muscle dysfunction (acute cardiac insufficiency),
- As a support measure for fluid accumulation in the brain (brain oedema),
- Decreased urine production (oliguria) following complications in pregnancy (preeclampsia), or after correction of possible blood volume deficit (note: Lasix should not be used to treat oedema and/or high blood pressure in preeclampsia),
- In the event of a critical increase in blood pressure (hypertensive crisis), alongside other therapeutic measures.

- If you are allergic to furosemide, sulfonamides (possible cross-allergy with furosemide) or any of the other ingredients of this medicine (listed in section 6),
- If you have kidney failure with no urine production (anuria), which does not respond to treatment with Lasix,
- If you have liver failure with consciousness disorders (coma and hepatic precoma),
- If you have a severe potassium deficiency,
- If you have a severe sodium deficiency,
- If you have a blood volume deficit (hypovolaemia) or body water deficit (dehydration),
- If you are breast-feeding (see also section on "Pregnancy and breast-feeding").

Warnings and precautions

Please talk to your doctor or pharmacist before using Lasix,
- If your blood pressure is very low,
- You are elderly, if you are on other medications that can cause a drop in blood pressure, and if you have other medical conditions that are risk factors for a drop in blood pressure,
- You have already existing (manifest) or underlying (latent) diabetes mellitus; regular monitoring of blood sugar levels is required,
- You have gout; regular monitoring of blood uric acid levels is required,
- You have difficulty passing urine (e.g. due to enlarged prostate, obstruction of the kidney, or ureterostenosis (narrowing of the tube that conveys the urine from the kidney to the bladder),
- Your blood protein level is decreased, e.g. in nephrotic syndrome (which is characterized by protein loss, lipid metabolism disorders and water accumulation); dosage must be carefully adjusted,
- You have rapidly progressive renal function disorder in connection with a serious liver disorder such as liver cirrhosis (hepatorenal syndrome),
- You have blood flow disorders in the vessels of your brain or heart, since you would be particularly at risk if you experienced a sharp drop in blood pressure.

In patients with urination disorders (e.g. due to enlarged prostate), Lasix may only be used if normal urine output can be restored, since a sudden flow of urine could result in obstruction (retention of urine), which could lead to an overdistension of the bladder.

Lasix increases excretion of sodium and chloride and consequently water. Excretion of other electrolytes (especially potassium, calcium and magnesium) is also increased. Since water/electrolyte balance disorders have often been observed during treatment with Lasix due to higher levels of water and electrolyte excretion, regular checks of the levels of certain substances in the blood are required.

Especially during long-term treatment with Lasix, certain blood tests, particularly potassium, sodium, calcium, bicarbonate, creatinine, urea, and uric acid, as well as blood glucose, should be performed regularly.

Particularly careful monitoring is required if you are at high risk for electrolyte disturbances, or if you have severe fluid loss (e.g. due to vomiting, diarrhoea, or excessive sweating). Any deficit in circulating blood volume, body water deficit, significant electrolyte disturbances or disturbances in acid-base balance must be corrected. This may require temporary adjustment of the Lasix treatment.

Underlying diseases (e.g. liver cirrhosis, cardiac insufficiency), concomitant medication and food can play a role in the possible development of electrolyte disturbances.

Weight loss due to increased urine output should not exceed 1 kg/day, regardless of how much urine is passed.

If you have a nephrotic syndrome (see above), the dose must be carefully adjusted due to the increased risk of side effects. The solution for injection must not be administered in combination with other medicines ("mixed injection") using the same syringe.

Please note that the pH of the ready-to-use solution for injection is weakly alkaline to neutral (pH not less than 7). Acid solutions must not be used, since the active substance may precipitate.

Use in combination with risperidone:

In placebo-controlled studies with risperidone in elderly patients with dementia, a higher mortality rate was observed in patients who were treated simultaneously with furosemide and risperidone as compared with those who received risperidone or furosemide alone. Caution is therefore necessary, and the benefits and risks of using this combination or of simultaneous treatment with other potent diuretics should be carefully weighed by your doctor. Loss of body water should be avoided.

There is a possibility of exacerbation or activation of systemic lupus erythematosus, an illness in which the immune system is directed against the body itself.

Children

Particularly careful monitoring is required in premature infants, since they are at risk for renal calcification or kidney stones. Monitoring methods: Include kidney function tests and an ultrasound of the kidneys.

In premature infants with conditions involving difficulty breathing (respiratory distress syndrome) who are given diuretic treatment with Lasix in the first weeks of life, there may be a higher risk that the vessel that bypasses the pulmonary circulation before birth will remain open (patent ductus arteriosus).

Effects of misuse for doping tests

Use of Lasix may yield positive results in doping tests. In addition, use of Lasix as a doping substance can be dangerous for your health.

Other medicines and Lasix

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effectiveness of the following drugs or groups of medicines may be affected by simultaneous treatment with Lasix.

- Glucocorticoids (cortisone), carbenoxolone or laxatives, as they may increase potassium loss, which can result in potassium deficiency.
- Medicines with an anti-inflammatory effect (nonsteroidal anti-inflammatory drugs, such as indomethacin and aspirin), as they may reduce the effect of Lasix. If treatment with Lasix results in a decrease in circulating blood volume or body water deficit, simultaneous use of nonsteroidal anti-inflammatory drugs may cause acute kidney failure.
- Probenecid (antigout agent), methotrexate (antirheumatic agent and immunosuppressant) and other drugs which, like furosemide, are excreted in the urine, as they may reduce the effect of Lasix.
- Phenytoin (a drug used to treat seizures and certain types of pain), as it has been reported to reduce the effect of Lasix. The effectiveness of the following drugs or groups of medicines may be affected by simultaneous treatment with Lasix.
- Certain cardiac medicines (glycosides), as the sensitivity of the heart muscle to these drugs may increase if a potassium or magnesium deficiency develops during treatment with Lasix.
- There is a higher risk of heart rate disturbances (ventricular arrhythmias, including torsades de pointes) in patients with electrolyte imbalances and when Lasix is used together with drugs that can cause certain ECG changes (prolongation of QT interval) (e.g. terfenadine, an antiallergic, and certain medicines used in heart rate disorders [class I and III antiarrhythmics]), and in the event of electrolyte disturbances.
- Salicylates (painkillers) used at high doses, as their side effects may be more intensive in the event of simultaneous use with Lasix.
- Medicines that damage the kidneys (nephrotoxic drugs) (e.g. antibiotics such as aminoglycosides, cephalosporins, polymyxins), as Lasix may make their harmful effects more intensive. Kidney function may deteriorate in patients receiving both Lasix and high doses of certain cephalosporins.
- Aminoglycosides (e.g. kanamycin, gentamicin, tobramycin) and other medicines that damage hearing (ototoxic drugs), as their effects may be increased by simultaneous use of Lasix. Any resulting hearing disturbance may not be reversible. Consequently, simultaneous use of the drugs mentioned above should be avoided.
- Cisplatin (treatment for malignant diseases), as simultaneous use with Lasix may result in hearing impairment. In addition, Lasix must be used with extra caution since it may make the harmful effects of cisplatin on the kidneys more intensive (nephrotoxicity).
- Lithium (used for certain forms of depression), as simultaneous use of Lasix may make the harmful effects of lithium on the heart and nerves more intensive (cardiotoxicity and neurotoxicity). Blood lithium levels should therefore be closely monitored in patients receiving these two drugs simultaneously.
- Medicines for high blood pressure, diuretic drugs, or other drugs that may lower blood pressure, as, if they are used at the same time as Lasix, blood pressure may decrease even more. Major drops in blood pressure leading to shock, and a deterioration of kidney function (with isolated cases of acute kidney failure) have been observed, particularly when using ACE inhibitors or angiotensin II receptor antagonists for the first time or introducing higher doses of these drugs. If possible, Lasix treatment should therefore be stopped temporarily, or at least the dose should be reduced for 3 days, before treatment with an ACE inhibitor or angiotensin II receptor antagonist is started or the dose increased.
- Probenecid, methotrexate, and other drugs which, like furosemide, are excreted via the kidneys, as Lasix may reduce the elimination of these drugs. High-dose treatment may result in high levels of active substances in the blood and increase the risk of side effects.
- Theophylline (used to treat asthma) or curare-like agents that cause muscle relaxation (muscle relaxants), as their effects may be more intensive through Lasix.
- Drugs that lower blood sugar levels (antidiabetics) or increase blood pressure (sympathomimetic drugs, e.g. adrenalin, noradrenalin), as their effects may be reduced by simultaneous use of Lasix.
- Risperidone: Caution is necessary in patients treated with risperidone, and the benefits and risks of using this combination or of simultaneous treatment with Lasix or other potent diuretics should be carefully weighed by your doctor.
- Simultaneous use of thyroid hormones (e.g. levothyroxine) and high doses of furosemide can affect thyroid hormone levels. Therefore, thyroid hormone levels should be monitored in patients receiving this combination.

Other interactions:

- Simultaneous use of cyclosporin A and Lasix is linked to a higher risk of arthritis due to gout, as a result of increased blood uric acid levels caused by furosemide and impaired urine excretion of uric acid caused by cyclosporin.
- In patients who are at high risk for renal injuries during x-rays with contrast agents, kidney function deteriorated after the examination using contrast agents more frequently in patients treated with Lasix than in those who only received intravenous fluids before the examination with contrast agents.
- In isolated cases, intravenous use of Lasix within 24 hours of taking chloral hydrate resulted in flushing, sweating attacks, agitation, nausea, and increase in blood pressure and the heart rate (tachycardia). Consequently, simultaneous use of Lasix and chloral hydrate should be avoided.

Lasix with food and drink

Eating large quantities of licorice under treatment with Lasix may increase potassium loss.

- **Pregnancy and breast-feeding**

Lasix must not be used during pregnancy unless your doctor considers it absolutely necessary, since the active substance furosemide crosses the placenta.

Furosemide is excreted in human milk and reduces the amount of milk produced.

Consequently, you should not be treated with Lasix if you are breast-feeding. If necessary, you must stop breast-feeding.

Driving and using machines

Even when this medicine is used as specified, it may affect your capacity to react to such an extent that it may impair your ability to drive, use machines, or work in areas of uneven footing. This particularly applies at the beginning of treatment, when increasing doses, when switching drugs, and in combination with alcohol.

Lasix contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say it is essentially 'sodium-free'.

3. HOW TO USE LASIX

Always use Lasix exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Posology

Dosage should be determined on a case-by-case basis and, above all, depending on how you respond to treatment. The lowest dose that achieves the desired effect should always be used.

Unless otherwise prescribed, the following dosages are recommended for adults:

For fluid accumulation in tissue (oedema) and/or in the abdomen (ascites) due to heart or liver disease:

Treatment should be started with 2–4 mL of Lasix (equivalent to 20–40 mg of furosemide) given intravenously. For oedema that is difficult to reduce, repeat this dose at appropriate intervals, if necessary, until normal urine output is restored.

For fluid accumulation in tissue (oedema) due to kidney disorders:

Initial dose of 2–4 mL Lasix (equivalent to 20–40 mg furosemide) given intravenously. For oedema that is difficult to reduce, repeat this dose, if necessary, at appropriate intervals until urination occurs.

If you have nephrotic syndrome, the dose must be carefully determined due to the increased risk of side effects.

For fluid accumulation in tissue (oedema) following burns:

The daily and/or unit dose ranges from 4 mL to 10 mL of Lasix (equivalent to 40–100 mg of furosemide). In exceptional cases and in patients with impaired kidney function, the dose may be up to 25 mL of Lasix (equivalent to 250 mg of furosemide).

Any blood volume deficit must be corrected before using Lasix.

For fluid accumulation in the lungs (pulmonary oedema), e.g. due to acute heart muscle dysfunction (acute cardiac insufficiency):

Use in combination with other treatments.

Initial dose of 2–4 mL Lasix (equivalent to 20–40 mg furosemide) given intravenously. If urine output does not increase, repeat the dose after 30–60 minutes, if necessary, by doubling the dose.

As a support measure for fluid accumulation in the brain (cerebral oedema):

The daily and/or unit dose can be between 4 mL and 10 mL of Lasix (equivalent to 40 mg–100 mg of furosemide). In exceptional cases, and in patients with impaired kidney function, the dose may be up to 25 mL of Lasix (equivalent to 250 mg of furosemide).

For decreased urine production (oliguria) following pregnancy complications (preeclampsia):

Use of this treatment must be weighed with extreme caution by your doctor!

Any blood volume deficit must be corrected before using Lasix.

The daily dose range between 1 mL and 10 mL of Lasix (equivalent to 10 mg–100 mg of furosemide).

Lasix should not be used to treat oedema and/or hypertension in preeclampsia!

For episodes of increased blood pressure (hypertensive crisis):

Use 2 mL–4 mL of Lasix (equivalent to 20 mg–40 mg of furosemide) along with other treatments.

Use in children:

Unless otherwise prescribed, in infants and children under 15 years of age, Lasix should be given by injection only in exceptional circumstances, i.e. life-threatening conditions. The average daily dose is 0.5 mg of furosemide/kg body weight. In exceptional cases, up to 1 mg of furosemide/kg body weight can be injected intravenously.

Method and duration of treatment

Lasix is usually injected intravenously (i.v.). This must be done slowly. The injection rate must not exceed 0.4 mL of Lasix per minute (equivalent to 4 mg of furosemide per minute). In **pa**tients with advanced renal insufficiency (serum creatinine

>5 mg/dL), the injection rate should not exceed 0.25 mL of Lasix per minute (equivalent to 2.5 mg of furosemide per minute). If the dose is increased to 25 mL of furosemide, (equivalent to 250 mg of furosemide), an infusion pump (dosing device) should be used. If necessary, the solution for injection can be diluted with normal saline (isotonic sodium chloride solution).

Intramuscular (i.m.) administration, i.e. injection into a muscle, should only be used in exceptional cases, if neither oral nor i.v. administration is possible. However, it is not suitable for acute conditions (e.g. pulmonary oedema).

The solution for injection must not be administered in combination with other medicines ("mixed injection") using the same syringe.

Please note that the pH of the ready-to-use solution for injection is weakly alkaline to neutral (pH not less than 7). Acid solutions must not be used, since the active substance may precipitate.

The chemical and physical stability of the ready-to-use medicine has been demonstrated for 24 hours at 25 °C. From a microbiological point of view, the ready-to-use medicine should be used immediately.

If the medicine is not used immediately, the user is responsible for storage duration and conditions.

To achieve optimal efficacy and suppress counterregulation, continuous furosemide infusion is preferable to repeated injections.

Furosemide should be administered intravenously only if oral administration is not possible or is ineffective (e.g. in patients with intestinal absorption) or if rapid action is required. As soon as treatment conditions allow, you should switch from Lasix injections to administration by mouth.

Your doctor decides on the duration of treatment. This is based on the type and severity of the disease.

If you feel that the effect of Lasix is too strong or too weak, talk to your doctor.

If you use more Lasix than you should

If you suspect an overdose because you have used more Lasix than you should have, alert a doctor immediately. The doctor can decide on the measures that may be necessary depending on the extent of overdose.

The signs of acute or chronic overdose depend on the severity of the salt and fluid losses.

Overdose may result in low blood pressure and blood circulation disorders when standing up from a lying position, electrolyte imbalances (decreased potassium, sodium, and chloride levels) and increased blood pH (alkalosis).

More severe fluid loss may result in a body water deficit and, due to blood volume losses, in circulatory collapse and thickening of the blood (haemoconcentration) with a tendency for thrombosis.

Sudden water and electrolyte depletions can result in confusion.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following categories are used to express the frequency of side effects:

Very common:	may affect more than 1 in 10 treated patients
Common:	may affect up to 1 in 10 treated patients
Uncommon:	may affect up to 1 in 100 treated patients
Rare:	may affect up to 1 in 1 000 treated patients
Very rare:	may affect up to 1 in 10 000 treated patients
Not known:	cannot be estimated from the available data

Possible side effects:

Blood

Common: Thickening of the blood (haemoconcentration, in case of excessive urine excretion).

Uncommon: Decrease in the number of certain blood cells called platelets (thrombocytopenia).

Rare: Increase in the number of certain white blood cells (eosinophilia), decrease in the overall number of white blood cells (leukopenia).

Very rare: Anaemia due to increased destruction of red blood cells (haemolytic anaemia), anaemia due to blood cell formation disorders in the bone marrow (aplastic anaemia), severe decrease in certain white blood cells with increased susceptibility to infections and poor general health (agranulocytosis).

Signs of agranulocytosis can include fever with chills, changes to the mucous membranes (the lining of certain organs or cavities) and throat pain.

Immune system

Uncommon: Allergic reactions of the skin and mucous membranes (see 'Skin').

Rare: Severe allergic reactions such as circulatory collapse (anaphylactic shock). The first signs of shock include skin reactions, such as severe flushing or hives, restlessness, headache, sweating attacks, nausea, and bluish discolouration of the skin.

Not known: Exacerbation or activation of systemic lupus erythematosus (an illness in which the immune system is directed against the body itself).

Metabolism and nutrition

(see "Warnings and precautions")

Very common: Electrolyte disturbances (including those involving symptoms), reduced body water and reduced circulating blood volume (particularly in older patients), increase in certain blood fats (triglycerides).

Common: Reduced sodium and chloride content in the blood (hyponatraemia and hypochloraemia, especially if sodium chloride intake is reduced), reduced potassium content in the blood (hypokalaemia, especially with a simultaneous decrease in potassium supply and/or increased potassium loss, e.g. due to vomiting or chronic diarrhoea); increased blood cholesterol, increased uric acid in the blood, and gout attacks.

Uncommon: Increased blood sugar levels (reduced glucose tolerance, hyperglycaemia). In patients with existing diabetes (established diabetes mellitus), this may lead to deterioration of patient metabolism. Underlying diabetes (latent diabetes mellitus) may be revealed.

Not known: Reduced calcium levels in the blood (hypocalcaemia), reduced magnesium levels in the blood (hypomagnesaemia), metabolic alkalosis (increase in pH value of the blood), pseudo-Bartter's syndrome (i.e. kidney function impairment induced by incorrect use of furosemide or long-term furosemide treatment, characterized by increase in blood pH value, loss of mineral salts and hypotension).

Symptoms that are often reported with sodium deficiency include listlessness, calf cramps, loss of appetite, debility, sleepiness, vomiting and confusion.

Potassium deficiency may lead to symptoms such as muscle weakness, abnormal sensations in the hands and feet (e.g. tingling, numb or painful burning sensations), paralysis, vomiting, constipation, build-up of excessive gas in the digestive tract, excessive urine output, abnormal feeling of thirst with excessive fluid intake and irregular pulse (e.g. excitation and conduction disorders of the heart). Severe potassium loss may result in intestinal paralysis (paralytic ileus) or consciousness disorders and even coma.

A calcium deficiency may, in rare cases, result in neuromuscular hyperexcitability (tetany).

As a result of magnesium deficiency, tetany and cardiac arrhythmias have been reported in rare cases.

Nervous system

Common: Brain disease (hepatic encephalopathy) may occur in patients with advanced liver failure.

Rare: Tingling, numb or painful burning sensations in the hands and feet (paraesthesia).

Not known: Dizziness, fainting and loss of consciousness, headache.

Ears

Uncommon: Hearing disorders, usually reversible, especially in patients with renal function disorders or decreased blood protein levels (e.g. in nephrotic syndrome) and/or if the medicine is injected too quickly into the vein. Deafness (sometimes irreversible).

Rare: Ringing in the ears (tinnitus).

Blood vessels/circulation

Very common (with intravenous infusions): Reduced blood pressure, including circulation disorders when standing up from a lying position.

Rare: Blood vessel inflammation (vasculitis).

Not known: Occlusion of blood vessels due to a clot (thrombosis, particularly in older patients).

Excessive urine output may be accompanied by circulation disorders (even circulatory collapse), especially in older patients and children, resulting, in particular, in headache, lightheadedness, visual disorders, dry mouth, thirst, low blood pressure and circulatory disorders, with a drop in blood pressure when standing up from a lying position.

Digestive tract

Uncommon: Nausea.

Rare: Vomiting, diarrhoea.

Very rare: Acute inflammation of the pancreas.

Liver and gall bladder

Very rare: Obstruction of bile flow (intrahepatic cholestasis), increase in certain liver values (transaminases).

Skin

Uncommon: Itching, hives (urticaria), rash, reactions of the skin and mucous membranes with redness, formation of blisters or scales (e.g. bullous dermatitis, erythema multiforme, pemphigoid, exfoliative dermatitis, purpura), increased sensitivity to light (photosensitivity).

Not known: Severe skin and mucous membrane reactions, for example with blisters or skin detachment (Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis [AGEP] [acute febrile drug eruption], drug eruption with eosinophilia and systemic symptoms); lichenoid reactions that manifest as small, itchy, reddish-purple, uneven changes to the skin, genitals or in the mouth.

Muscular system

Not known: Cases of serious muscle problems (rhabdomyolysis) have been reported, often in relation to severe potassium deficiency states (see section on "Do not use Lasix").

Kidneys and urinary tract

Very common: Increased blood creatinine.

Common: Increased urine output.

Rare: Kidney inflammation (tubulo-interstitial nephritis).

Not known: Increased sodium in urine, increased chloride in urine, increased urea in blood, signs of impaired urine excretion (e.g. in patients with an enlarged prostate, build-up of urine in the kidneys, ureterostenosis). This can even lead to urinary obstruction (urinary retention) and the resulting complications (see "Warnings and precautions"), kidney stones and/or calcification of kidney tissue in premature babies, kidney failure (see "Using other medicines and Lasix").

Congenital diseases

Not known: Increased risk of the vessel that shunts pulmonary circulation before birth remaining open (patent ductus arteriosus), if premature babies are treated with furosemide in the first weeks of life.

General disorders and reactions at injection site

Rare: Fever.

Not known: Local reactions such as pain following intramuscular injection.

If a side effect occurs suddenly or becomes more severe, inform your doctor immediately, since some drug reactions may become life-threatening in certain circumstances. The doctor will decide what measures must be taken and whether the therapy can be continued.

At the first sign of a hypersensitivity reaction, Lasix should not be used again.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LASIX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoules and the outer packaging after EXP. The expiry date refers to the last day of that month.

Storage conditions

Store in outer packaging to protect the ampoules from light. Store at a temperature no higher than 30°C

Shelf-life after preparation

Chemical and physical stability of the ready-to-use medicine has been demonstrated for 24 hours at 25 °C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lasix 20 mg solution for injection contains

The active substance is furosemide sodium.

1 ampoule filled with 2 mL of solution for injection contains 21.3 mg of furosemide sodium (equivalent to 20 mg of furosemide).

The other ingredients are:

Sodium chloride, sodium hydroxide, water for injections.

What Lasix 20 mg solution for injection looks like and contents of the package

Lasix is a clear, colourless solution.

Lasix is available in packs of 5 ampoules each containing 2 mL.

Not all pack sizes may be marketed.

Marketing Authorization Holder

Sanofi-Aventis Deutschland GmbH
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This leaflet was last revised in October 2021.