

PATIENT INFORMATION LEAFLET

DESAL[®] 20 mg /2 ml IM/IV Solution for Injection

Applied intramuscularly or intravenously.

- **Active ingredients:** Furosemide 20 mg
- **Excipients:** Sodium hydroxide, Sodium chloride, and water for injection.

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.*
- *Tell your doctor that you are using this medicine when you visit your doctor or a hospital.*
- *Always follow the instructions in this leaflet. Do not use lower or higher doses than prescribed.*

What is in this leaflet:

- 1. What DESAL Ampoule is and what it is used for?**
- 2. What you need to know before you use DESAL Ampoules.**
- 3. How to use DESAL?**
- 4. Possible side effects**
- 5. How to store DESAL Ampoules?**

1. What DESAL Ampoule is and what it is used for?

DESAL is available in 2 ml ampoule form containing 20 mg furosemide as active substance administered intramuscularly or intravenously. It is available in packages containing 5 and 100 ampoules. It is also available in tablet form in the market.

DESAL is one of a group of medicines called diuretics. Diuretics are drugs that increase the excretion rate of urine from the kidneys and cause loss of water and salt. DESAL is a potent diuretic.

Your doctor has prescribed you DESAL for one or more of the following reasons:

- Excessive amount of fluid retention in the body due to respiratory failure, edema, liver enlargement and excessive fluid associated with your marked disease due to chronic heart failure.
- Excessive fluid retention in the body due to excess fluid not being discarded which associated with chronic renal failure.
- The maintenance of fluid excretion in acute renal failure. Including due to pregnancy or burns.
- Excessive fluid retention in the body due to excess fluid not being discarded which associated with the signs and symptoms in the kidneys (if the treatment with diuretic is required).
- Excessive fluid retention in the body due to excess fluid not being discarded which associated with liver disease (if treatment with aldosterone antagonists needs to be supported)
- Hypertension

- Crisis caused by high blood pressure (as a supporting treatment)
- Support of forced diuresis (e.g. poisoning).

2. What you need to know before you use DESAL Ampoules.

Do not use DESAL in the following cases:

- If you are allergic to furosemide, which is the active ingredient of the drug, or to any of the other ingredients of the drug.
- If you are allergic to sulfonamide antibiotics and sulfonylurea drugs which used in diabetes treatment
- If you have lost lots of body fluid (vomiting, diarrhea, or excessive sweating)
- If you have a disorder that causes excessive reduction in the volume of your body fluids (including blood).
- If you have kidney failure leads to a lack of urine production and this condition does not respond to the treatment with DESAL.
- If the potassium level in your blood is too low.
- If the sodium level in your blood is too low.
- If you have a condition like coma due to a brain function disorder that develops due to a severe disease in your liver.
- If you are breastfeeding your baby.

Take special care with DESAL injection:

- If you have difficulty in passing water such as bladder emptying disorders, prostatic hyperplasia, and narrowing of the urinary tract causing partial urinary tract obstruction (Your doctor may want to follow you carefully to make sure your urine is excreted, especially during the first stage of DESAL treatment.)

Your doctor maybe wants to follow you closely in the following cases.

- Low blood pressure
- Some diseases where low blood pressure considered a serious health conditions: significant narrowing or blockage in the heart vessels or blood vessels supplying the brain.
- Diabetes with or without symptoms
- Gout disease
- Failure in kidney function associated with severe liver disease (Hepatorenal syndrome).
- If you have a disorder that causes a low level of protein in your blood (for example, this can happen in a serious kidney condition called nephrotic syndrome; your doctor will carefully adjust the dose of your drug)
- If it should be used in preterm infants (your doctor may want to monitor your kidney function and perform ultrasonography against the risk of kidney stones formation or calcification foci in the kidneys).

During treatment with DESAL, your doctor may recommend regular blood tests of your blood sodium, potassium, and creatinine levels, which are electrolytes in your blood. Monitoring should be performed if you have a high risk of developing electrolyte imbalances or if there is significant fluid loss due to vomiting, diarrhea, or excessive sweating.

Concomitant use with risperidone (used to treat some psychiatric diseases and dementia):
Concomitant use of risperidone and DESAL in patients with dementia can result in serious side effects such as death. Therefore, in cases where the use of risperidone and DESAL together is considered necessary, your doctor will determine the treatment plan based on the ratio of the benefit that this plan will provide.

Tell your doctor if any of the above warnings apply to you, even for a period in the past.

Using DESAL with food and drink

DESAL is used intravenously or intramuscularly (by injection). Therefore, its interaction with food and drink is not expected.

Pregnancy

Talk to your doctor or pharmacist before using the medicine.

DESAL must not be given during pregnancy unless there are compelling medical reasons. Therefore, the pregnancy status should be evaluated before starting treatment.

If you become pregnant during treatment, your doctor may stop the medication and start treatment with another drug or continue your treatment by closely monitoring your baby's development in the uterus.

If you notice that you are pregnant during your treatment, consult your physician immediately.

Use in Lactation

Talk to your doctor or pharmacist before using the medicine.

Furosemide passes into the breast milk, so do not use DESAL while breastfeeding. If you need to be treated with DESAL, stop giving milk to protect the baby from drug that is excreted in the breast milk.

Driving and using machines

DESAL may cause a marked decrease in blood pressure, difficulty in concentration, and reduction in the capacity to react. So be careful when driving and using machines.

Important information about some of the ingredients of DESAL

It does not contain excipients that require special caution.

Taking other medicines with Desal

Medicines that are not recommended to be used together:

- Chloral hydrate it is use for sleeping problems
- Aminoglycosides and other ototoxic drugs (drugs that have a harmful effect on hearing)

medications that should use with caution when taken together

- Cisplatin (used to treat cancer)
- Lithium (used to treat psychiatric diseases)
- ACE inhibitors or angiotensin II receptor antagonist (used to treat cardiovascular diseases)
- Risperidone (used to treat psychiatric diseases and dementia)

medications that should use carefully when taken together

- Non-steroidal anti-inflammatory drugs, including aspirin (pain reliever and anti-inflammatory)
- Phenytoin (used to treat epilepsy)
- Corticosteroids, carbenoxolone, licorice root (used in gastrointestinal diseases)
- Digitalis preparations (used to treat cardiovascular diseases)
- Probenecid (used in gout disease)
- Methotrexate (used to treat cancer)
- Drugs used to treat diabetes
- Epinephrine, norepinephrine (due to its properties to increase blood pressure)
- Curare-type muscle relaxants
- Theophylline (used to treat respiratory diseases)
- Some cephalosporins
- Cyclosporin A (used during organ transplants)
- Contrast agents used to increase the visibility of organs in x-ray examinations.

If you are currently using any prescription or non-prescription medication or have used it recently, please tell your doctor or pharmacist about them.

3. How to use DESAL?

Instructions for administration and dose/frequency of administration:

The correct dose of your medicine will be decided by your doctor depending on your illness.

Method and route of administration:

The I.V administration of DESAL is indicated in cases where oral administration is not feasible is not efficient (for example in case of reduced intestinal absorption) or when a quick effect is required. In cases where parenteral administration is used, the switch to oral administration is recommended, as soon as possible.

Special age groups:**Use in children:**

Your doctor will determine the dosage and method of administration depending on your child's age, body weight and disease.

Use in elderly:

Your doctor will adjust the dose considering the possible impairments in kidney and liver function in elderly patients and patients with poor general condition

Special patients:**Hepatic / renal failure:**

Your doctor will determine the dose of your medicine depending on your disease and the severity of your kidney / liver problems.

Other:

If you have heart failure or severe blood pressure, your doctor will carefully determine the dose you need by considering such conditions.

If you have the impression that the effect of DESAL is too strong or too weak, you should tell your doctor or pharmacist.

If you used more DESAL than you should have:

DIESEL will be used under medical supervision, so necessary procedure will be taken to prevent such a case from developing. If this case happened; appropriate treatment will be applied.

If you forget to use DESAL:

Since DESAL will be used under medical supervision, necessary precautions will be taken to prevent such a situation from developing.

Effects that may occur when you stop using DESAL

If you stop using DESAL treatment without your doctor's approval, your blood pressure may rise again, or excessive fluid retention may occur in your body.

4. What are the possible side effects?

Like all medicines, DESAL may cause side effects in patients who are sensitive to any of the ingredients of this medicine.

If any of the following side effects happen, stop using this medicine and tell your doctor immediately or go to the emergency service at your nearest hospital.

- Hypersensitivity reactions such as itching, urticaria, rashes or bullous lesions. causing redness like lace on the hands and feet which usually passes spontaneously.
- A skin disease that usually appears on the arms and legs and it is characterized by blisters-bullae filled inside the skin.
- An inflammatory type of skin disease with exfoliation (exfoliative dermatitis)
- Photosensitivity reaction, it appears with red bruise like Needle-head (purpura).
- Sudden hypersensitivity reaction
- Inflammation in the skin and around the eyes with hyperemia, redness and swelling (Stevens-Johnson syndrome).
- A serious disease on the skin with fluid-filled blisters (toxic epidermal necrolysis)
- Blood clot (causing pain, swelling or tenderness in the legs).

These are serious side effects. If you have one of these, you have a serious allergic reaction to DESAL.

You may need urgent medical attention or hospitalisation.

Other reported side effects are listed below. Tell your doctor or pharmacist if any of these side effects become serious or you notice any side effects not listed below in this leaflet.

Side effects are defined as shown in the following categories:

Very Common: It can be seen in at least 1 of 10 patients.

Common: less than one in 10 patients, but more than one in 100 patients

Uncommon: Less than one in 100 patients, but more than one in 1000 patients

Rare: less than one in 1000 patients, but more than one in 10000 patients

Very rare: Less than one in 10,000 patients can be seen.

Unknown: It cannot be estimated from the available data.

Very Common

- Changes in the concentrations of chemicals in the blood (electrolyte disturbances)
- Decrease in blood volume (hypovolemia) and water loss from the body (dehydration), especially in the elderly
- Increase the amount of creatinine in the blood and blood fats called triglycerides
- Lowering of blood pressure (including low blood pressure when standing up from sitting or lying down)

Common

- Hemoconcentration (Increase in blood concentration due to decrease in blood fluid)
- Decreased blood levels of sodium, chlorine, and potassium. And raised blood levels of creatinine and cholesterol.
- Gout attacks (disease characterized by increased uric acid causing inflammation and pain in the joints)

- In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur (impaired brain functions due to liver failure).
- An increase in the amount of urine

Uncommon

- Decrease in the number of platelets in the blood (unusual bleeding or bruising)
- Decrease in sensitivity to glucose that should be considered in diabetics.
- Hearing disorders and sometimes irreversible deafness in patients with abnormal decreases in the amount of protein in the blood, especially those with severe kidney damage.
- Nausea
- Itching, rash

Rare

- White blood cell deficiency (leukopenia)
- Increased number of eosinophilic cells (a type of allergy cell) in the blood
- Numbness
- Ringing in the ears
- Inflammation of a blood vessel (vasculitis)
- Vomiting, diarrhea
- Inflammation of Kidney
- Fever

Very rare:

- Agranulocytosis (decrease in the number of white blood cells), aplastic anemia (serious decrease in the number of blood cells), hemolytic anemia.
- Severe pains in your abdomen or back, which may be a symptom of acute pancreatitis
- Stop or slow biliary fluid flow due to an intra-liver cause, an increase in liver enzymes

Unknown:

- Low levels of calcium and magnesium in the blood, increased urea, dry mouth due to metabolic alkalosis, weakness, fatigue, restlessness, seizures, muscle weakness or cramps, low blood pressure, irregular or fast heartbeat.
- Pseudo-bartter Syndrome in long-term use (manifested by vomiting, inability to urinate and confusion.)
- High levels of sodium and chloride in urine, inability to urinate
- In preterm babies, accumulation of calcium salts in the kidneys, which causes irreversible kidney damage, kidney stones formation.
- High risk of continuing "patent ductus arteriosus", a type of cardiovascular disease (when the gap between the two major arteries leaving the heart does not close after birth and remain open after delivery) in preterm infants within the first week of life.
- Pain at the Injection Site

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects includes any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. In addition, you can report this side effects to Turkey Pharmacovigilance Center by one of the following 2 ways:

- 1- Online at: www.titck.gov.tr then click on the “Medication Side Effect Report” icon.
- 2- By calling 0800 314 00 08 (the side-effect notification line).

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

5. How to store DESAL?

Keep out of the reach and sight of children • Store below 25°C, keep the ampoules in the outer carton in order to protect from light.

Use the medicine in conformity with the expiry date.

• *DESAL Ampoules should not be used after the expiry date which is printed on the carton and ampoules*

Do not dispose of expired or unused drugs!

Give it to the collection system determined by the Ministry of Environment.

Marketing Authorisation Holder:

STOT PHARMA İlaç San.ve Dış Tic. Ltd. Şti.

Emek Mah. 29 Sk. No:4 A - Antakya-Hatay

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