

Rare:

- Dizziness,
- Headache,
- Itching,
- Rash

Unknown:

- Voice disorders,
- Muscle weakness,
- Decreased appetite

These are mild side effects of BIOFENACIN.

Reporting of the side effects

Talk with your doctor, pharmacist or nurse if you experience any side effect that is included or not included in this patient information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via clicking “Drug Side Effect Report” icon on www.titck.gov.tr or via calling the side effect report line on 0800 314 00 08. By reporting experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug.

If you encounter any side effect that is not included in this patient information leaflet, consult a doctor and pharmacist.

5. How to store BIOFENACIN

Keep BIOFENACIN out of the sight and reach of children and in its package.

BIOFENACIN should be stored at room temperature below 25°C.

Use in line with the expiry date.

Do not use BIOFENACIN after the expiry date indicated on the package.

Do not throw away drugs that have expired or are not being used! Give them to the collection system determined by the Ministry of Environment and Urbanism.

The holder of trademark is
“BioactiveT, United Kingdom.”

Marketing Authorisation Holder:

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PATIENT INFORMATION LEAFLET

BIOFENACIN 5 mg film coated tablet

It is taken orally.

- Active Substance : Contains 5 mg solifenacin succinate.
- Excipient(s) : Lactose monohydrate (obtained from bovine milk), pregelatinised starch, hypromellose (E464), sodium stearyl fumarate, polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol (E1521), talc (E553b), yellow iron oxide (E172).

Read this LEAFLET carefully before you start to use this medicine. It contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please consult your doctor or pharmacist.
- This medicine is prescribed for you personally. Do not give it to others.
- During the use of this medicine, when you visit a doctor or a hospital, tell your doctor that you are using this medicine.
- Follow the directives in this leaflet strictly. Do not use higher or lower dose of the medicine than the one recommended to you.

In this patient information leaflet:

- 1. What BIOFENACIN is and what it is used for**
- 2. What you need to know before you take BIOFENACIN**
- 3. How to take BIOFENACIN**
- 4. Possible side effects**
- 5. How to store BIOFENACIN**

Topics are included.

1. What BIOFENACIN is and what it is used for
BIOFENACIN belongs to a drug group known as urinary antispasmodic.
Light yellow, round, biconvex, film coated tablet. BIOFENACIN is presented in packages of 30 and 90 tablets. Tablet contains lactose monohydrate obtained from bovine milk.
BIOFENACIN is used to treat the symptoms of an overactive urinary bladder. These symptoms include: having a sudden urge to urinate, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

2. What you need to know before you take BIOFENACIN
Do not USE BIOFENACIN in the following conditions

- If:
- you are allergic (hypersensitive) to solifenacin succinate or any of the other ingredients of BIOFENACIN (e.g. rash, itching or shortness of breath),
 - you are undergoing kidney dialysis,
 - you are being treated with medicines that may decrease the elimination of BIOFENACIN from the body (for example, ketoconazole) and suffer from a serious kidney disease or moderate liver disease,
 - you have been told by your doctor that you are sensitive to certain sugars,
 - you suffer from a serious liver disease,
 - you are unable to pass urine or to empty your bladder completely (urinary retention),
 - you have a serious stomach or bowel disease (including toxic megacolon, a complication associated with ulcerative colitis),
 - you suffer from a muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles,
 - you suffer from increased pressure in the eyes, with partial loss of eyesight (glaucoma).

USE BIOFENACIN WITH SPECIAL CARE in the following conditions

- If:
- you have an obstruction in your urinary bladder, which makes urinating difficult, or have difficulty in passing urine (thin urine flow),
 - you have some obstruction of the digestive system (constipation),
 - you are at risk of your digestive system slowing down (stomach and bowel movements),
 - you suffer from reflux disease (including heartburn) or hernia (hiatus hernia),
 - you suffer from a serious kidney disease,
 - you suffer from a moderate liver disease,
 - you have certain symptoms (called autonomic neuropathy) caused by damage to nerves that stimulate some internal organs.

Before starting BIOFENACIN, your doctor will assess whether there are other causes for your need to pass urine frequently, such as heart or kidney diseases or urinary system infections. If you have inflammation of the urinary tract, your doctor will prescribe you an antibiotic (treatment against particular bacterial infections).

If these cautions are valid for you, even for a period in the past, please consult your doctor.

Using BIOFENACIN with food and drink

BIOFENACIN can be taken on an empty or full stomach. Film coated tablet is taken by swallowing as a whole with sufficient amount of water.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

Since there is no data regarding its use during pregnancy, BIOFENACIN is not recommended to be used during pregnancy.

Consult your doctor or pharmacist immediately if you notice that you are pregnant during your treatment.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

Do not use BIOFENACIN during breastfeeding period.

Driving and using machines

BIOFENACIN may cause blurry vision and rarely stupor and tiredness. If you are experiencing any of these side effects, do not drive and use machines.

Important information about some of the excipients of BIOFENACIN

This product contains lactose. If you have been told by your doctor previously that you have intolerance to some sugars, consult your doctor before using this medicinal product.

Using with other medicines

If you are concomitantly taking other medicines while using BIOFENACIN, this may adversely affect the function of medicines and may cause side effects. Consult your doctor or pharmacist before starting BIOFENACIN if you are taking any of the following medicines:

- other medicines of the same type (anticholinergic medicines) as effects and side effects of both medicines can be enhanced.
- cholinergic receptor agonists (one of the most common cholinergic receptor agonists, pilocarpine, is used in the treatment of glaucoma), as they can reduce the effect of BIOFENACIN.
- medicines which make the digestive system work faster (e.g. metoclopramide and cisapride). BIOFENACIN can reduce their effect.
- medicines like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the elimination rate of BIOFENACIN from the body.
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the elimination rate of BIOFENACIN from the body and reduce its effect.
- medicines belonging to bisphosphonates, as they can cause or worsen inflammation of the esophagus (esophagitis).

If you are using a prescribed or non-prescribed medicine currently, or have used recently, please inform your doctor or pharmacist about these.

3. How to use BIOFENACIN

Instructions for proper use and dose/dosing intervals:

- Unless otherwise recommended by your doctor, follow these instructions.
- Check with your doctor or pharmacist if you are not sure.
- Take a tablet of 5 mg or 10 mg once a day.
- Your doctor will tell you which is the most appropriate dose for you.
- Take BIOFENACIN at the same time every day.

Administration route and method:

BIOFENACIN is taken orally and it should be swallowed as a whole with a drink. BIOFENACIN can be taken on an empty or full stomach Do not break the tablets.

Various age groups:

Pediatric use:

Safety and efficiency of BIOFENACIN in children has not been determined. Therefore, do not use BIOFENACIN in children.

Geriatric use:

Same dose administered to adults.

Special administration conditions:

Renal failure:

If you have serious kidney disease, do not take BIOFENACIN more than 5 mg daily.

Hepatic failure:

If you have moderate liver disease, do not take BIOFENACIN more than 5 mg daily.

If you have the impression that the effect of BIOFENACIN is either very potent or very weak, talk to your doctor or pharmacist.

If you used more BIOFENACIN than you should:

If you used more BIOFENACIN than you should, talk to a doctor or a pharmacist or apply to the emergency department of nearest hospital and tell them how many tablets you have taken.

If a child has accidentally taken BIOFENACIN, seek medical advice immediately.

Overdose may cause the following effects:

Headache, dry mouth, dizziness, drowsiness and blurred vision.

In case of serious overdose; hallucinations, over-excitability, seizures, respiratory problems (respiratory failure), elevated heart rate (tachycardia), inability to pass urine (urinary retention) and dilated pupils (dilation).

If you forget to use BIOFENACIN:

Take it as soon as you remember, unless it is time to take your next dose. Never take more than one dose per day. If you are in doubt, talk to your doctor or pharmacist.

Do not use double doses to make up the missed dose.

Possible effects when treatment with BIOFENACIN is terminated:

Always consult your doctor if you consider stopping treatment.

If you stop taking BIOFENACIN, your symptoms of overactive bladder may return or worsen.

4. Possible side effects

Like all medicines, people who are sensitive to any of the ingredients of BIOFENACIN can experience side effects.

If you have an allergic reaction or a severe skin reaction (e.g. blistering and peeling of the skin), inform your doctor or pharmacist immediately.

Angioedema (skin allergy that appears by swelling that occurs in the tissue just below the surface of the skin) with airway obstruction has been reported in some patients using solifenacin succinate. In case of angioedema, treatment with solifenacin succinate should be discontinued and appropriate treatment should be administered and/or necessary precautions should be taken.

If any of the below mentioned side effects are observed, inform your doctor or contact to the emergency department of your nearest hospital IMMEDIATELY:

Side effects are classified as shown in the below listed categories.

Very Common	: Observed in at least one of 10 patients.
Common	: May be observed in less than one in 10 patients, but more than one in 100 patients.
Uncommon	: May be observed in less than one in 100 patients, but more than one in 1000 patients.
Rare	: May be observed in less than one in 1000, but more than one in 10000 patients.
Very rare	: May be observed in less than one in 10000 patients.
Unknown	: Cannot be estimated from the available data.

Rare:

- Accumulation of urine in the bladder (urinary retention),
- Accumulation of large amount of hardened stool in the large intestine (fecal impaction),
- Vomiting,
- Intestinal obstruction

Very rare:

- Hallucinations, confusion,
- Skin allergies associated with edema in the subcutaneous tissue (angioedema)

Unknown:

- Irregular heartbeat, feeling your heartbeat, faster heartbeat

These are all serious side effects. You may need immediate medical intervention.

If any of the below mentioned side effects are observed, please tell your doctor:

Very common side effects (> 10 %):

- Dry mouth

Common side effects (> 1 %):

- Constipation, nausea, indigestion (symptoms such as abdominal fullness, burping, heartburn), abdominal pain, stomach discomfort,
- Blurred vision

Uncommon side effects:

- Urinary system infections, inflammation of the urinary bladder (cystitis), difficulty in passing urine,
- Abnormal or impaired sense of taste,
- Dry skin, dry eyes, dry throat or nasal passages,
- Fatigue, somnolence