

PATIENT INFORMATION LEAFLET
NORM-ASIDOZ 1000 mg gastro-resistant tablets

It is taken orally.

- **Active substance:** Contains 1000 mg sodium bicarbonate.
- **Excipients:** Sodium starch glycolate, colloidal silicon dioxide, Microcrystalline cellulose, hydroxy propyl cellulose, simethicone, opadry white (Lactose monohydrate (derived from cow's milk), hydroxypropyl methyl cellulose, titanium dioxide, macrogol), magnesium stearate, acryl eze clear (methacrylic acid: ethyl acrylate copolymer, talc, macrogol, colloidal silicon dioxide (anhydrous), sodium bicarbonate, sodium lauryl sulfate).

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- Keep these instructions for use. You can need to read again.
- If you have other questions, please talk your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not pass it on to others.
- During the use of this medicine, when you go to a doctor or hospital, tell your doctor that you are using this medicine.
- Follow exactly what is written in this instruction. Do not use **high** or **low** doses other than the recommended dose for the drug.

In this leaflet:

- 1. What is NORM-ASIDOZ and what is it used for?**
- 2. Things to consider before using NORM-ASIDOZ**
- 3. How to use NORM-ASIDOZ?**
- 4. What are the possible side effects?**
- 5. How to store NORM-ASIDOZ**

Headings are included.

1. What is NORM-ASIDOZ and what is it used for?

NORM-ASIDOZ is a gastro-resistant (intestinal dissolving) tablet and is available in blister packages. It is white or slightly yellowish in color, oblong (oval shaped) and has the appearance of a tablet without notch.

2. Things to consider before using NORM-ASIDOZ NORM-ASIDOZ is a tablet that belongs to the group of drugs (antacids) that treat acidosis. This group of drugs is generally used in cases where the acidity of the blood due to metabolism is high. These tablets release sodium and bicarbonate, which can be absorbed in the small intestine.

NORM-ASIDOZ is used in adults and children over 14 and 14 years old.

NORM-ASIDOZ is used in the treatment of recurrent metabolic acidosis (conditions where the acidity of the blood is high) seen in patients with chronic kidney failure.

DO NOT USE NORM-ASIDOZ in the following situations.

If;

- You have hypersensitivity (allergy) to sodium bicarbonate or any of the excipients listed at the beginning of this leaflet of NORM-ASIDOZ.
- Alkalosis (excessively alkaline body fluids and low acidity of the blood)
- Hypokalemia (blood potassium level below normal)
- You have a complaint of hypernatremia (excessive amount of sodium in the blood)
- You are on a low sodium (salt) diet

USE NORM-ASIDOZ CAREFULLY in the following situations

Consult your doctor or pharmacist before using NORM-ASIDOZ.

NORM-ASIDOZ should be used with caution in the following situations:

- Hypoventilation (decreased respiratory rate)
- Hypocalcemia (low calcium level in the blood)
- Hyperosmolar disorders (increased concentration of substances such as sugar, amino acids, sodium, potassium, calcium in the blood)

Additional measures taken by your doctor

The effects of NORM-ASIDOZ should be monitored by your doctor at weekly intervals (pH, standard bicarbonate and alkaline reserve measurement), especially at the beginning of treatment and after high doses are initiated. Likewise, substances found in plasma, especially sodium, potassium and calcium, should be monitored.

Regular laboratory examinations are essential during long-term treatment. Any condition of alkalosis (excessive alkalinity of body fluids and excessive acidity of blood) can be easily corrected by reducing the dose.

Using NORM-ASIDOZ with food and drink

There is no data on the use of NORM-ASIDOZ with food and drink.

Pregnancy

Consult your doctor or pharmacist before using this medication.

Data on the use of NORM-ASIDOZ in pregnant women is limited. Limited data obtained from animals have shown that NORM-ASIDOZ does not harm the unborn baby.

Sodium bicarbonate is easily absorbed and can be passed from mother to baby.

NORM-ASIDOZ should be used with caution in pregnant women when the doctor finds it necessary.

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

Breast-feeding

Consult your doctor or pharmacist before using this medication.

It is not known whether sodium bicarbonate is excreted in human milk. Animal studies have shown that very little sodium bicarbonate passes into breast milk. Since there is insufficient information about the effect of sodium bicarbonate on newborns and infants, NORM-ASIDOZ should be used with caution after the benefit / risk assessment by your doctor.

Vehicle and machine use

The effect of NORM-ASIDOZ on the ability to drive and use machines is insignificantly less.

Important information about some of the excipients contained in NORM-ASIDOZ

NORM-ASIDOZ contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Usage with other drugs

In some cases, sodium bicarbonate treatment can affect the excretion of weak acids and weak bases, as it increases the pH (alkalinity / alkalinity) of the urine.

Since sodium bicarbonate increases the pH of the digestive system, it may affect the absorption of the following weakly acidic or alkaline drug groups from the digestive system:

- Sympathomimetics (drug group used in the treatment of diseases such as low blood pressure, nasal congestion, distraction, etc.),

- Anticholinergics (a group of drugs used in the treatment of insomnia, dizziness, some digestive system diseases and respiratory diseases),
- Tricyclic antidepressants (a group of drugs used in the treatment of depression),
- Barbiturates (a group of drugs used in the treatment of anxiety disorders, epilepsy, etc.),
- H2-blockers (a group of drugs used in some stomach diseases),
- Captopril (a drug used in the treatment of high blood pressure (hypertension)),
- Quinidine (a drug used in the treatment of diseases with heart beat irregularity (arrhythmia))

Sodium bicarbonate may affect the solubility of drugs excreted in the urine:

- Ciprofloxacin (a drug belonging to the antibiotics group)

Functional interactions may occur in association with increased potassium excretion:

- Glucocorticoids and mineralocorticoids (a group of drugs that help reduce inflammation)
- Androgens (a group of drugs that mimic male sex hormones),
- Diuretics (a group of drugs that increase urine excretion from the body)

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

3. How to use NORM-ASIDOZ?

Instructions for appropriate use and dose / administration frequency:

You should always use NORM-ASIDOZ as your doctor has advised you. If you are not sure how to use it, consult your doctor or pharmacist.

The dosage of your medicine is adjusted according to the severity of your symptoms and your body's response.

Unless your doctor recommends NORM-ASIDOZ differently, the doses normally stated in adults are as follows:

Starting dose : 2-3 tablets per day

Continuation dose : Maximum 8 tablets per day

Depending on the symptoms your body shows, the dose given to you may be higher and can be adjusted by your doctor.

Route of administration and method:

Tablets should be taken during the day. Tablets should not be chewed or broken. The tablets should be swallowed whole with a glass of water.

Due to the risk of developing hypernatremia (excessive amounts of sodium in the blood) and metabolic alkalosis (excessive alkalinity of body fluids and low acidity of the blood) sodium bicarbonate should not be used for a long time without monitoring by your doctor.

Different age groups:**Use in children:**

The safety and efficacy of NORM-ASIDOZ in children under 14 years of age has not been investigated. No data are available for this age group. NORM-ASIDOZ should not be used in this age group.

Use in the elderly:

There is no data on the use of NORM-ASIDOZ in the elderly.

Special use cases:**Kidney failure:**

NORM-ASIDOZ is a drug used in the treatment of kidney failure disease.

Liver failure:

There is no data on the use of NORM-ASIDOZ in patients with liver failure.

If you have an impression that the effect of NORM-ASIDOZ is too strong or weak, talk to your doctor or pharmacist.

If you have used more NORM-ASIDOZ than you should:

- Vertigo (dizziness caused by a problem in the body's balance system)
- Muscle weakness
- Tiredness
- Cyanosis (bruising)
- Hypoventilation (suppression / reduction of breathing)
- Alkalosis (excessive alkalinity of body fluids and excessive lowering of blood acidity) accompanied by tetanic symptoms (involuntary contraction of muscles) can be seen. As a result,

apathy (abnormal insensitivity to the environment), confusion (confusion), ileus (bowel obstruction) and circulatory disturbance can be observed.

In some cases, acute hypernatremia (excessive accumulation of sodium) may occur, with symptoms such as severe confusion, seizures and coma.

If you have had one or more of these cases before and you are unsure that you are taking more than you should, seek medical attention as soon as possible.

If you have used more than you should use NORM-ASIDOZ, talk to a doctor or pharmacist.

If you forget to use NORM-ASIDOZ:

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with NORM-ASIDOZ is terminated:

If you stop taking NORM-ASIDOZ, you may prevent your treatment from being successful.

Do not stop taking the drug without your doctor's advice.

Consult your doctor before ending your treatment.

For any other questions on the use of this medicine, consult your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, NORM-ASIDOZ can cause side effects, but these effects are not seen in everyone.

The following side effects may occur as a result of using NORM-ASIDOZ:

Side effects are listed in the following categories:

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

Common: It can be seen less than one in 10 patients, but more than one in 100 patients.

Uncommon: It can be seen less than one in 100 patients, but more than one in 1.000 patients.

Rare: It can be seen less than one in 1.000 patients, but more than one in 10.000 patients.

Very rare: It can be seen less than one in 10.000 patients.

Unknown: It can be seen in a small number of patients that cannot be determined from the available data.

Unknown:

- Abdominal pain and gas
- Muscle tenderness (hypocalcemic tetany) due to low calcium levels in case of overdose of sodium bicarbonate
- Increased severity of existing gastrointestinal complaints (eg diarrhea)
- In case of long-term use, kidney stone formation (transformation of calcium and magnesium phosphate into kidney stones)

If any of these affect you severely, tell your doctor.

If you encounter any side effects not mentioned in these instructions for use, inform your doctor or pharmacist.

5. Storage of NORM-ASIDOZ

Keep NORM-ASIDOZ in places out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

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

Use in accordance with the expiry date.

Do not use NORM-ASIDOZ after the expiry date indicated on the label or package.

If you notice any defects in the product and / or package, do not use NORM-ASIDOZ.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing authorization holder::

Drogsan İlaçları San. ve Tic. A.S.

Oguzlar Mah. 1370. Sok. No: 7/3

06520 Balgat / ANKARA

Manufacturing place:

Drogsan İlaçları San. ve Tic. A.S.

Esenboğa Merkez Mah. Cubuk Cad.

No: 31 06760 Çubuk / ANKARA

This patient information leaflet was approved on 08/03/2019.