SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

NORM-ASIDOZ 1000 mg gastro-resistant tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Sodium bicarbonate	1000 mg

Excipients:

Lactose monohydrate *	14,40 mg

* Made from cow's milk.

For excipients see 6.1.

3. PHARMACEUTICAL FORM

Gastro-resistant tablet.

White or slightly yellowish, oblong, notchless tablet.

4. CLINICAL PROPERTIES

4.1. Therapeutic indications

NORM-ASIDOZ is indicated for the maintenance treatment of metabolic acidosis and recurrent metabolic acidosis in adults and patients older than 14 and 14 years of age with chronic renal failure (chronic renal failure and renal tubular acidosis).

The safety and effectiveness of NORM-ASIDOZ in children under the age of 14 have not been investigated. No data are available for this age group. NORM-ASIDOZ should not be used in this population.

Acidosis should be treated with infusion in patients with an arterial pH value below 7.2.

4.2. Posology and method of administration

Posology / Application frequency and duration:

Adults:

The dose depends on the severity of the metabolic acidosis treated.
The acid-base values of the patient should be monitored regularly and the dose should be adjusted according to the patient's response to treatment.

Treatment of metabolic acidosis in chronic kidney disease
For the treatment of metabolic acidosis due to chronic kidney disease, sodium bicarbonate therapy is usually started with 2-3 tablets per day in adults and given in divided doses.
Its dosage is adjusted so that the plasma bicarbonate concentration is not less than 22 mmol / l.
Gastro-resistant formulations of sodium bicarbonate up to 8 grams per day have been shown to be effective in controlling metabolic acidosis in patients with chronic kidney disease. However, some patients may require higher doses of sodium bicarbonate depending on the severity of acidosis.
Due to the sodium content of sodium bicarbonate, patients' fluid and electrolyte balance should be carefully monitored throughout the use of the drug.

Treatment of metabolic acidosis in renal tubular acidosis

1. *Distal renal tubular acidosis*

In adult patients with distal renal tubular acidosis (Type I), the initial daily dose is 0.5-2 mmol / kg and it is given in 4 or 5 divided doses. The dosage is adjusted according to the patient's response and tolerance until hypercalciuria (excessive calcium in the urine) and metabolic acidosis are controlled. Alternatively, an adult dose of 48-72 mmol (approximately 4-6 grams) daily is recommended.

2. *Proximal renal tubular acidosis*

Patients with proximal renal tubular acidosis (Type 2) generally require higher doses; 4-10 mmol / kg daily oral doses are given in divided doses.

Method of Application:
Tablets should not be chewed or broken. It should be swallowed with a glass of water.
Due to the risk of developing hypernatremia and metabolic alkalosis, sodium bicarbonate should not be used for a long time without being monitored by a doctor.

Additional information on special populations

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 liver failure.

Pediatric population:

The safety and effectiveness of NORM-ASIDOZ in children under the age of 14 have not been investigated. There is not enough data about the use of NORM-ASIDOZ in pediatric population. NORM-ASIDOZ should not be used in this population.

Geriatric population:

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

4.3. Contraindications

NORM-ASIDOZ is contraindicated in individuals who are hypersensitive to the active ingredient or any of the excipients (see section 6.1).

It is contraindicated in those with alkalosis, hypokalaemia, hypernatremia or those on a low sodium diet.

4.4. Special use warnings and precautions

NORM-ASIDOZ should be used with caution in patients with hypoventilation, hypocalcemia and hyperosmolar disorder.

The effects of NORM-ASIDOZ should be monitored at weekly intervals, especially at the beginning of treatment and after higher doses (pH value, standard bicarbonate, measurement of alkali reserve, etc. (see section 4.2) Likewise, plasma electrolytes, especially sodium, potassium and calcium should be monitored regularly.

Regular laboratory examinations are essential during long-term treatment. Any alkalosis condition can be easily corrected by dose reduction.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this drug.

4.5. Interaction with other medicinal products and other forms of interaction

Drug interaction studies with gastro-resistant sodium bicarbonate have not been conducted.

In general, interactions with other drugs may occur due to changes in the pH of the gastrointestinal tract or urine.

The probability of an interaction in the gastrointestinal system is considered low due to gastro-resistance.

In some cases, elimination of weak acids and bases can be affected by sodium bicarbonate therapy, which increases the pH of the urine. This example may apply to the administration of sympathomimetics, anticholinergics, tricyclic antidepressants, barbiturates, H2-blockers, captopril and quinidine.

The potential effect of sodium bicarbonate on the solubility of medicinal products eliminated in urine such as ciprofloxacin should be considered.

Functional interactions with glucocorticoids and mineralocorticoids, androgens and diuretics may occur in connection with increased potassium excretion.

Additional information on special populations

There are no interaction studies regarding special populations.

Pediatric population:

There are no interaction studies in pediatric populations.

4.6. Pregnancy and lactation

General advice

Pregnancy category: C

Women with childbearing potential / Contraception (Contraception)

There are no data that require contraception during the use of sodium bicarbonate in women of childbearing potential.

Sodium bicarbonate can be used in women of childbearing potential.

NORM-ASIDOZ has no known effect on birth control methods.

Pregnancy period

There is not enough data on the use of sodium bicarbonate in pregnant women. Limited data from animal studies have shown that sodium bicarbonate does not have a teratogenic effect on animals (see section 5.3). The potential risk for humans is unknown.
It should be noted, however, that oral sodium bicarbonate can be easily absorbed and cross the placental barrier.
NORM-ASIDOZshould be used with caution during pregnancy and should not be used unless necessary.

Lactation period

It is not known whether NORM-ASIDOZ passes into human milk. Available pharmacokinetic data from animals indicate that sodium bicarbonate or its metabolites pass into milk in very small amounts. Sodium bicarbonate administered at therapeutic doses is not expected to have any effect on the breastfed newborn / infant. Since there is insufficient information on the effects of sodium bicarbonate in newborns / infants, sodium bicarbonate should be used with caution and after a comprehensive benefit / risk assessment during breastfeeding.

Reproductive ability / Fertility

It is not known whether sodium bicarbonate affects fertility.

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Very common (≥1/10); common (≥1/100 ila <1/10); uncommon (≥1/1.000 ila <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), unknown (cannot be estimated from the available data).

Gastrointestinal diseases

Not known: Flatulence (gas) and abdominal pain

Musculoskeletal and connective tissue bone disorders

Unknown: Hypocalcemic tetany (muscle sensitivity due to low calcium) due to overdose of sodium bicarbonate, increase in the severity of existing gastrointestinal complaints (diarrhea, etc.)

Kidney and urinary tract diseases

Not known: Formation of calcium or magnesium phosphate stones in the kidney as a result of long-term sodium bicarbonate use.

4.9. Overdose and treatment

Oral sodium bicarbonate administration in absolute or relative overdose (eg in the case of renal failure) may cause alkalosis accompanied by signs of vertigo (dizziness), muscle weakness, fatigue, cyanosis, hypoventilation, and tetany. Later, apathy (indifference to the environment), confusion (confusion), ileus (intestinal obstruction), circulatory collapse (circulatory collapse) can be observed. Treatment of overdose of sodium bicarbonate is done by correcting fluid, electrolyte (calcium, potassium and chloride when necessary) and acid-base imbalances.

In individual cases, acute hypernatremia with signs of severe confusion, seizures and coma may prevail. In these cases, fluid administration (glucose solutions, hypoosmolar electrolyte solutions) and saluretics are indicated.

5. PHARMACOLOGICAL PROPERTIES:

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in the treatment of acid-related disorders.

ATC code: A02X

The main pharmacological property of sodium bicarbonate is based on the physiological role of the HCO_3^-/CO_2 buffer system.

The sodium bicarbonate contained in NORM-ASIDOZ is in the form of tablets that release absorbable sodium and bicarbonate in the small intestine, resistant to stomach acid.

5.2. Pharmacokinetic properties

General features:

Absorbation

After oral administration, NORM-ASIDOZ passes through the stomach unchanged, and bicarbonate is released only after reaching the small intestine. Sodium bicarbonate is absorbed in the small intestine. If the plasma bicarbonate level is below 24 mmol / l, almost all of the HCO_3^- (bicarbonate) is re-absorbed after renal filtration.

Distribution

Hydrogen carbonate placental barrier readily; It crosses the blood-brain barrier slowly.

Biotransformation

Depending on the metabolic state, after the reaction of hydrogen carbonate and hydrogen ion, carbon dioxide and water are formed in the plasma. The transformation of hydrogen carbonate to carbon dioxide and water is controlled by the enzyme carbonic anhydrase.

Elimination

Depending on the metabolic state, carbon dioxide, which is formed by the reaction of hydrogen carbonate and hydrogen ion, is excreted by the lungs.

If the plasma bicarbonate level is above 24 mmol / L, some of the bicarbonate is excreted by the kidneys.

5.3. Preclinical safety data

Sodium and bicarbonate are physiological components of animal and human plasma. Limited preclinical data are available from medicinal products containing sodium bicarbonate. These limited data indicate that sodium bicarbonate presents no special hazard for humans when used in therapeutic concentration.

After the administration of high dose sodium bicarbonate to mice and rats, no teratogenic effect was detected in mice and rats.

6. PHARMACEUTICAL PROPERTIES

6.1. List of excipients

Sodium starch glycolate

Colloidal silicon dioxide

Microcrystalline cellulose

Hydroxypropyl 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

6.2. Incompatibilities

There is no interaction between the active ingredient and excipients or between the primary packaging material.

Microcrystalline cellulose pH 102, one of the auxiliary substances, with strong oxidants; sodium starch glycolate type A is incompatible with vitamin C.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at room temperature below 25ºC.

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

6.5. Nature and content of the packaging

PVC / PVDC-Al Foil containing 50 gastro resistant tablets is packaged in a blister.

6.6. Disposal of remnants of human medicinal products and other special measures

Unused products or waste materials should be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging Waste Control Regulation".

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

2019/149 (in Turkey)

9. FIRST REGISTRATION DATE / REGISTRATION RENEWAL DATE

Fırst regıstratıon date: 08.03.2019 (in Turkey)

Regıstratıon renewal date: -

10. RENEWAL DATE OF SPC

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