Package leaflet: Information for the patient

Nephrotrans 500 mg gastro-resistant capsules, soft
Active substance: sodium hydrogen carbonate

Read all of this leaflet carefully before you start taking 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.

What is in this leaflet

1. What Nephrotrans 500 mg is and what it is used for

Nephrotrans 500 mg is used for the treatment of metabolic acidosis (high blood acidity) or as a maintenance treatment to prevent metabolic acidosis from returning in adults with chronic renal impairment (poor kidney function). Nephrotrans 500 mg contains 500 mg of the active substance sodium hydrogen carbonate in the form of a gastro-resistant soft capsule, for oral use.

2. What you need to know before you take Nephrotrans 500 mg

Do not take Nephrotrans 500 mg
- if you are allergic to sodium hydrogen carbonate, peanuts, soya or any of the other ingredients of this medicine (listed in section 6).
- if your blood alkali levels are too high (metabolic alkalosis).
- if you have low potassium levels in your blood (hypokalaemia).
- if you have high sodium levels in your blood (hypernatraemia).
- if you are on a low-sodium diet.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nephrotrans 500 mg.

- The effect of Nephrotrans 500 mg will initially be monitored by your doctor every one to two weeks (e.g. by pH measurement), especially at higher doses. Blood plasma electrolytes, especially sodium, potassium and calcium, will also be regularly monitored. Further dosing can be determined based on the outcome of these checks. Low blood acidity (hyperalkalisation) can be corrected by taking a lower dose.

- Particular care is needed if you suffer from depressed breathing (hypoventilation), low blood calcium levels (hypocalcaemia) or high blood salt levels (hyperosmolar conditions).

- Nephrotrans 500 mg contains 137 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 7% of the recommended maximum daily dietary intake of

sodium for an adult. Taking into account the recommended daily dose range of Nephrotrans 500 mg at 6 to 10 capsules a day this corresponds to 40-70% of the adult recommended maximum daily dietary intake for sodium. The sodium content should be taken into account in long-term treatment with high dosages. If necessary, a low-salt or strict low-salt diet should be followed to counteract the further increase of existing high blood pressure.

Children and adolescents
The safety and efficacy of Nephrotrans 500 mg has not been established in children and adolescents, therefore Nephrotrans 500 mg is not recommended for children and adolescents.

Other medicines and Nephrotrans 500 mg
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nephrotrans 500 mg can interact with other medicines and affect how they are absorbed and excreted. Consequently, the effects of these medicines may be stronger or weaker.
This applies, for example, to:

- sympathomimetic agents (medicines that increase the activity of the sympathetic nervous system, a part of the autonomic nervous system)
- anticholinergic agents (medicines that inhibit the action of acetylcholine, the main transmitter of the parasympathetic nervous system)
- tricyclic antidepressants
- barbiturates (medicines used in epilepsy)
- H_2 antagonists (medicines to block the production of stomach acid)
- captopril (medicine used to treat high blood pressure, known as an ACE inhibitor)
- quinidine (medicine used to treat heart rhythm disorders)
- glucocorticoids and mineralocorticoids (e.g. cortisone)
- androgens (sex hormones)
- diuretics that increase the excretion of potassium (water tablets)
- medicines eliminated via urine (e.g. ciprofloxacin, an antibiotic).

Nephrotrans 500 mg with food, drink and alcohol
There are no known interactions with stimulants, food and drink.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There have been no studies on the use of this medicine during pregnancy and breast-feeding. The risk from the condition, however, is estimated to be higher than the assumed risk of taking Nephrotrans 500 mg. Nephrotrans 500 mg should only be used during pregnancy or breast-feeding after consultation with your doctor.

Driving and using machines
Nephrotrans 500 mg has no influence on the ability to drive and use machines.

Nephrotrans 500 mg contains sorbitol, soya-bean oil and propylene glycol
Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.
Nephrotrans 500 mg contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.
This medicine contains 8 mg propylene glycol in each capsule.

3. How to take Nephrotrans 500 mg

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Based on your blood levels, they will adjust the dosage depending on the severity of your acidosis (high acid levels in your blood). If the pH of your blood is very low (below pH 7.2), an infusion (a drip) is more suitable to correct your high acid levels.

Dosage
The usual recommended dose is between 3 and 5 g sodium hydrogen carbonate per day.
This is equivalent to 6 to 10 capsules Nephrotrans 500 mg per day.

Method of administration
The capsules should be swallowed whole in doses divided throughout the day with sufficient liquid. Do not chew or open the capsules, as this will destroy their gastro-resistant function.

Do not take this medicine without medical supervision for prolonged periods, as there is a possibility that you may develop high blood sodium levels or low blood acidity (alkalosis).

If you take more Nephrotrans 500 mg than you should
- Symptoms of overdose that may occur include: dizziness, muscle weakness, tiredness, bluish discoloration of the skin or mucous membranes (cyanosis), shallow breathing and seizure-like muscle spasms due to increased excitability in nerve-muscle transmission (symptoms of tetany). This may later be followed by listlessness (apathy), confusion, bowel obstruction and circulatory collapse. These are signs of low blood acidity (alkalosis). Treatment consists of correcting the fluid and electrolyte balance, particularly with the supply of calcium, potassium and, if necessary, chloride.
- In individual cases, symptoms of acute hypernatraemia (high blood sodium levels) may also predominate, with confusion, increased excitability and even seizures and coma. In such cases, fluid administration (e.g. glucose solutions and hypo-osmolar electrolyte solutions) and diuretics (water tablets) are crucial.
- If the dose is exceeded, muscular hyperexcitability due to low calcium (hypocalcaemic tetany) is possible. In patients with pre-existing disorders of the gastrointestinal tract, e.g. diarrhoea, such disorders may get worse.

If you suspect an overdose with Nephrotrans 500 mg, please tell your doctor. Depending on the severity of the overdose, he/she can decide on any measures that may be required.

If you forget to take Nephrotrans 500 mg
Do not take a double dose to make up for a forgotten dose. If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule.

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.

Very rare (may affect up to 1 in 10,000 patients)
The soya-bean oil contained in Nephrotrans 500 mg may very rarely cause allergic reactions.

Other side effects (not known: frequency not known based on the available data)
Gastrointestinal symptoms such as flatulence and abdominal pain, may occur.
Long-term use of Nephrotrans 500 mg may encourage the formation of calcium or magnesium phosphate stones in the kidneys.

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. You can also report side effects directly via:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Nephrotrans 500 mg

Do not store above 25°C.
Store in the original package in order to protect from light.

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 carton and blister after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nephrotrans 500 mg contains

- The active substance is: sodium hydrogen carbonate.
- The other ingredients are: yellow beeswax, hydrogenated soya-bean oil, partially hydrogenated soya-bean oil, refined rapeseed oil, soya lecithin, iron oxide (E172), titanium dioxide (E171), glycerol, gelatine, partially dehydrated liquid sorbitol, hydrochloric acid 25%, hypromellose, hydroxypropylcellulose, talc, polyethylene glycol, methacrylic acid - ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, propylene glycol, glycerol monostearate, purified water.

Please read section 2. "What you need to know before you take Nephrotrans 500 mg" for warnings about soya and sorbitol, as well as the sodium and propylene glycol content.

What Nephrotrans 500 mg looks like and contents of the pack

Nephrotrans 500 mg are elongated oval, russet/white gastro-resistant capsules, soft.
Nephrotrans 500 mg is available in packs with 100 gastro-resistant capsules, soft and in hospital packs with 500 gastro-resistant capsules, soft.

Not all pack sizes may be marketed.

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