Dear Patient,
Please read this leaflet carefully, because it contains important information regarding the use of this medication. Please consult your doctor or pharmacist, if you have any questions

PATIENT INFORMATION

b i c a N o r m®

Active ingredient: Sodium hydrogen carbonate

Composition
1 tablet contains:

Medically active ingredients:
Sodium hydrogen carbonate 1000 mg

Na^+	11,9 mmol
HCO_3^-	11,9 mmol

Other ingredients:
Poly (O-carboxymethyl) starch, sodium salt
Microcrystalline cellulose
Copovidone
Potato starch
Highly disperse silicium dioxide
Calcium icosanoate
Hypromellose
Titanium dioxide (E 171).
Macrogol 6000
Talcum
Methacryl acid - ethyl acrylate copolymer (1:1) (Ph. Eur.)
Sodium hydroxide

Pharmaceutical form and content
Packet with 100 gastric juice resistant tablets.

b i c a N o r m® belongs to a group of medicines called acidosis therapeutic agents.

Manufactured by:
Fresenius Medical Care Deutschland GmbH
D-61346 Bad Homburg v.d.H.
Tel.: 06172 / 609-0

Indications
Metabolic acidosis in chronic renal insufficiency, and renal tubular acidosis.

Contraindications

When should I not take b i c a N o r m® ?
Do not take **b i c a N o r m®** in cases of
– alkalosis
– lowered potassium levels in the blood (hypopotassemia),
– low-sodium diet

What do I have to consider if I am pregnant or breast-feeding?
There are no reports on adverse effects of taking **b i c a N o r m®** during pregnancy or lactation.

What about children and the elderly?
The use of **b i c a N o r m®** by children and the elderly is the same as the use by adults.

Other precautions and warning notices

Which precautions do I need to take?
One gastric juice resistant tablet contains c. 11.9 mmol (273 mg) sodium. If you have to follow a low-sodium diet, you need to take this into account.

Will it affect my ability to drive a car or operate machinery?
b i c a N o r m® does not negatively affect your ability to drive a car or operate machinery.

Interaction with other medication

Which other medications affect the effect of b i c a N o r m®?
Because of it strongly alkaline pH values, sodium hydrogen carbonate is incompatible with most other medication. In combination with solutions containing calcium, magnesium, or phosphate in particular, it can result in precipitations.

Raising the pH-value in the urine can affect the absorption and excretion of weak acids and bases. This applies for example to sympathomimetics, anticholinergics, tricyclic antidepressant, barbiturates, H2-blockers, captopril, clorazepate, and chinidine. Functional interaction can occur with glucocorticoids and mineralocorticoids, with androgens, and with diuretics that increase potassium excretion.

A possible impact on the solubility of drugs eliminated in the urine (e.g. Ciprofloxazin), has to be taken into account.

Please not that this also applies to any recently taken medication.

Which stimulants, food, or drink should I avoid?
There are no known interactions with any stimulants, food, or drink.

Dosage guide, method and duration of treatment

How much b i c a N o r m® should I take and how frequently should I take b i c a N o r m® ?
For the oral alkalinisation of urine, a daily dose of 2-4 g is given in two administrations. The desired pH-value in the urine is achieved by adjusting the dosis as appropriate.

How and when should I take b i c a N o r m® ?
Take the film-coated tablets at mealtimes, swallowed unchewed with a little liquid (e.g. water).
As a basic rule in oral administration, you should observe an interval of one to two hours between taking **b i c a N o r m®** and any other medication.

How long should I continue to take b i c a N o r m® ?
Because of the risk of hypernatremia and of developing alkalosis, **b i c a N o r m®** should not be taken without supervision for an extended period. In extended use, at the very least the kidney function, ph-values in the urine, and possibly the blood gases should be checked. Your doctor will decide how long you need this treatment.

Overdose and other application errors

What should I do if I have taken too much b i c a N o r m® (intentional or accidental overdose)?
Possible overdose symptoms are muscular weakness, abnormal fatigue, and shallow breathing.
Please inform your doctor, if you suspect an overdose of **b i c a N o r m®** . Depending on the severity of the overdose, your doctor will decide on the course of treatment, which may be required.

What happens if I have taken too little b i c a N o r m® ?
If you have taken too little **b i c a N o r m®** or if you have forgotten to take it altogether, just take your normal dose at the next scheduled time.

What happens if I need to interrupt my treatment or finish it early?
Please consult your doctor, if you interrupt or finish taking **b i c a N o r m®** ahead of schedule, e.g. because of a side effect.

Side effects

Which possible side effects can occur when using b i c a N o r m®?
Long term use can favour the formation of calcium or magnesium phosphate stones in the kidneys.
If you experience any side effects not listed in this patient information leaflet, please inform your doctor or pharmacist.

Notes and information regarding the shelf life of this drug
The expiry date is printed on the package. Please do not use this medication after that date!

How should I store b i c a N o r m® ?
Do not store at temperatures exceeding 25°C !

Always make sure to store your **b i c a N o r m®** tablets out of the reach of children.

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