

Kalfree

For normalization of potassium balance and prevent kidney stones.

1.56 g Potassium / 2.5 g Citrate Effervescent Tablets

Active Substance: Potassium Citrate

The active ingredient is present in the effervescent tablet after implementation as potassium citrate, potassium hydrogen carbonate and citric acid.

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take Kalfree effervescent tablets carefully to get the best results from it

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet please tell you doctor or pharmacist

In this leaflet:

1. What Kalfree effervescent tablet are and what it is used for.
2. Before you take Kalfree effervescent tablets.
3. How to take use Kalfree effervescent tablets.
4. Possible side effects.
5. How to store Kalfree effervescent tablets.
6. Further information.

1. WHAT KALFREE EFFERVESCENT TABLET ARE AND WHAT IT IS USED FOR

Kalfree effervescent tablets are potassium mineral for normalization of potassium balance and prevent of kidney stones.

Therapeutic areas:

For potassium supplementation in the following situations:

- Markedly low blood potassium concentrations (hypokalemia 3.2 mmol/l), especially in subjects with a metabolism-related excess of acid in the blood (metabolic acidosis)
- Potassium-related disorders of nerve and muscle activity (hypokalemic neuromuscular disorders) or disorders of heart rhythm.
- Low blood potassium concentrations (hypokalemia) in subjects receiving treatment with digitalis-based heart drugs.

To prevent low blood potassium concentrations (hypokalemia) in the following situations:

- Too much acid in the blood due to ketone bodies (ketoacidosis), for example due to diabetes.

To prevent the recurrence of kidney stones (kidney stone metaphylaxis):

- in the presence of calculi (e.g. when the small canals in the kidney are unable to excrete sufficient quantities of hydrogen ions, i.e., in subjects with renal tubular acidosis)
- Excessively low citrate excretion (hypocitraturia < 320 mg/day of various causes)
- Uric acid calculi.

2. BEFORE YOU TAKE KALFREE EFFERVESCENT TABLETS

Do not take Kalfree effervescent tablets if you are allergic (hypersensitive) to active substances: potassium citrate, potassium hydrogen carbonate, anhydrous citric acid or any of the other ingredients of Kalfree effervescent tablets.

3. HOW TO TAKE KALFREE EFFERVESCENT TABLETS

a) for potassium-related disorders of nerve and muscle activity or heart rhythm disorders and to avoid offset low blood potassium concentrations:

The dosage will depend on the extent of depletion to be corrected although, as a rule, 40 to 80 mmol of potassium per day should suffice. A daily dose of 160 mmol should not be exceeded. Single doses should not exceed 40 mmol potassium, i.e. 1 Kalfree effervescent tablet.

b) to prevent recurrence of kidney stones:

The physician should choose a dosage such that more than 320 mg of citrate is excreted per day and the urine pH is 6.2-6.8. These values can be achieved by administering 1-2 effervescent tablets per day. Single doses should not exceed one Kalfree effervescent tablet i.e. 40 mmol potassium. A daily dose of 4 effervescent tablets should not be exceeded.

Method of Administration:

For oral use (after dissolving). Fully dissolve 1 Kalfree effervescent tablet in a glass of water (100 - 200 ml). Add fruit juice for taste if desired and drink the solution in sips over a period of 10 to 15 minutes. The product is better tolerated when taken with meals. A daily dose of 2 or more effervescent tablets is to be taken spread over the day (e.g. morning, noon, evening).

Duration of Administration:

It is advisable to continue taking Kalfree effervescent tablets for as long as the cause of your potassium depletion persists and to prevent recurrence of kidney stones. In other cases of potassium depletion the deficit can usually be resolved within a number of days or weeks. Please speak to your doctor or pharmacist, if you mean that the effect of Kalfree effervescent tablets is too weak or too strong.

If you take more Kalfree effervescent tablets than you should

Normally functioning kidneys rapidly excrete excessive potassium. Dangerously high blood potassium concentrations are likely only in cases of major overdose. Since excessively high blood potassium concentrations impair the normal functioning of the heart, it is essential to consult a doctor without delay in the event of major overdose. The doctor can determine the blood potassium concentration through a lab test and/or perform an ECG to check your heart rhythm. The doctor can also take suitable measures to heart function and blood potassium concentrations. If blood potassium concentrations are only slightly above normal, normalization without further treatment may occur following normal excretion of potassium through the kidneys.

If you forget to take Kalfree effervescent tablets

Do not take a double dose to make up for a forgotten tablet. If you forgot one dose of Kalfree effervescent tablets, you can make up for it by taking the tablet when you realize your mistake. However, you should not take more than one effervescent tablet at a time and you should not exceed the total daily dose.

If You stop taking Kalfree effervescent tablets

If you are supposed to take Kalfree effervescent tablets to correct or prevent potassium depletion, then you need this intake of Kalfree effervescent tablets to maintain your potassium balance. Without the additional intake of potassium from Kalfree effervescent tablets, your dietary intake of potassium will not be sufficient to cover your current potassium requirement

Therefore, if you interrupt or stop taking treatment with Kalfree effervescent tablets, you may develop potassium depletion with potentially harmful effects on your heart, nervous system and muscle function.

If you are supposed to take Kalfree effervescent tablets to prevent recurrence of kidney stones, treatment with potassium citrate in Kalfree effervescent tablets is necessary in order to control the composition of your urine. Without the additional intake of potassium citrate from Kalfree effervescent, the composition of the urinary constituents in your urine will promote the development of kidney stones. Your urine will be too acidic and you will have an unfavorable ratio of the urinary components that promote kidney stones to those that help to prevent them. If you interrupt or stop treatment with Kalfree effervescent tablet your kidney stones may recur. If you have any questions on the use of this product ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, Kalfree effervescent tablet can cause side effects although not everybody gets them. The following frequency tables are commonly used to assess side effects:

Very common	Less than 1 in 10 persons treated
Common	Less than 1 in 10 but more than 1 in 100 person treated
Uncommon	Less than 1 in 100 but more than 1 in 1000 persons treated
Rare	Less than 1 in 1000 but more than 1 in 10000 persons treated
Very rare	Less than 1 in 10000 persons treated, including individual cases

The following side effects have been observed:

Kalfree effervescent tablet may produce nausea and vomiting in predisposed patients, Eructation, heart burn, bloating, abdominal pain and diarrhea have also reported.

Allergic reactions, such as itching and facial swelling, have been reported in a few cases in patients with known allergies (e.g. hay fever, house dust allergy).

If you notice any side effects that are not described in this package insert, please tell your doctor or pharmacist.

What action should be taken if side effects occur:

Any nausea or other gastrointestinal side effects listed above require no specific treatment, provided they are actually caused by Kalfree effervescent tablet. To prevent these effects you should make sure to dissolve Kalfree effervescent tablet fully in a sufficient amount of water. Do not drink the solution too quickly and never take it on an empty stomach. Please follow the instructions given in the "dosage instructions" section.

If you develop an allergic reaction (hypersensitivity reaction) you should tell your doctor and stop taking Kalfree effervescent tablet it is advisable to have your doctor investigate which ingredient in the Kalfree effervescent tablet caused the allergic reaction so that you can avoid this substance in the future in other medicines and foodstuffs.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KALFREE EFFERVESCENT TABLETS.

Keep out of the reach and sight of children.

Do not use Kalfree effervescent tablet after the expiry date which is started on the label, carton after "best before" the expiry date refers to last day of the month.

Keep the container in the outer carton. Do not store above 30°C.

Keep the container tightly closed in order to protect from moisture.

Do not use Kalfree effervescent tablet if you notice: the tablets are dampish.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Kalfree effervescent tablet contains

- The active substances are:

- 2.17 g potassium citrate (pH-Eur.)
- 2.00 g potassium hydrogen carbonate
- 2.057 g citric acid

- The other ingredients are:

- Maltodextrine, Sorbitol, Isomalt
- saccharine
- Acesulfam K
- macrogol 6000
- lemon flavour

What Kalfree effervescent tablet looks like and contents of pack

Kalfree effervescent tablet is a round flat white coloured tablet. Packed 20 tablets are consisting in an oblong plastic box of polypropylene with white plug of original pack.

Distributed by:
BioActiveT PHARMA, United Kingdom.

BioActiveT

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