PATIENT INFORMATION LEAFLET

ALKAFIZZ MIXED BERRY

(EFFERVESCENT GRANULES)

SCHEDULING STATUS

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL DOSAGE FORM

ALKAFIZZ MIXED BERRY (Effervescent Granules)

Read all of this leaflet carefully because it contains important information for you.

ALKAFIZZ MIXED BERRY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use ALKAFIZZ MIXED BERRY carefully to get the best results from it.

- **Keep this leaflet; you may need to read it again.**
- **Do not share ALKAFIZZ MIXED BERRY with any other person.**
- **Ask your pharmacist if you need more information or advice.**
- **You must see a doctor if your symptoms worsen or do not improve after 5 days.**

WHAT ALKAFIZZ MIXED BERRY CONTAINS

The active substances are sodium citrate, sodium bicarbonate, citric acid anhydrous and tartaric acid. Each 4 g of ALKAFIZZ MIXED BERRY contains sodium citrate 0,613 g, sodium bicarbonate 1,716 g, citric acid anhydrous 0,702 g and tartaric acid 0,858 g. The other ingredients are mixed berry flavour and contains sugar (liquid glucose).

WHAT ALKAFIZZ MIXED BERRY IS USED FOR

ALKAFIZZ MIXED BERRY belongs to a group of medicines acting on the genito-urinary system. ALKAFIZZ MIXED BERRY is used to relieve gastric acidity as well as for its urinary alkalinising properties.

ALKAFIZZ MIXED BERRY can be used to relieve symptoms of inflammation of the bladder, including prevention of crystals forming in the urine due to the use of sulphonamides.

BEFORE YOU USE ALKAFIZZ MIXED BERRY

Do NOT take ALKAFIZZ MIXED BERRY if you:

- are allergic to sodium citrate, sodium bicarbonate, citric acid anhydrous and tartaric acid or to any of the other ingredients of ALKAFIZZ MIXED BERRY**.**
- have severe kidney problems. Please discuss this with your doctor.
- have metabolic disturbances with alkalosis, hypocalcaemia or hypochlorhydria.
- are currently taking any of the following medicines:
    - urinary tract antiseptics which require acid urine, such as methanamine mandelate and methanamine hippurate.
- Should be used with care in patients suffering from renal insufficiency.

Take special care with ALKAFIZZ MIXED BERRY:

Before using ALKAFIZZ MIXED BERRY you should speak to your doctor if you:

- are currently taking other medicines, as ALKAFIZZ MIXED BERRY may interact with these medicines and cause unwanted or adverse effects.
- suffer from kidney insufficiency/ problems. You may have to go for blood tests to determine if your kidneys are functioning properly.
- are taking other antacids and you have compromised kidney function, as this may result in the absorption of dangerously high amounts of aluminium.
- are suffering from congestive heart failure and high blood pressure.
- are suffering from an ulcer of the stomach or gut.

- have cirrhosis of the liver.
- have swelling of the feet, hands or ankles (peripheral oedema).
- have been diagnosed with pulmonary oedema (fluid accumulating in the lungs).
- are pregnant and suffering from eclampsia (seizures in pregnant women with high blood pressure).
- are on a sodium-restricted diet, as you should not take ALKAFIZZ MIXED BERRY.

Please note that this alkalinising agent does not eradicate bacteriuria although it may temporarily relieve lower urinary tract symptoms.

Taking ALKAFIZZ MIXED BERRY with food and drinks

ALKAFIZZ MIXED BERRY must be taken on an empty stomach and followed with additional water.

Pregnancy and breastfeeding

The safe use of ALKAFIZZ MIXED BERRY in pregnant or breastfeeding mothers has not been established. If you are breastfeeding your baby, ALKAFIZZ MIXED BERRY should be taken with care.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving or using machinery

ALKAFIZZ MIXED BERRY has no sedative effects and should be safe to use during driving and using machinery.

Important information about some of the ingredients of ALKAFIZZ MIXED BERRY.

ALKAFIZZ MIXED BERRY contains sodium and sugar. If you are on a sodium restricted diet or suffer from diabetes mellitus, do not take ALKAFIZZ MIXED BERRY.

Taking other medicines with ALKAFIZZ MIXED BERRY

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are taking any of the following medicines, please discuss the use of ALKAFIZZ MIXED BERRY with your doctor, as you may require special precautions:

- urinary tract antiseptics, such as methenamine mandelate and methenamine hippurate (an antibiotic that eliminates bacteria that causes urinary tract infections) (see ″Do not take ALKAFIZZ MIXED BERRY ″).
- *Antacids*

  Any other antacid, including aluminium-containing antacids, since it may cause abnormally high alkalinity of the blood and body fluids, may promote the development of kidney stones and may cause elevated sodium levels in the blood. It may cause absorption of dangerously high amounts of aluminium
- Quinolone antibiotics, e.g. ciprofloxacin, norfloxacin, ofloxacin
- Salicylates, e.g. aspirin used for pain, inflammation and fever and methyl salicylate / wintergreen oil, for treatment of skin conditions and joint pain
- Tetracyclines, doxycycline used as antibiotics

  You should not take ALKAFIZZ MIXED BERRY within 1 to 2 hours of these antibiotics.
- *Ketoconazole*

  You should take ALKAFIZZ MIXED BERRY at least 2 hours after ketoconazole.

HOW TO TAKE ALKAFIZZ MIXED BERRY

Do not share medicines prescribed for you with any other person. Always take ALKAFIZZ MIXED BERRY exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults

Add one to two 5 mL medicines measures (4 to 8 g) in half a glass of cold water, 3 to 4 times daily, taken on an empty stomach and followed with additional water. Drink the solution only after effervescence is complete.

Long-term therapy: One 5 mL (4 g) medicine measure daily.

Children (6 to 12 years)

Add one 5 mL medicine measure (4 g) in half a glass of cold water, 2 or 3 times daily, taken on an empty stomach and followed with additional water. Allow the child to drink the solution only after effervescence is complete.

If you have the impression that the effect of ALKAFIZZ MIXED BERRY is too strong or too weak, talk to your doctor or pharmacist.

If you take more ALKAFIZZ MIXED BERRY than you should

In the event of an overdosage, or if someone has taken your medicine by mistake, you, or this person, may experience side effects such as those listed below.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ALKAFIZZ MIXED BERRY

Always take ALKAFIZZ MIXED BERRY as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next day, skip the missed

dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose. Continue with your normal dose on the regular schedule as prescribed by your doctor or as directed above.

POSSIBLE SIDE EFFECTS

ALKAFIZZ MIXED BERRY can have side effects. Not all side effects reported for ALKAFIZZ MIXED BERRY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALKAFIZZ MIXED BERRY, please consult your doctor, pharmacist or other healthcare professional for advice.

- Abdominal distention, flatulence, belching and nausea may occur if ALKAFIZZ MIXED BERRY effervescent granules are taken before effervescence is complete (see "**HOW TO TAKE ALKAFIZZ MIXED BERRY** ").

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma, especially if you suffer from impaired kidney function. These are symptoms of metabolic alkalosis.
- muscle hypertonicity (spasms), twitching and tetany, especially if you have low blood calcium levels.
- increased thirst, dizziness, fast heartbeat, high blood pressure, irritability, muscle twitching, restlessness, seizures, swelling of feet or lower legs, weakness, oedema and possible effect on the cerebral, pulmonary or peripheral circulations (excessive doses may lead to sodium overloading and hyperosmolality).

Check with your doctor or pharmacist if any of the following side effects develop, continue or become bothersome:

- stomach cramps, diarrhoea or loose bowel movement.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ALKAFIZZ MIXED BERRY

Store in a cool dry place, at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep the container tightly closed.

Do not refrigerate or freeze.

Keep the bottle in the outer carton.

Do not use the medication after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF ALKAFIZZ MIXED BERRY

Available in clear round glass bottles with a white screw cap and a dosage measure, packed in an outer carton.

Each bottle contains 600 g to 120 g effervescent granules.

IDENTIFICATION OF ALKAFIZZ MIXED BERRY

White to straw-coloured granules with a berry odour and a sweet mixed berry taste.

After reconstitution with water, a clear to straw coloured solution with a berry odour and a sweet mixed berry taste is obtained.

REGISTRATION NUMBER

45/18.3/0183

NAME AND BUSSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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