

Package leaflet: Information for the patient

Kacital 1080 mg modified-release tablets potassium citrate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kacital is and what it is used for
2. What you need to know before you take Kacital
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1. What Kacital is and what it is used for

Kacital contains the active substance potassium citrate. Potassium citrate increases urinary pH which makes the urine less acidic and thereby less likely to form kidney stones.

Kacital is used

- to treat and/or prevent kidney stones;
- to treat hypocitraturia (a metabolic disorder with a low level of citrate excreted in the urine);
- to treat distal renal tubular acidosis (when kidneys do not remove acids from the blood into the urine as they should) with calcium kidney stones.

2. What you need to know before you take Kacital

Do not take Kacital

- if you are allergic to potassium citrate, or any of the other ingredients of this medicine listed in section 6;
- if you have severely impaired kidney function;
- if you have active or persistent urinary tract infection;
- if you have significant or complete obstruction of the urinary tract;
- if you have excessive potassium in your blood (hyperkalaemia);
- if you have severely impaired heart function;
- if you have uncontrolled diabetes;
- if your adrenal glands are not working properly;
- if your blood and body fluids acid-base balance is disrupted (metabolic or respiratory alkalosis);
- if you have a peptic ulcer;
- if you have a condition in which food stays in your stomach for longer than it should (delayed gastric emptying);
- if you suffer from bowel obstruction;
- if you are taking a medicine that delays gastrointestinal motility (anticholinergics).

Warnings and precautions

Talk to your doctor or pharmacist before taking Kacitalif you have:

- a condition where you cannot excrete potassium, Kacital may cause excessive potassium in your blood (hyperkalaemia) and cardiac arrest which may be fatal. Your doctor will monitor you and take blood tests prior to initiation of therapy and every three months for the duration of the therapy..
- severely reduced liver function;
- sickle cell anaemia.

Other medicines and Kacital

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how Kacital works and vice versa. Concomitant use with the below medicines:

- may increase the level of potassium in your blood:
 - o potassium-sparing diuretics (to treat reduce blood pressure, fluid build-up in tissue (oedema), heart conditions), e.g., amiloride, eplerenone, spironolactone, triamterene;
 - o finerenone (to treat chronic kidney disease in connection with type 2-diabetes);
 - o angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, aliskiren, beta-blockers (to reduce high blood pressure);
 - o digoxin and other cardiac glycosides (to treat different heart conditions);
 - o drospirenone (oral contraceptive, hormone replacement therapy);
 - o heparin (blood thinner);
 - o nicorandil (to treat angina);
 - o nonsteroidal anti-inflammatory drugs (NSAIDs) (to reduce pain, fever, inflammation), e.g., indomethacin.
- may increase the effect of the below medicines:
 - o Alpha-/beta-agonists (indirect-acting) (to treat ADHD, narcolepsy, nasal congestion, asthma);
 - o Amantadine (to treat symptoms of Parkinson's disease);
 - o mecamlamine (to reduce high blood pressure);
 - o memantine (to treat dementia);
 - o quinine (to treat malaria, leg cramps and similar conditions);
 - o amphetamines (stimulants that speed up the body's system);
 - o aluminium hydroxide (to treat heartburn, acid indigestion).
- may increase the risk of abdominal pain (stomach ulcers):
 - o anticholinergics (medicine that delays gastrointestinal motility).
- may increase the risk of formation of crystals in urine:
 - o antibiotics (e.g., amoxicillin, sulfamethoxazole + trimethoprim, or ciprofloxacin).

Kacital with alcohol

You should not drink alcohol when taking Kacital as this may result in the medicine being released too quickly in your body.

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.

Pregnancy

Your doctor will only treat you with this medicine if strictly necessary and under strict medical surveillance.

Breast-feeding

Kacital can be used during breast-feeding.

Driving and using machines

Kacital does not affect your ability to drive and use machines.

Kacital contains potassium

Kacital contains 390 mg of potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Kacital

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be taken with meals or within 30 minutes after meals to avoid any stomach reactions.

Kacital is a “modified release” tablet which releases the medicine gradually. The tablets must, therefore, be swallowed whole with enough liquid and should not be taken with alcohol, crushed, chewed or dissolved as this may result in the medicine being released too early and may cause irritation in the mouth or throat.

You should take Kacital in conjunction with a diet that avoids foods high in salt, avoid the use of table salts and increase your intake of fluids. This will help you pass more urine and optimize Kacital’s effectiveness in treating kidney stones and other conditions. It will also help prevent kidney problems.

Your doctor will monitor you closely and take regular blood tests.

The recommended dose is

Severe hypocitraturia (urinary citrate < 150 mg/day)

Initial dose: 60 mEq/day (6 tablets) in 3 divided daily doses.

Mild hypocitraturia (urinary citrate > 150 mg/day)

Initial dose: 30 mEq/day (3 tablets) in 3 divided daily doses.

If necessary, the dose may be increased as long as the maximum dose of 100 mEq/day is not exceeded.

Moderately impaired kidney function

Your kidney function will be monitored regularly.

Impaired liver function

Kacital should be used with caution.

If you take more Kacital than you should

You should immediately seek medical attention if you think that you or anyone else may have taken too many Kacital tablets even if there are no signs of discomfort or poisoning.

Signs of overdose include depression, mental confusion, paraesthesia (e.g., tingling sensation, numbness); muscle weakness and sometimes paralysis of the extremities, which can develop gradually or in stages; slow heartbeat (bradycardia); low blood pressure which may in some cases be serious (leading to irregular heartbeat, possibly heart attack and sudden death).

If you forget to take Kacital

If you forget to take a tablet, leave out that dose completely. Take your next dose at the normal time it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Kacital

Do not stop taking Kacital tablets unless your doctor tells you to.
Your doctor will decide when treatment with Kacital should be stopped.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience any of these potentially serious side effects:

Not known (frequency cannot be estimated from the available data)

- burning and heavy feeling in the pit of the stomach, mild nausea, vomiting, loss of appetite and weakness caused by damage to the mucosal lining in your stomach;
- bloody vomit and/or black stools due to bleeding in the stomach and intestines;
- constipation, vomiting, inability to pass stool or gas, swelling of the abdomen due to intestinal obstruction;
- muscle weakness, confusion, difficulty speaking due to too much potassium in your blood (hyperkalaemia).

Other possible side effects

Very common (may affect more than 1 in 10 people)

- stomach pain;
- mild nausea.

Common (may affect up to 1 in 10 people)

- upper stomach pain;
- diarrhoea;
- dyspepsia;
- difficulty swallowing;
- inflammation of the oesophagus;
- vomiting;
- gaseousness (bloating, belching, flatulence);
- rash.

You may notice the remnants of the tablet wax matrix in your faeces. This is normal. Do not be concerned.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Kacital

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. 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 Kacital contains

- The active substance is potassium citrate.
Each tablet contains 1080 mg of potassium citrate (10 milliequivalents), equivalent to 390 mg of potassium.
- The other ingredients are carnauba wax (E 903) and magnesium stearate (E 470b).

What Kacital looks like and contents of the pack

Cream coloured to yellow, oval, biconvex, uncoated tablets. Tablet size approx. 18.5 mm.

Pack size: 100 modified-release tablets.

The tablets are packed in a plastic bottle and closed with a tamper evident cap. The bottle is packed in a box.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

AT, BE, DE, IE, NL: Kacital

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