

Package leaflet: Information for the user

Resincalcio 99.75% w/w Powder for Oral/Rectal Suspension

calcium polystyrene sulfonate

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.

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1. What Resincalcio is and what it is used for

Resincalcio contains a medicine called calcium polystyrene sulfonate.

This belongs to a group of medicines called “ion exchange resins”.

Resincalcio is used to treat something called “hyperkalaemia”. This is when there is too much potassium in your blood. It works by attaching to potassium in your gut. This prevents potassium from entering your bloodstream and lowers potassium levels in your blood back to normal. It is often given to people who have kidney problems and people on dialysis.

2. Before you use Resincalcio

Do not use Resincalcio

- if you are allergic (hypersensitive) to calcium polystyrene sulfonate or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have been told that you have a low level of potassium in your blood
- if you have been told you have problems that result in high levels of calcium in your body such as thyroid problems or some types of cancer
- if your gut is partially or completely blocked (obstructive bowel disease)
- if you are taking a sweetener called sorbitol (a «sugar-free» sweetener used to sweeten food). This is because taking sorbitol and Resincalcio at the same time can cause narrowing of the gut wall (gastrointestinal stenosis) and reduced blood flow to the gut wall (intestinal ischemia) causing severe damage to your gut (necrosis and perforation). You must not take any sorbitol whilst using Resincalcio
- it must not be administered orally in newborns.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Resincalcio.

Take a special care with Resincalcio

Talk to your doctor, pharmacist or nurse before taking Resincalcio:

- if it is for your baby, and they were premature, had a low birth-weight or have reduced gut movement,
- if you suffer from constipation.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Resincalcio.

Taking other medicines

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Resincalcio can affect the way other medicines work. Also, some medicines can affect the way Resincalcio works.

In particular, check with your doctor if you are taking the following medicines:

- Medicines that contain salts such as magnesium, potassium or calcium. Ask your doctor if you are not sure
- Some medicines for constipation (laxatives) that contain magnesium
- Some medicines for indigestion (antacids) that contain magnesium or aluminium
- Digoxin or similar medicines from digitalis - for heart problems
- Levothyroxine or thyroxine - for an under-active thyroid
- Lithium - for mental illness

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using Resincalcio.

Taking Resincalcio with food and drink

See section 3.

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 for advice before using this medicine.

Driving and using machines

It is not known whether the administration of calcium polystyrene sulfonate may impair your ability to drive or use machines.

3. How to use Resincalcio

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

- The dose will depend on the results of blood tests
- For children the dose is also worked out according to how much the child weighs

Having the medicine

- Resincalcio can be given by mouth or put into the back passage (rectum).
- If given by mouth, mix with a small amount of water and stir until it is thoroughly mixed. The powder does not dissolve but forms a suspension. You may add more water to the mixture to help you swallow the medicine. If powder remains in the glass after drinking, add more water, stir and drink immediately. You may need to do this again to make sure that you have taken all the powder.
- Resincalcio can also be made into a paste with something sweet, such as jam or honey.
- It should not be mixed with fruit juice, this will stop the medicine working properly.
- If given by mouth, it is important to sit up while taking the medicine so that you do not breathe in any powder into your lungs.
- If given by the back passage you should try to keep the medicine in your back passage for at least 9 hours. Then it needs to be thoroughly washed out.

How much is normally given:

Adults (including the elderly)

By mouth

- The usual dose is 15 g (three spoonfuls) three or four times a day

- Take at least 3 hours before or 3 hours after other oral medicines you may be taking. If you suffer from gastroparesis (a condition where your stomach can't empty itself in the normal way), leave at least 6 hours before or after taking other oral medicines.

Into the back passage

- The usual dose 30 g (six spoonfuls) once a day

In some cases, the medicine may be given both by mouth and into the back passage. This is where your potassium levels need to be lowered more quickly.

Use in children

If your child cannot take the medicine by mouth, it may be given into the back passage.

- The daily dose is 1 g for each kilogram of bodyweight
- Once the medicine has started working the dose may be lowered to 0.5 g daily for each kilogram of bodyweight

New born babies

Resincaico is only given into the back passage.

- The daily dose is between 0.5 g and 1 g for each kilogram of bodyweight.

It is important to give the right dose for children and babies. If too much is given, children and babies could get serious constipation.

If you use more Resincaico than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will be checking your progress and checking the medicine that you are given. Ask them if you are not sure why you are getting a dose of medicine.

If you are given too much Resincaico the following effects may happen:

- Feeling irritable or confused
- Being unable to concentrate
- Muscle weakness and poor reflexes leading to paralysis
- Breathing problems
- Faster or pounding heartbeat
- Muscle cramps

If you forget to use Resincaico

Your doctor or nurse will give instructions about when to have your medicine. It is unlikely that a dose will be missed. If you think that you may have missed a dose, talk to your doctor or nurse.

Do not take a double dose to make up for a forgotten dose.

If you stop using Resincaico

Keep having Resincaico until your doctor tells you to stop. If you stop having Resincaico, your illness may come back.

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.

Talk to your doctor or nurse if you get any of the following side effects:

Common (may affect up to 1 in 10 people)

- feeling tired, confused, having muscle weakness, cramps or a change in heart rate. These may be due to having low levels of potassium in your body
- high levels of calcium in your blood
- low levels of magnesium in your blood
- nausea

- vomiting
- constipation

Uncommon (may affect up to 1 in 100 people)

- loss of appetite
- diarrhoea
- stomach upset, pain in your gut or blockage of the gut
- gastrointestinal ulcer
- intestinal obstruction

Rare (may affect up to 1 in 1,000 people)

- large, hard, dry stool mass (faecalomas) in severe cases, particularly in children following rectal administration. Gastrointestinal concretions (bezoars) following oral administration.
- necrosis of the colon, which could lead to intestinal perforation which is sometimes fatal, especially if it is administered together with sorbitol (a laxative).

Very rare (may affect up to 1 in 10,000 people)

- feeling short of breath or coughing. This could be the first sign of a serious chest infection. This can be caused by accidentally breathing in this medicine.

5. How to store Resincalcio

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

Do not store above 30 °C.

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

After first opening of the container, keep it tightly closed and do not store above 30°C. Shelf life after first opening of the container is 1 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 Resincalcio contains

- The active substance is calcium polystyrene sulfonate. Each 100 g powder for suspension contain 99.75 g calcium polystyrene sulfonate.
- The other ingredients are: vanilla flavour.

What Resincalcio looks like and contents of the pack

Resincalcio is a fine golden or brown fine powder with slight vanilla flavour.

Resincalcio is supplied in:

- Plastic multidose container with 400 g of powder fitted with a screw cap with a safety seal, and with a plastic measuring spoon, which, when filled level, contains 5 g of powder.
- Box of 26 sachets containing 15 g of powder.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Yahmaa Medical Company

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Manufacturer

Laboratorios Rubió, S.A.

Industria, 29

Pol. Ind. Comte de Sert
08755 Castellbisbal – Barcelona
Spain

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To report any side effects:

Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
Fax: +966-11-205-7662
Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340
Toll free phone: 8002490000
E-mail: npc.drug@sfda.gov.sa
Website: www.sfda.gov.sa/npc

Other GCC States:

- Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risk.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**