

Resonium A[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Resonium A?

Resonium A contains the active ingredient sodium polystyrene sulfonate. Resonium A is used to help remove excessive amounts of potassium from the blood. For more information, see Section [1. Why am I using Resonium A?](#) in the full CMI.

2. What should I know before I use Resonium A?

Do not use if you have ever had an allergic reaction to Resonium A or any of the ingredients listed at the end of the CMI, have a bowel obstruction, or have low levels of potassium. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Resonium A?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Resonium A and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Resonium A?

- Resonium A can be given by mouth or rectally (via the back passage).
- The usual oral doses are 15 g three to four times daily for adults, and 1 g/kg of body weight in divided doses for children. Take Resonium A at least 3 hours before or 3 hours after other oral medications.
- The usual rectal (back passage) doses are 30 - 50 g in 150 mL of water or 10% dextrose in water, as a retention enema for adults, with lower dosages usually used for infants and children. Your pharmacist will make this up. For infants and children, this enema will usually be given by a doctor or nurse.

More instructions can be found in Section [4. How do I use Resonium A?](#) in the full CMI.

5. What should I know while using Resonium A?

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|-----------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist |
|-----------------------------|--|

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| | <p>you visit that you are using Resonium A.</p> <ul style="list-style-type: none">● Be sure to keep all of your appointments with your doctor so that your progress can be checked.● If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.● Call your doctor straight away if you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately. |
| Things you should not do | <ul style="list-style-type: none">● Do not take more than the recommended dose unless your doctor tells you to.● Do not give this medicine to anyone else, even if they have the same condition as you.● Do not use this medicine to treat any other |

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| | <p>complaints unless your doctor tells you to.</p> <ul style="list-style-type: none"> • Do not stop taking Resonium A, or lower the dosage, without checking with your doctor. |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> • Keep Resonium A in a cool, dry place where the temperature stays below 30°C. • Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it in the bathroom or near a sink, in the car, or on window sills. Keep it where young children cannot reach it. |

For more information, see Section [5. What should I know while using Resonium A?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include nausea and vomiting, constipation, diarrhoea, muscle cramps, loss of appetite and gastric irritation. Speak to your doctor if you have any of these less serious side effects and they worry you. Serious side effects include swelling of the face,

lips, mouth or throat, which may cause difficulty in swallowing or breathing, hives, fainting, severe stomach pain, rectal pain, bloating, severe constipation, severe nausea and vomiting, black, blood or tarry stools, coughing up blood, or vomit that looks like coffee grounds. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Resonium A[®]

Active ingredient: *sodium polystyrene sulfonate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Resonium A. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Resonium A.**

Where to find information in this leaflet:

- [1. Why am I using Resonium A?](#)
- [2. What should I know before I use Resonium A?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Resonium A?](#)
- [5. What should I know while using Resonium A?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Resonium A?

Resonium A contains the active ingredient sodium polystyrene sulfonate. This sodium polystyrene sulfonate contains sodium atoms. This sodium is swapped for potassium in the body, particularly in the large intestine. Resonium A does not enter the

bloodstream from the intestine. It is passed (with the potassium ions) with the faeces.

Resonium A is used to help remove excessive amounts of potassium from the blood.

2. What should I know before I use Resonium A?

Warnings

Do not use Resonium A if:

- you are allergic to sodium polystyrene sulfonate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- a bowel obstruction
- low levels of potassium (less than 5 mmol/L)

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - any heart conditions
 - high blood pressure
 - problems with your bowel or constipation
 - delayed gastric emptying
 - you have abnormal bowel movements (after surgery or drug usage), as these may cause a variety of disorders including colonic distension and severe

constipation (bowel movements occur less often than usual or consist of hard, dry stools that are often painful or difficult to pass)

- kidney problems
- oedema (swelling with fluid)
- plan to have surgery
- take any medicines for any other condition
- you are taking a sweetener called sorbitol (a sugar-free sweetener used to sweeten food). This is because taking Resonium A alone or taking sorbitol 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 Resonium A.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take it if you are pregnant or intend to become pregnant. Like most medicines of this kind, Resonium A is not recommended to be used during pregnancy.

Do not take it if you are breastfeeding or intend to breastfeed. It is not known whether Resonium A passes into breast milk.

Newborn babies

- Do not give oral Resonium A to newborn babies. Orally administered Resonium A has caused bowel obstruction in newborns.
- Resonium A should only be given rectally to newborns.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Resonium A and affect how it works. These include:

- sorbitol
- digoxin, a medicine used for heart problems
- laxatives
- thyroxine, a medicine for hypothyroidism
- lithium, a medicine which can be used to treat bipolar disorder
- antacids containing aluminium or magnesium

These medicines may be affected by Resonium A, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

Take Resonium A at least 3 hours before or 3 hours after other oral medications.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Resonium A.

4. How do I use Resonium A?

Resonium A can be given by mouth or rectally (via the back passage).

How much to take / use

- The amount of Resonium A you need to take will depend upon the amount of potassium in your blood.
- Your doctor will decide exactly how much Resonium A you need to take.
- Follow the instructions provided and use Resonium A until your doctor tells you to stop.

The usual doses are:

Oral

Adults:

- 15 g three to four times daily.

Children:

- 1 g/kg of body weight in divided doses.

Resonium A powder is usually given by mouth as a suspension in a small amount of water (3-4 mL per gram of powder), or it may be mixed with some sweetened liquid (but not fruit juices, which contain potassium). For children it is preferably given with a drink (not a fruit juice

because of the high potassium content) or a little jam or honey.

Do not mix Resonium A with fruit juices or sorbitol.

Take Resonium A at least 3 hours before or 3 hours after other oral medications.

If you have been diagnosed with delayed gastric emptying, ask your doctor for instructions on when to take Resonium A.

Once the mixture has been prepared it should be used straight away. If it needs to be stored, it should be stored for no longer than 24 hours. Once reconstituted, Resonium A is a cream to light brown coloured suspension in which small white particles may be visible.

Rectal (via the back passage)

Adults:

- 30 - 50 g in 150 mL of water or 10% dextrose in water, as a retention enema. Your pharmacist will make this up.

Infants & children:

- Lower dosages are usually used.
- You will usually be given the enema by a doctor or nurse.

If you forget to take / use Resonium A

Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much Resonium A

If you think that you have used too much Resonium A, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Large doses of Resonium A may cause serious potassium ion deficiency. If you take too much you may feel irritable, confused, have muscle weakness, have diminished reflexes or paralysis.

5. What should I know while using Resonium A?

Things you should do

Take Resonium A exactly as prescribed.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will regularly check the potassium, calcium and magnesium levels in your blood. The doctor may change the dose or stop the Resonium A depending on what the results of these blood tests are.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Resonium A.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Call your doctor straight away if you:

- If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

Remind any doctor, dentist or pharmacist you visit that you are using Resonium A.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Resonium A, or lower the dosage, without checking with your doctor.

Looking after your medicine

- Keep Resonium A in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <p>Gastrointestinal or gut-related:</p> <ul style="list-style-type: none">• nausea and vomiting• constipation• diarrhoea• muscle cramps• loss of appetite• gastric irritation | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are mild side effects of this medicine and are usually short-lived.</p> |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <p>Allergic reaction-related:</p> <ul style="list-style-type: none">• swelling of the face, lips, mouth or throat, which | <p>Call your doctor straight away, or go straight to the Emergency</p> |

| Serious side effects | What to do |
|---|--|
| <p>may cause difficulty in swallowing or breathing</p> <ul style="list-style-type: none"> ● hives ● fainting <p>Gastrointestinal or gut-related:</p> <ul style="list-style-type: none"> ● severe stomach pain, rectal pain ● bloating, severe constipation ● severe nausea and vomiting ● black, blood or tarry stools, coughing up blood, or vomit that looks like coffee grounds | <p>Department at your nearest hospital if you notice any of these serious side effects.</p> <p>If you have them, you may have had a serious allergic reaction to Resonium A. You may need urgent medical attention or hospitalisation.</p> <p>These side effects are very rare.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects as follows:

Australia: Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

New Zealand: Medsafe online at <https://www.medsafe.govt.nz/safety/report-a-problem.asp>

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Resonium A contains

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| Active ingredient (main ingredient) | Each 100 g contains 99.934 g of sodium polystyrene sulfonate |
| Other ingredients (inactive ingredients) | vanillin saccharin |
| Potential allergens | Resonium A does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes. |

Do not take this medicine if you are allergic to any of these ingredients.

What Resonium A looks like

Resonium A is a buff-coloured powder with a vanilla odour.

Resonium A comes in a container containing 454 g of powder. The container also contains a plastic spoon which, when filled level measures 15 g of powder (Aust R 15497).

Who distributes Resonium A

Resonium A is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

Resonium A is supplied in New Zealand by:

sanofi-aventis new zealand limited

Level 15, PwC Tower

15 Customs Street West,

Auckland 1010, New Zealand

Freecall No: 0800 283 684

Resonium A is made in France.

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