



Risedronate for brittle bones

This leaflet is about the use of risedronate for the treatment of brittle bones in children. This may be due to osteogenesis imperfecta or other forms of osteoporosis.



This leaflet is for parents and carers about how to use this medicine in children. Our information sometimes differs from that provided by the manufacturers, because their information is usually aimed at adults. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.

Name of drug

It is important that you follow the instructions on how to give risedronate.

Risedronate sodium

Brand names: Actonel, Actonel Once a Week

Why is it important to take this medicine?

Risedronate will help to make your child's bones stronger so that they are less likely to break (fracture).

What is risedronate available as?

- **Tablets:** 5 mg, 30 mg (once daily) (contain lactose)
- **Tablets:** 35 mg (once weekly) (contain lactose)

When should I give risedronate?

- **Risedronate 5 mg and 30 mg tablets** are given **once each day**. This should be in the morning. Ideally this should be as soon as your child gets up. Give the medicine at about the same time each day so that this becomes part of your child's daily routine, which will help you to remember.
- **Risedronate 35 mg tablets** are given **once each week**. This should be the same day each week. To help you remember, choose a day when your child has a regular activity such as a swimming lesson, or a favourite television programme. It may be helpful to note the day in your diary or phone.

How much should I give?

Your doctor will work out the amount of risedronate (the dose) that is right for *your* child. The dose will be shown on the medicine label.



It is important that you follow your doctor's instructions about how much to give.

How should I give it?

There is a risk that risedronate can damage your child's food pipe (oesophagus) if not taken correctly. It is important that you follow these instructions to avoid this risk.

Risedronate tablets are best taken **in the morning** once your child is out of bed, and at least 30 minutes before they have their first food or drink of the day.



- Your child should swallow the tablet whole with a glass of water (150 mL).
- Your child **should not lie down for 30 minutes after taking the tablet**.
- If your child takes risedronate as soon as they get up in the morning, they **should not have anything to eat or drink for at least 30 minutes after taking the tablet**. If they are thirsty they can have some more water.
- Your child can have the risedronate tablet at another time of the day if this is more convenient. In this case, **they should not have any food or drink (except water) for 2 hours before or after taking the medicine**.
- They should not take the tablet at bedtime.

When should the medicine start working?

It will take several months for your child's bones to get stronger. You are unlikely to see any difference in your child, although they may have less bone pain.

What if my child is sick (vomits)?

- If your child is sick less than 30 minutes after having a dose of risedronate, give them the same dose again.
- If your child is sick more than 30 minutes after having a dose of risedronate you **do not** need to give them another dose. Wait until the next normal dose.

If your child is sick again, seek advice from your GP, pharmacist or hospital. They will decide what to do based on your child's condition and the specific medicine involved.

What if I forget to give it?

Risedronate 5 mg and 30 mg tablets

If you forget to give risedronate first thing in the morning, it can be given later in the day, as long as this is at least 12 hours before the next dose is due. Your child must not have anything to eat or drink for 2 hours before or after taking the risedronate. They must not take risedronate at bedtime.

Risedronate 35 mg tablets

Give the missed dose when you remember and then continue to give it once a week, starting one week after you give the missed dose. Your child must not have anything to eat or drink for 2 hours before or after taking the risedronate (30 minutes if you give it first thing in the morning).


What if I give too much?


You are unlikely to do harm if you give an extra dose of risedronate by mistake. If you are concerned that you may have given too much, contact your doctor or local NHS services (details at end of leaflet). Have the medicine or packaging with you if you telephone for advice.

Are there any possible side-effects?

We use medicines to make our children better, but sometimes they have other effects that we don't want (side-effects).

Side effects you must do something about

 If your child has pain in the upper part of their stomach or lower chest, or a burning feeling rising in the throat, they may have an inflammation in their oesophagus (food pipe). Contact your doctor straight away.

 If your child has a rash and is also generally unwell and has a fever (high temperature) or unusual bruises or bleeding, contact your doctor or take your child to hospital **straight away**, as this may indicate a more serious reaction.

Other side-effects you need to know about:

- Your child may get stomach pain and feel sick (nausea) or be sick (vomit) and may get diarrhoea or constipation (difficulty doing a poo) when they first start taking risedronate. This should settle down as their body gets used to the medicine. If it is still a problem after a week, contact your doctor.
- Your child may get headaches and feel dizzy or light-headed, especially when they stand up.
- Your child may get flu-like symptoms (headache, aches and pains) when they first start taking risedronate. Contact your doctor if you are worried.

There may, sometimes, be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor. You can report any suspected side-effects to a UK safety scheme at www.mhra.gov.uk/yellowcard

Can other medicines be given at the same time as risedronate?

- You can give your child medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to.
- If your child takes any mineral or vitamin supplements that contain iron or calcium, give these at a different time of day from risedronate. Leave a gap of at least 2 hours between giving risedronate and the supplement.
- If your child takes medicines for indigestion (antacids), give these at a different time of day from risedronate. Leave a gap of at least 2 hours between giving risedronate and these medicines.
- If you think your child needs a medicine for indigestion (antacids), check with your doctor first. See section: Side effects you must do something about.
- Check with your doctor or pharmacist **before** giving any other medicines to your child. This includes herbal or complementary medicines.

Is there anything else I need to know about risedronate?

- Your doctor may suggest that your child has a bone biopsy before starting treatment with risedronate (a small piece of bone is taken under anaesthetic).
- Your child may have a special scan called a DXA every 6 months while taking risedronate, to see how well it is working.
- Your child may also have an X-ray of their skeleton once a year to check how the size and shape of their bones has changed while taking risedronate.

General advice about medicines

- Try to give medicines at about the same times each day, to help you remember.
- If you are not sure a medicine is working, contact your doctor but continue to give the medicine as usual in the meantime. Do not give extra doses, as you may do harm.
- Only give this medicine to *your* child. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- If you think someone else may have taken the medicine by accident, contact your doctor for advice.
- Make sure that you always have enough medicine. Order a new prescription at least 2 weeks before you will run out.
- Make sure that the medicine you have at home has not reached the 'best before' or 'use by' date on the packaging. Give old medicines to your pharmacist to dispose of.

Where should I keep this medicine?

- Keep the medicine in a cupboard, away from heat and direct sunlight. It does not need to be kept in the fridge.
- Make sure that children cannot see or reach it.
- Keep the medicine in the container it came in.

Who to contact for more information

Your child's doctor, pharmacist or nurse will be able to give you more information about risedronate and about other medicines used to treat brittle bones.

You can also get useful information from:

England: NHS 111 - Tel 111 - www.nhs.uk

Scotland: NHS 24 - Tel 111 - www.nhs24.scot

Wales: NHS 111 Wales - Tel 111 - www.111.wales.nhs.uk

Northern Ireland: NI Direct - www.nidirect.gov.uk

Brittle Bone Society: Tel 01382 204446

www.brittlebone.org

www.medicinesforchildren.org.uk



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The primary source for the information in this leaflet is the British National Formulary for Children. For details on any other sources used for this leaflet, please contact us through our website, www.medicinesforchildren.org.uk. We take great care to make sure that the information in this leaflet is correct and up-to-date. However, medicines can be used in different ways for different patients. It is important that you ask the advice of your doctor or pharmacist if you are not sure about something. This leaflet is about the use of these medicines in the UK, and may not apply to other countries. The Royal College of Paediatrics and Child Health (RCPCH), the Neonatal and Paediatric Pharmacists Group (NPPG), WellChild and the contributors and editors cannot be held responsible for the accuracy of information, omissions of information, or any actions that may be taken as a consequence of reading this leaflet.