

APO-Riluzole Tablets

Contains the active ingredient riluzole

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055 (Australia Only)

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about riluzole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Riluzole. It contains the active ingredient Riluzole.

It is used to treat people with amyotrophic lateral sclerosis, which can cause muscle degeneration leading to muscle weakness. It is a form of Motor Neurone Disease.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

It is important to remember that you may not feel any different when you take riluzole. The benefits of using riluzole may not be noticeable to you.

You should not stop taking riluzole without speaking to your doctor first

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have liver disease**
- **You are pregnant.**

Riluzole may affect your developing baby if you take it during pregnancy.

- **You are breastfeeding.**

Riluzole may pass into human breast milk.

- **You are hypersensitive to, or have had an allergic reaction to, riluzole or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of

the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver disease
 - kidney disease
 - lung disease
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.

4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
5. You have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with riluzole. These include:

- theophylline - a medicine used to treat asthma.
- amitriptyline - a medicine used to treat depression
- tacrine - a medicine used in patients with Alzheimer's Disease
- some types of antibiotics e.g. rifampicin and quinolones
- omeprazole - a medicine used to treat gastric ulcers.
- some medicines used to treat depression e.g. Clomipramine and fluvoxamine
- diazepam - a medicine for sedation.

- diclofenac - a medicine used to reduce pain and inflammation.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with riluzole.

Tell your doctor if you smoke and how much coffee you drink.

Nicotine and caffeine may affect the amount of Riluzole in your body.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow tablets with a full glass of water or other liquid.

When to take it

Riluzole should not be taken immediately before or after meals, especially meals which may contain food high in fat.

Riluzole may not work as well if it is taken at the same time as your meals.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

Do not stop taking riluzole unless your doctor tells you to, even if you feel better.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor, or the Poisons Information Centre (Tel: 13 11 26 in Australia or 0800 764 766 in New Zealand).

Alternatively go to the Accident and Emergency department at your nearest hospital, Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed

- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause drowsiness or dizziness in some people. Make sure you know how you react to it before you

drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking riluzole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- stomach ache, nausea or vomiting
- headache
- joint stiffness
- skin problems e.g. rash, flaking skin
- dizziness
- sleepiness
- weakness or loss of strength

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- irregular or fast heartbeat
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- swelling of the hands, feet or legs
- tingling sensations around the mouth
- shortness of breath or difficulty breathing
- Severe upper stomach pain, often with nausea and vomiting
- If your skin becomes itchy or yellow or if you start to bleed or bruise easily. You may be developing a liver problem.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to riluzole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Riluzole looks like

The 50 mg tablets are white to off white coloured, film coated, capsule shaped, biconvex tablets "APO" engraved on one side and "RI-50" engraved on other side

APO-Riluzole comes in blister packs of 56 tablets

APO-Riluzole also comes in bottles* of 56, 100 & 500 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 50 mg of riluzole as the active ingredient.

It also contains the following inactive ingredients:

- Calcium hydrogen phosphate
- microcrystalline cellulose
- croscarmellose sodium

- magnesium stearate
- hypromellose
- macrogol 8000
- titanium dioxide
- purified talc

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Riluzole 50 mg tablets (blister pack):

AUST R 168091.

APO-Riluzole 50 mg tablets (bottle): AUST R 168094.

Sponsor

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