

4-AP (4-aminopyridine)

This leaflet provides important information about using 4-AP. 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 4-AP.

Where to find information in this leaflet:

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- 2. What should I know before I use 4-AP?
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1. Why am I using 4-AP?

4-AP contains the active ingredient 4-Aminopyridine.

4-AP is belongs to a group of medicines called potassium channel blockers. They work by stopping

potassium leaving the nerve cells which have been damaged by MS.

This medicine is thought to work by letting signals pass down the nerve more normally, which allows you to walk better.

4-AP is used in adult patients with Multiple

Sclerosis (MS) to improve walking.

Your doctor may prescribe 4-AP for another purpose.

Ask your doctor if you have any questions about why

4-AP has been prescribed for you.

There is no information on the use of this medicine in those below 18 years of age.

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

2. What should I know before I use 4-AP?

Warnings

Do not use 4-AP if:

- you are allergic to 4-Aminopyridine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath;
 - wheezing or difficulty breathing;
 - swelling of the face, lips, tongue or other parts of the body;
 - rash, itching or hives on the skin.
- You are currently taking other forms of 4aminopyridine.
- Taking 4-AP with other forms of 4-Aminopyridine may increase the risk of seizures, fits or convulsions.
- Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines. Always check the ingredients to make sure you can use this medicine.
- You have ever had a seizure, or you have been told by your doctor you have a high risk of seizure (also referred to as a fit or convulsion)

4-AP may increase the risk of seizures, fits or convulsions. Some patients may be at a higher risk of seizure than others, due to other ongoing medical conditions. Your doctor will discuss your full medical history to advise on your seizure risk.

- You have serious problems with your kidneys. In patients with serious kidney disease 4-AP may increase the risk of side effects. Your doctor will be especially careful if 4-Aminopyridine is given at the same time as any medicine which may affect how your kidneys eliminate medicines for example carvedilol, propranolol, and metformin.
- Do not take 4-AP if the packaging is torn or shows signs of tampering.
- Do not take 4-AP if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Check with your doctor if you:





- you are allergic to any other medicines, foods, dyes, or preservatives take any medicines for any other condition
- you have or have had any other health problems or medical conditions, including:
 - Problems with your kidneys
 - History of a seizure (also referred to as a fit or convulsion)
 - Sudden, repeated attacks of facial nerve pain known as trigeminal neuralgia

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 <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the benefits and risks of using

4-AP when pregnant or breastfeeding.

[Relevant condition-specific or medicinespecific subheading(s)]

 This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

3. What if I am taking other medicines?

Some medicines may interfere with 4-AP and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect 4-AP.

4. How do I use 4-AP?

How much to take / use

• Follow the instructions provided and use 4-AP until your doctor tells you to stop.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Your doctor will assess whether 4-AP is working for you with a walk test after an initial 8 weeks of treatment. If a response isn't seen, your doctor will stop treatment.

 Follow the instructions provided and use 4-AP until your doctor tells you to stop.

When to take / use 4-AP

 Follow all directions given to you by your doctor, pharmacist, or MS education nurse carefully. They may differ from the information contained in this leaflet.

How to take 4-AP

- Take 4-AP exactly as your doctor has prescribed.
- Swallow each tablet whole, with a drink of water.
- Do not divide, crush, dissolve, suck or chew the tablet, as this may increase your risk of side-effects.

If you forget to use 4-AP

4-AP should be used regularly at the same time each

day. If you miss your dose at the usual time, do not take a

double dose to make up for the dose you missed.

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 use too much 4-AP

If you think that you have used too much 4-AP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

If you take too much 4-AP, you may:

- Feel dizzy
- Become confused
- · Feel agitated with trembling or shaking
- Notice increased sweating
- Have a seizure, fit or convulsion
- Temporarily lose your memory

5. What should I know while using 4-AP?

Things you should do

Keep all your doctor's appointments so your progress

can be checked.

Your doctor may do some tests from time to time to prevent

unwanted side effects.

Call your doctor straight away if you:

- are about to be started on any new medicines, remind your doctor or pharmacist that you are taking 4-AP.
- are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during the surgery.

- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests. Remind any doctor, dentist or pharmacist you visit that you are using 4-AP.

Things you should not do

- Do not take 4-AP to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take more than the recommended dose.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- If you stop taking it suddenly, your condition may worsen, or you may have unwanted sideeffects...

Driving or using machines

Be careful before you drive or use any machines or tools until you know how 4-AP affects you.

This medicine may cause dizziness or a feeling of unsteadiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything

else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in their container until it is time to take them. If you take the tablets out of their container they may not keep well.
- Keep 4-AP in a cool, dry place where it stays below 25°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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

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?

4-AP helps most people with MS, but it may have unwanted side effects in some people.

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
Digestion system-related: Feeling sick (nausea) Being sick (vomiting) Constipation Upset stomach Nervous system-related: Dizziness Feeling unsteady Anxiety Numbness or tingling of the skin Tremor (minor shaking) Nerve pain in the face occurring for the first time Worsening of facial nerve pain in	Speak to your doctor if you have any of these less serious side effects and they worry you.

people with trigeminal neuralgia

• Spinning sensation (vertigo)

Urinary tract-related:

• Urinary tract infection

Nonspecific side effects:

- Headache
- Feeling weak
- Difficulty sleeping
- Sore throat
- Back pain

Serious side effects

Serious side effects	What to do
Nervous system-related:	Call your
Seizure (also known as a fit	doctor
or convulsion)	straight away,
This is a serious side effect.	or go straight
You may need urgent	to the
medical attention.	Emergency
	Department
Allergic reaction-related:	at your
Difficulty breathing	nearest
(shortness of breath)	hospital if you
Swelling of the face,	notice any of
mouth, lips, throat, or	these serious
tongue	side effects.
Reddening or itching of the	side effects.
skin	Serious side
	effects are
These are very serious side effects.	
	rare.
You may need urgent	
medical	
attention or hospitalisation.	

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 to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 4-AP contains

Active ingredient	4-aminopyridine
(main ingredient)	
Other ingredients	inulin
(inactive ingredients)	
Potential allergens	None

4-AP does not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes.

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

Who distributes 4-AP

The Compounding Lab

1/45 Crosby Rd, Albion, Brisbane QLD 4010

CALL: 07 3862 6000 / 1300 282 311

FAX: 07 3256 0801

EMAIL: enquiries@compoundinglab.com.au

ORDER ONLINE: www.compoundinglab.com.au

ORDER APP: thecompoundinglab

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