

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AVONEX Solution for Injection (also known as 'Pre-Filled Syringe'). It does not contain all the available information. It does not take the place of talking to your specialist, doctor or pharmacist.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.biogen.com.au. The updated leaflet may contain important information about AVONEX and its use that you should be aware of.

All medicines have benefits and risks. Your doctor has weighed the benefits AVONEX is expected to have for you, against the risks of using it.

If you have any questions about using this medicine, ask your doctor or pharmacist or contact the Multiple Sclerosis (MS) Society in your State.

Keep this leaflet, you may need to read it again.

What AVONEX is used for

AVONEX is used for the treatment of relapsing forms of Multiple Sclerosis (MS). AVONEX treatment has been shown to:

- Slow the progression of disability
- Reduce the number of relapses
- Delay the onset of definite MS after an illness suggesting MS

The cause of MS is not yet known. MS affects the brain and spinal cord. In MS, the body's immune system reacts against its own myelin (the 'insulation' surrounding nerve fibres). In relapsing forms of MS, people have 'exacerbations' from time to time (e.g. blurred vision, weakness in the legs or arms, or loss of control of bowel or bladder function). They are followed by periods of recovery. Recovery may be complete or incomplete. If it is incomplete there is 'progression of disability'.

AVONEX belongs to a group of medicines called interferons. Interferons exist naturally in the body to help fight viral infections and regulate the body's immunity.

Although the exact mechanism of interferons in MS is unknown, it is thought that AVONEX works by decreasing the unwanted immune reaction against myelin.

There is no information on the use of this medicine in those below 12 years of age.

Ask your doctor if you have any questions about why AVONEX has been prescribed for you.

Your doctor may have prescribed AVONEX for another reason.

AVONEX is available only with a doctor's prescription.

Use only for the person for whom it has been prescribed.

Before you use AVONEX

When you must not use it

Do not use AVONEX if you have an allergy to:

- AVONEX or any other interferon beta
- Any of the other ingredients listed at the end of this leaflet

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.

Do not use AVONEX if you have severe depression, and particularly if you are having suicidal thoughts.

Depression is common in people with MS and in those using medicines like AVONEX.

Tell your doctor if you are feeling depressed, or having suicidal thoughts.

Your doctor can help you decide whether you should use AVONEX or not.

Do not use AVONEX if you are pregnant or trying to become pregnant.

It may affect the development of your baby if you use it during pregnancy.

If you wish to become pregnant and are having treatment with AVONEX, please discuss this with your doctor.

Do not use AVONEX after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. Do not use

AVONEX if the medicine is cloudy, contains particles or is discoloured.

It should be colourless or slightly yellow.

If it has expired or is damaged or looks differently than it should, return it to your pharmacist for disposal.

If you are not sure whether you should use this medicine, talk to your doctor or pharmacist.

Before you use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had:

- Depression or problems with your moods, or if you have ever considered committing suicide
- A seizure, fit or convulsion
- Liver or kidney problems
- Heart problems
- Bleeding problems, bruising easily, frequent infections (these could be signs of lower than normal blood counts in your bone marrow)

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor can help you decide if you will use AVONEX or breastfeed. You should not do both.

If you have not told your doctor about any of the above, tell them before you start using AVONEX.

Taking other medicines

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

In particular, tell your doctor if you are taking any medicine:

- Used to treat epilepsy (prevent fits)
- Used to treat depression

- That affects the bone marrow, such as medicines to treat cancer.

Ask your doctor, nurse or pharmacist if you have any questions about medicines to be careful with or avoid while using AVONEX.

How to use AVONEX

Follow all directions given to you by your doctor, MS education nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to use

The usual full dose of AVONEX is 30 micrograms once a week, given as a 0.5 mL injection.

Starting AVONEX

If you are new to AVONEX, your doctor or MS nurse may advise you to gradually increase your dose to minimise potential side effects of AVONEX, such as flu-like symptoms, before taking the full dose.

How to use it

Starting AVONEX

AVONEX is given by injection into muscle, usually in the thigh or upper arm. The buttock is not a suitable site for injection. Your doctor will recommend an injection site suitable for you.

How to inject

Many people with MS learn to give themselves the injection or have it given by a carer.

Self-injection needs to be taught and practised. It is important that a qualified health care professional supervises your first injection.

Your doctor may teach you to self-inject or arrange for an MS education nurse to do so.

Talk to your doctor or the MS Society for more information.

After being taught to self-inject, you should refer to the leaflet in the pack for step-by-step instructions about how to prepare and inject AVONEX.

AVONEX Solution for Injection is pre-mixed ready for you to use and should be stored in a refrigerator. It is recommended that you remove it from the refrigerator about half-an-hour before you want to use it. This allows the temperature of the medicine to approach room temperature.

Do not use heat sources (heater or hot water) to warm it.

Heating can damage this medicine.

Always inspect AVONEX Solution before use.

The medicine should be clear and colourless or slightly yellow.

Do not inject if the solution is discoloured or cloudy or contains particles.

Talk to your specialist, doctor or pharmacist or contact the MS Society, if you have any questions about how to use AVONEX.

How long to use it

The positive effects of AVONEX are not seen immediately. They occur with long-term treatment. It is important to continue treatment with AVONEX unless your doctor tells you to stop.

If you forget to use it

If it is less than 2 days before your next injection, skip the dose you missed and have your next injection when you are meant to.

Otherwise, have it as soon as you remember and then resume your regular weekly dosing schedule.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist or contact the MS Society in your State.

If you have trouble remembering your injections, ask your pharmacist or MS education nurse for some hints.

It is important not to miss injections as this can affect the success of your treatment.

If you use too much (overdose)

Immediately telephone the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), if you think you or anyone else may have used too much AVONEX.

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

While you are using AVONEX

Things you must do:

If you become pregnant while on treatment with AVONEX, immediately tell your doctor.

You and your doctor will decide what is best for you and your baby. It is likely that your doctor will recommend you stop using AVONEX during your pregnancy.

If you are a female of childbearing age and are sexually active, you should use birth control during treatment with AVONEX.

Always talk to your doctor or pharmacist before taking any other medicine while you are using AVONEX.

If he or she recommends that you take a medication to reduce symptoms of pain and inflammation, follow their advice carefully. Do not take more than the recommended dose.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you are about to have any blood tests, tell your doctor that you are using AVONEX.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do blood tests before you start treatment and from time to time to monitor your progress and prevent unwanted side effects.

Things you must not do

Do not give AVONEX to anyone else, even if they appear to have the same condition as you.

Do not stop using AVONEX or change the dosage, without checking with your doctor.

Things to be careful of

Be careful drinking alcohol while you are on treatment with AVONEX.

Rarely, people treated with interferons including AVONEX, have experienced serious liver problems. It is not known whether this risk is increased by alcohol but it is possible.

Talk to your doctor or pharmacist about this if you want more information.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using AVONEX.

AVONEX helps most people with MS but it may have unwanted effects in a few people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor, MS nurse or pharmacist to answer any questions you may have.

The most common side effect is to feel 'flu-like' symptoms, e.g. mainly tiredness, muscle aches, shivering and fever. Your doctor or MS nurse may advise you to gradually increase your dose of AVONEX during the first 3 weeks of treatment to help reduce these symptoms. These side effects generally occur less often as therapy continues.

To help further reduce these symptoms, your doctor may advise you to take a medication (e.g., paracetamol, ibuprofen) to reduce fever, pain and inflammation before your injection and for up to one day afterwards.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Headache
- Nausea, vomiting or diarrhoea
- Abdominal (stomach) pain
- Chest pain
- Migraine
- Joint or muscle pain, stiffness or spasms
- Dizziness, feeling faint
- Sleeplessness
- Soreness, redness or bruising at the injection site
- Loss of appetite
- Runny nose, coughing
- Increased sweating (sometimes at night) or flushing
- Rash
- Strong and frequent urge to urinate, with pain or burning sensation when urinating
- Reduced sensitivity to touch

The above list includes the more common side effects of AVONEX. These effects might also be related to your general health or the MS process, or to a combination of these.

Tell your doctor as soon as possible if you notice any of the following:

- Unusual confusion, anxiety, worsening of depression, severe mood swings or thoughts of suicide

- Seizures, fits, convulsions or fainting
- Yellowing of the skin and eyes (also called jaundice)
- Breathlessness, persistent coughing, swelling in hands, feet or lower arms and legs, or palpitations
- Unusual bleeding or bruising
- Hives or itchy skin
- Difficulty breathing
- Increased tiredness

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
These could be symptoms of an allergic reaction.
- Discharge from the injection site or pain, redness or swelling that does not go away, tissue destruction (necrosis)

Call your doctor straight away if you experience signs of pulmonary arterial hypertension such as difficulty breathing or increased tiredness. Pulmonary arterial hypertension is a disease of severe narrowing of the blood vessels in the lungs resulting in high blood pressure in the blood vessels that carry blood from the heart to the lungs. Pulmonary arterial hypertension has been seen at various time points during treatment, including several years after starting treatment with Avonex.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

Some side effects can only be found when your doctor does tests from time to time to check your progress. They include changes in thyroid function, liver function or blood counts.

After using AVONEX

Storage

Keep your AVONEX in the sealed tray until it is time to use it.

The medicine will not keep as well if taken out of the sealed tray.

Keep AVONEX in the refrigerator at 2°C to 8°C.

If necessary, you can keep AVONEX out of the refrigerator for up to 7 days. If out of the refrigerator, store the sealed tray in a cool dry place where the temperature stays below 30°C.

Do not use any AVONEX that has been out of the refrigerator for more than 7 days (refer to Disposal below).

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

AVONEX MUST NOT BE FROZEN.

Do not place in the freezer or freezing compartment of a refrigerator.

Keep AVONEX where children cannot reach it.

Disposal

Please read the package insert carefully for full details, including safe disposal of needles and syringes after use.

If your doctor tells you to stop using AVONEX or the expiry date has passed, ask your pharmacist what to

do with any medicine that is left over.

Product description

Each pack of AVONEX contains 4 sealed blister trays. Use 1 blister tray for each weekly treatment. A pack of AVONEX provides treatment for 4 weeks.

Your pack of AVONEX already includes a needle for injection. It may be possible for your doctor to prescribe you a shorter and thinner needle depending on your body type. Talk to your doctor if you are interested in whether this is appropriate for you.

AVONEX Solution does not contain any preservative.

Use on one occasion only.

Do not reuse needles or syringes.

What it looks like

Each blister tray contains:

- 1 pre-filled syringe of sterile AVONEX Solution
- 1 needle

Ingredients

Each pre-filled syringe of AVONEX Solution contains 30 micrograms of interferon beta-1a in 0.5 mL of ready-to-use solution. It also contains:

- Sodium acetate
- Glacial acetic acid
- Arginine hydrochloride
- Polysorbate 20
- Water for injections

Further information

You can obtain more information from your doctor, pharmacist or the MS Society in your State.

Supplier

**AVONEX is supplied in Australia
by:**

Biogen Australia Pty Ltd

ABN 30 095 760 115

Level 4

2 Banfield Road

Macquarie Park

NSW 2113

AVONEX is supplied in NZ by:

Biogen NZ Biopharma Limited

Auckland

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