

AVONEX®

Interferon beta-1a

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') and AVONEX Powder for Injection (also known as 'BIO-SET®'). It does not contain all the available information. It does not take the place of talking to your specialist, doctor or pharmacist.

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.

You can also telephone the MS ALLIANCE Helpline on 1800 852 289 in Australia or 0800 852 289 in NZ for additional assistance on using AVONEX.

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

What AVONEX is used for

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

- Slow the usual progression of disability
- Reduce the risk of relapse
- 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
- Any of the other ingredients listed at the end of this leaflet

Do not use AVONEX Powder for Injection (BIO-SET) if you have an allergy to human albumin.

AVONEX Solution for Injection (Pre-Filled Syringe) does not contain human albumin.

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. You should always talk to 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
- A problem with your heart
- Bone marrow suppression

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

It is recommended that you not use AVONEX if planning to breastfeed. Your doctor can discuss with you the possible risks involved.

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

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 dose of AVONEX is 30 micrograms once a week.

AVONEX Solution is given as a 0.5 mL injection.

AVONEX Powder is given as a 1mL injection.

Starting AVONEX

Your doctor or MS nurse may provide you with an AVOSTARTCLIP titration kit to help gradually increase your dose of AVONEX during the first 3 weeks of treatment. This is to help limit flu-like symptoms. The AVOSTARTCLIP is designed for use with AVONEX solution for injection and attaches to the syringe to enable this gradual dose increase.

How to use it

Starting AVONEX

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

You will be provided with an AVOSTARTCLIP titration kit containing 3 different coloured clips (labelled week 1, 2 and 3). Each clip can be attached onto the AVONEX Pre-filled Syringe and enables either a quarter, a half or a three-quarter dose of AVONEX to be injected

during your first 3 weeks of treatment.

Each AVOSTARTCLIP should be used once and then discarded along with any remaining AVONEX.

For further details on use, please follow the instructions provided with the AVOSTARTCLIP titration kit.

If you are commencing therapy on Powder for injection, you should speak to your doctor or MS nurse as to how to gradually increase your dose.

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. 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 or telephone the MS ALLIANCE Helpline (1800 852 289 in Australia or 0800 852 289 in NZ) 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. Patient support kits are available by telephoning the MS Alliance on 1800 852 289 in Australia or 0800 852 289 in NZ.

AVONEX Solution for Injection is pre-mixed ready for you to use. 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.

AVONEX Powder for Injection must be mixed with Water for Injections before use.

It is important to not shake AVONEX when mixing it.

Shaking can damage this medicine. Mix the AVONEX Powder with the sterile Water only when you are ready to use it. If you mix the Powder and are interrupted, you can keep the mixed product for a maximum of 6 hours but only if it is stored in the refrigerator at 2°C to 8°C.

Do not put it in the freezer.

Always inspect AVONEX Solution before use and AVONEX Powder after it has been mixed.

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, contact the MS Society, or telephone the MS Alliance on 1800 852 289 in Australia or 0800 852 289 in NZ, 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, contact the MS Society in your State, or

telephone the MS ALLIANCE Helpline (1800 852 289 in Australia or 0800 852 289 in NZ).

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.

It may interfere with the results of some tests.

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 about this with your doctor or pharmacist 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. headache, tiredness, muscle aches, joint pain, 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 to reduce 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:

- Fatigue
- Nausea, vomiting or diarrhoea
- Pain or migraine
- Muscle stiffness or spasms
- Dizziness
- Sleeplessness
- Soreness, redness or bruising at the injection site
- Loss of appetite
- Runny nose
- Increased sweating or flushing
- Menstrual upsets
- Rash
- Hair loss
- Reduced sensitivity to touch

The above list includes the more common side effects of AVONEX, or these effects might 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

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
- Discharge from the injection site or pain, redness or swelling that does not go away

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 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. These 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 Solution in the refrigerator at 2°C to 8°C.

If necessary, you can keep AVONEX Solution 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 Solution that has been out of the refrigerator for more than 7 days (refer to Disposal below).

Keep AVONEX Powder in a cool dry place where the temperature stays below 25°C.

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 and Powder do not contain preservatives.

Use on one occasion only.

Do not reuse vials, needles or syringes.

Solution for Injection

Australian Register Number:

AUST R 95419

What it looks like

Each Solution for Injection 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

Powder for Injection

Australian Register Number:

AUST R 79752

What it looks like

Each Powder for Injection blister tray contains:

- 1 vial of sterile AVONEX Powder with attached BIO-SET device
- 1 pre-filled syringe of sterile Water for Injections
- 1 needle

Ingredients

Each vial of AVONEX contains 30 micrograms of interferon beta-1a as a sterile, white to off-white powder. It also contains:

- Human albumin
- Sodium chloride

- Sodium phosphate (monobasic and dibasic)

A syringe of sterile Water for Injections is provided with AVONEX Powder to dissolve the medicine ready for injection.

Further information

You can obtain more information from your doctor, pharmacist or the MS Society in your State, or by telephoning the MS Alliance on 1800 852 289 in Australia or 0800 852 289 in NZ.

Supplier

AVONEX is supplied in Australia by:

Biogen Australia Pty Ltd

ABN 30 095 760 115

Level 3

123 Epping Road

North Ryde NSW 2113

Australia

AVONEX is supplied in NZ by:

Biogen NZ Biopharma Limited

C/- ProPharma

54 Carbine Road

Mt Wellington

Auckland

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