PATIENT INFORMATION LEAFET

SCHEDULING STATUS: S4

AVONEX 30 micrograms/0,5 ml solution for injection

Interferon beta-1a

Pre-filled syringe

Sugar free

Read all of this leaflet carefully before you start using AVONEX.

Even if you have used AVONEX before, some of the information may have changed.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Avonex has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

(Notes information)

This leaflet is changed from time to time.

Please check every time you get your prescription refilled to see if the leaflet has been updated.

What is in this leaflet

1. What AVONEX is and what it is used for
2. What you need to know before you use AVONEX
3. How to use AVONEX
4. Possible side effects
1. How to store AVONEX
5. Contents of the pack and other information
6. How to inject AVONEX

1. What AVONEX is and what it is What AVONEX is

The active substance in Avonex is a protein called *interferon beta-1a*. Interferons are natural substances made in your body to help protect you from infections and diseases. The protein in Avonex is made up of exactly the same ingredients as interferon beta that is found in the human body.

What AVONEX is used for

Avonex is used to treat Multiple Sclerosis (MS). Treatment with Avonex can help to prevent you from

getting worse, although it will not cure MS.

Everyone has their own set of MS symptoms. These can include:

- Feeling off-balance or light headed, walking problems, stiffness and muscle spasms, tiredness, numbness
- in the face, arms or legs
- Acute or chronic pain, bladder and bowel problems, sexual problems and problems seeing things
- Difficulty in thinking and concentrating, depression.

MS also tends to flare up from time to time: this is called a relapse.

(Notes information)

Avonex works best when you use it at the same time, once a week, on a regular basis.

Do not stop your Avonex treatment without speaking to your neurologist.

Avonex can help to reduce the number of relapses that you have and slow down the disabling effects of MS. Your doctor will advise you for how long you can use Avonex or when to stop.

How AVONEX works

Multiple sclerosis is linked to nerve (brain or spinal cord) damage. In MS, your body's defence system reacts against its own myelin – the 'insulation' that surrounds nerve fibres.

When myelin is damaged, the messages between the brain and other parts of the body are disrupted. This is what causes the symptoms of MS. Avonex seems to work by stopping your body's defence system from attacking the myelin.

2. What you need to know before you use AVONEX

Do not use AVONEX

- **If you are allergic** to interferon beta, or any of the other ingredients of Avonex (listed in section 6).
- **If you have severe depression** or think about committing suicide.

Talk to a doctor straightaway if any of these apply to you.

(Notes information)

Avonex and allergic reactions. Because Avonex is based on a protein, there is a small chance of an allergic reaction.

More about depression. If you have severe depression or thoughts about suicide, you must not use Avonex.

If you have depression, your doctor may still prescribe Avonex for you, but it's important to let your doctor know if you have had depression or any similar problems affecting your moods.

Warnings and precautions

Talk to your doctor before using Avonex if you have or have had in the past:

- **Depression** or problems affecting your moods
- **Thoughts about committing suicide**.

Changes to your mood, thoughts about suicide, feeling unusually sad, anxious or worthless, should be reported to your doctor immediately.

- **Epilepsy** or other seizure disorders not controlled by medication
- **Serious kidney or liver problems**
- **A low number of white blood cells or platelets**, which can cause an increased risk of infection, bleeding or anaemia

- **Heart problems,** which can cause symptoms such as chest pain (*angina*), particularly after any activity; swollen ankles, shortness of breath (*congestive heart failure*); or an irregular heartbeat (*dysrhythmias*).

Talk to your doctor if you have any of these conditions, or if they worsen whilst taking Avonex.

Blood clots in the small blood vessels may occur during your treatment. These blood clots could affect your kidneys. This might happen several weeks to several years after starting Avonex.

Your doctor may want to check your blood pressure, blood (platelet count) and the function of your kidneys.

Tell your doctor you are using Avonex:

If you are having a blood test. Avonex may interfere with the results.

(Notes information)

Sometimes you will need to remind other medical staff that you are being treated with Avonex.

For example, if you are prescribed other medicines, or if you have a blood test, Avonex may affect the other medicines or the test result.

Other medicines and AVONEX

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines and medicines obtained without a prescription).

Tell your doctor if you are using, have recently used or might use any other medicines, especially those used to treat epilepsy or depression. Avonex may affect other medicines or be affected by them.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using Avonex.

If you are breastfeeding, you should consult with your Healthcare Professional to decide either to discontinue breastfeeding or abstain from treatment, as there are limited studies regarding breastfeeding.

Driving and using machines

If you feel dizzy, do not drive. Avonex makes some people feel dizzy. If this happens to you, or if you get any other side effects that could affect your ability, do not drive or use machines.

Important information about some of the ingredients of AVONEX

This medicine is essentially 'sodium-free'. It contains less than 23 mg (1 mmol) sodium in each weekly dose.

3. How to use AVONEX

Do not share medicines prescribed for you with any other person. Always use Avonex exactly as your doctor

has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose

One injection of Avonex, once a week.

Try to use Avonex at the same time on the same day each week.

Not for children

Avonex is not to be used in children below the age of 10 years.

Injecting yourself:

You can inject Avonex yourself without the help of your doctor, if they have trained you to do this. The instructions on how to inject yourself are at the end of this leaflet (see section 7*, How to inject AVONEX*).

If you have trouble handling the syringe, ask your doctor who may be able to help.

(Notes information)

There are more details on how to inject Avonex at the end of this leaflet.

If you have problems handling the syringe, talk to your doctor about using a syringe grip. This is a specially designed holder to help you with injecting Avonex.

How long to use Avonex

Your doctor will tell you how long you need to keep using Avonex. It is important to continue using Avonex regularly. Do not make changes unless your doctor tells you.

If you inject more AVONEX than you should

You should only have one injection of Avonex, once a week. If you have used more than one injection of Avonex in a three-day period, **contact your doctor or pharmacist straight away for advice.** If neither is available, contact the nearest hospital or poison control centre.

If you miss an injection of AVONEX

If you miss your usual weekly dose, inject a dose as soon as you can. Then leave a week before using Avonex again. Continue injecting on this new day every week. If you have a preferred day for using Avonex, talk to your doctor about managing the dose, to get back to your preferred day. Do not use two injections to make up for a missed injection.

4. Possible side effects

Avonex can have side effects. Not all side effects reported for Avonex are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Avonex, please consult your healthcare provider for advice.

(Notes information)

Although the list of possible side effects can seem worrying, it’s possible that you may not have any of them.

Serious side effects: get medical help

Serious allergic reactions

If you get any of these:

- Swelling of the face, lips or tongue
- Difficulty breathing
- A rash.

Call a doctor immediately. Do not use any more Avonex until you have spoken to a doctor.

Depression

If you get any symptoms of depression:

- Feeling unusually sad, anxious or worthless.

Call a doctor immediately.

Liver problems

If you get any of these symptoms:

- Yellowing of your skin or the whites of your eyes *(jaundice)*
- Itching all over
- Feeling sick, being sick *(nausea and vomiting)*
- Easy bruising of the skin.

Call a doctor immediately as they may be signs of a possible liver problem.

Side effects seen in clinical trials

(Notes information)

Side effects seen in clinical trials. These are the side effects that people reported when Avonex was being tested. The figures are based on how many people said they'd had them. It gives you an idea how likely you are to get similar side effects.

Frequent side effects

Flu-like symptoms – headache, muscle aches, chills or a fever: see *Flu-like symptoms*, below

- Headache
- Loss of appetite
- Feeling weak and tired
- Difficulty sleeping
- Depression
- Flushing
- Runny nose

- Diarrhoea *(loose stools)*
- Feeling or being sick *(nausea or vomiting)*
- Numbness or tingling of skin
- Rash, bruising of the skin
- Increased sweating, night sweats
- Pain in your muscles, joints, arms, legs or neck
- Muscle cramps, stiffness in the joints and muscles
- Pain, bruising and redness at the injection site
- Changes to blood tests. Symptoms you might notice are tiredness, repeated infection, unexplained bruising or bleeding.

Less frequent side effects

- Hair loss
- Changes to your monthly period
- Burning feeling at the site of injection
- Difficulty breathing
- Kidney problems including scarring that may reduce your kidney function

If you get some or all of these symptoms:

- Foamy urine
- Fatigue
- Swelling, particularly in the ankles and eyelids, and weight gain.

Tell your doctor as they may be signs of a possible kidney problem.

- Blood clots in the small blood vessels that can affect your kidneys (thrombotic thrombocytopenic purpura or haemolytic uremic syndrome). Symptoms may include increased bruising, bleeding, fever, extreme weakness, headache, dizziness or light-headedness. Your doctor may find changes in your blood and the function of your kidneys.

If any of the effects trouble you, talk to your doctor.

Other side effects

(Notes information)

These effects have been seen in people using Avonex, but we do not know how likely they are to happen.

- An underactive or overactive thyroid
- Nervousness or anxiety, emotional instability, irrational thoughts or hallucinations (seeing or hearing things that are not real), confusion or suicide
- Numbness, dizziness, seizures or fits and migraines
- An awareness of your heartbeat (*palpitations*), a rapid or irregular heartbeat, or heart problems which would have the following symptoms: a reduced ability to exercise, inability to lie flat in bed, shortness of breath or swollen ankles
- Liver problems as described above
- Nettle rash or blister-like rash, itching, worsening of psoriasis if you have it
- Swelling or bleeding at the site of injection, tissue destruction (necrosis) or chest pain after an injection
- Gaining or losing weight
- Changes to test results, including changes to liver function tests
- Pulmonary arterial hypertension – 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.

If any of the effects trouble you, talk to your doctor.

Effects of the injection

- **Feeling faint:** Your first injection of Avonex may be given by your doctor. It may make you feel faint.

You may even actually faint. This is unlikely to happen again.

- **Just after an injection, your muscles may feel tense or very weak** – as though you are having a relapse. This is rare. It only happens when you inject and the effects soon pass. They may happen any time after starting on Avonex.
- **If you notice any irritation or skin problems** after an injection, talk to your doctor.

Flu-like symptoms

(Notes information)

Three simple ways to help reduce the impact of flu-like symptoms:

1. **Use your Avonex injection just before bedtime**. This may allow you to sleep through the effects.

2. **Take paracetamol or ibuprofen half an hour** before your Avonex injection and continue taking it for up to a day. Speak to your doctor or pharmacist about a suitable dose.

3. **If you have a fever, drink plenty of water** to keep you hydrated.

Some people find that after injecting Avonex, they feel like they have flu. Signs are:

- Headache
- Muscle aches
- Chills or a fever.

These symptoms are not really flu.

You can't pass it on to anyone else. They are more frequent when you first start using Avonex. As you keep using your injections, the flu-like symptoms gradually decrease.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online

under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more information on the safety of Avonex.

5. How to store AVONEX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label.

Store in a refrigerator (between 2 ºC and 8 °C).

Do not freeze.

Store in the original package (sealed plastic tray) in order to protect from light.

Avonex can also be stored at room temperature (between 15 °C and 30 °C) for up to one week.

Do NOT use Avonex if you notice:

- The pre-filled syringe is broken.
- The sealed plastic tray is damaged or opened.
- The solution is coloured or you can see particles floating in it.
- The tamper evident cap has been broken.

Return all unused medicines to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What AVONEX contains

The active substance is: Interferon beta-1a 30 micrograms/0,5 ml

The other ingredients are: Sodium acetate, trihydrate; acetic acid glacial, arginine hydrochloride, polysorbate 20 and water for injections.

What AVONEX looks like and contents of the pack

Avonex Solution for Injection is a clear colourless solution and comes as a ready to use injection.

In a box of Avonex there are four ready to use (pre-filled) syringes, each with 0,5 ml of a clear, colourless liquid inside. Each syringe is packed in a sealed plastic tray. A separate needle to give the injection is also included in the tray.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd.

106 16th Road, Midrand, 1686

This leaflet was last revised in

09 July 2025

Registration number

A40/34/0502

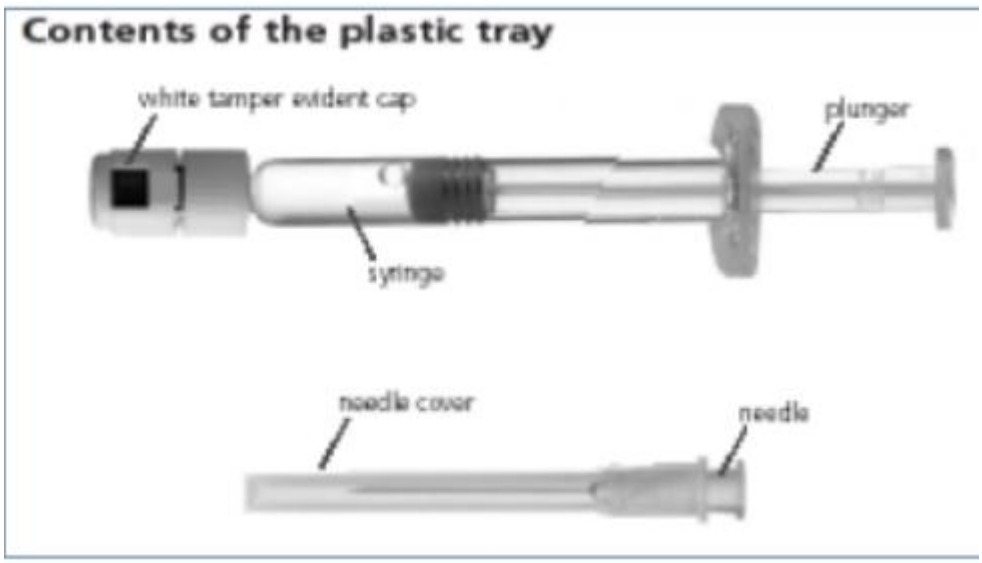
How to inject AVONEX

You should have had training in how to inject Avonex

These notes are a reminder. If there's anything you're not sure about, check with your doctor or pharmacist.

Where to inject

- **Avonex is injected into a muscle,** for example, the upper thigh muscle. Injection of Avonex into the buttocks is not recommended.
- **Use a different injection site each week**. This means less risk of irritation to your skin and muscle.
- **Do not use** any area of skin that is bruised, sore, or infected, or if there is an open wound.



A. Getting Ready

1. **Remove one sealed plastic tray from the refrigerator**
   - Check the expiry date on the lid of the tray. Do not use it if it is out-of-date.
   - Peel back the paper lid completely. Check the blister tray contains one pre-filled syringe and one injection needle (see picture "Contents of the plastic tray").
2. **Leave the syringe to warm up**
   - Leave it at room temperature for half an hour. This makes the injection more comfortable than injecting straight from a refrigerator.

Tip: Do not use external heat sources such as hot water to warm the syringe.

3. **Wash your hands thoroughly** with soap and water and dry them.

4. **Prepare alcohol wipes and sticking plasters** (not supplied) if you need them.

Find a clean, hard surface to lay out the items needed for your injection. Lay the tray down on it.

B. Preparing the injection

1. 

Check the liquid in the syringe

It should be clear and colourless. If the solution is cloudy, coloured or contains any floating particles, do not use the pre-filled syringe.

2. 

Remove the syringe cap

The syringe has a white tamper-evident cap.

Make sure the cap is intact and has not been opened.

If it looks like it has been opened, do not use that syringe.

Hold the syringe so that the white cap is facing up.

Bend the cap at a right angle until it snaps off.

Do not touch the connection port.

Do not push on the plunger.

3. 

Fit the needle

Open needle to expose the connection port. Keep the cover on.

Press the needle onto the syringe.

Turn it clockwise until it locks into place.



Tip: Make sure the injection needle is firmly attached to the syringe.

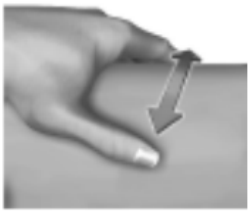
Otherwise it may leak.

Now pull off the plastic needle cover. Do not twist it.

Tip: If you twist the needle cover to remove it, you may accidentally remove the needle as well.

C. Giving the injection

1. **Clean and stretch the injection site**



If you need to, use an alcohol wipe to clean the skin at the injection site you've chosen. Allow the skin to dry.

With one hand, stretch the skin around the injection site.

Relax your muscle.

2. **Make the injection**



Insert the injection needle with a quick dart-like thrust at right angles to the skin, into the muscle.

The needle must go all the way in.

Press the plunger slowly until the syringe is empty.

3. **Pull the needle out**



Keep the skin stretched tightly or squeeze the skin around the injection site, and pull out the needle.

If you use alcohol wipes, hold one on the injection site.

Put a plaster over the site of injection if you need to.

Dispose of the rubbish properly



After you have finished each injection, put the needle and syringe into a special container (such as a sharps bin), not in ordinary rubbish.

Waste paper and used wipes can be put in an ordinary rubbish bin.