

PLEGRIDY®

(PLEGG-rih-dee)

peginterferon beta-1a (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Plegridy.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your pharmacist 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/products/plegridy-CMI.pdf

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Plegridy is used for

Plegridy is a prescription medicine used to treat people with relapsing forms of Multiple Sclerosis (MS). It is not known if Plegridy is safe and effective in people under 18 or over 65 years of age.

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'.

Plegridy belongs to a group of medicines called interferons. The active substance in Plegridy is peginterferon beta-1a. Peginterferon beta-1a is a long-acting form of interferon. Interferons exist naturally in the body to help fight viral infections and regulate the body's immunity.

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

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

Your doctor may have prescribed it for another reason.

Plegridy is available only with a doctor's prescription.

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

Before you use Plegridy

When you must not use it

Do not use Plegridy if you have an allergy to:

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

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

Do not use Plegridy:

- If you have severe depression or think about committing suicide
- If you are already pregnant

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

Do not use Plegridy if the medicine is coloured, cloudy, or contains floating particles.

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 problems

- Bleeding problems, bruising easily, frequent infections
- Heart problems
- Thyroid problems
- Bone marrow suppression.

Do not start using Plegridy if you are already pregnant.

If you could get pregnant, you need to use contraception while you use Plegridy.

Tell your doctor:

- If you are pregnant or plan to become pregnant
- If you want to breastfeed

Your doctor can discuss with you the risks and benefits involved.

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

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.

Plegridy may interact with some other medicines that are broken down by the liver:

- medicines to treat epilepsy
- medicines to treat depression

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

How to use Plegridy

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

They may differ from the information contained in this leaflet.

How much to use

Plegridy is only to be injected once every 14 days (two weeks).

Plegridy is injected under the skin (subcutaneously). Try to use Plegridy at the same time on the same day every time you inject.

How to use it

Starting Plegridy

If you are new to Plegridy your doctor or MS nurse may advise you to gradually increase your dose so that you can adjust to the effects of Plegridy before taking the full dose. You will be provided with a Titration Pack containing your first two injections. For further details on use, please follow the instructions provided with the Titration Pack.

The recommended starting dose is a single injection of Plegridy 63 micrograms, followed by a single injection of Plegridy 94 micrograms two weeks later.

Use the record table printed on the inside lid of the Titration Pack to keep a track of your injection dates.

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 nurse to do so.

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 Plegridy.

Continuing to use Plegridy

You will be provided with an Administration Dose Pack containing your next injections.

The recommended third dose is a single injection of Plegridy 125 micrograms (full dose), two weeks after the second dose.

Full doses of Plegridy 125 micrograms are then recommended every 14 days (two weeks).

Keep referring to the leaflet for detailed instructions on how to use Plegridy.

How long to use it

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

If you forget to take it

Inject as soon as you remember and then resume your regular dosing schedule. However, never inject more than once in a 7-day period.

Do not take 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.

If you have trouble remembering to take your medicine, ask your pharmacist or MS nurse for some hints.

If you take too much (overdose)

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

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

While you are using Plegridy

Things you must do

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

If you are a female of childbearing age and are sexually active, you

should use birth control during treatment with Plegridy.

If you have new or worsening depression or suicidal thoughts, immediately tell your doctor:

This could include feeling hopeless or bad about yourself, thoughts of hurting yourself or suicide, irritability (getting upset easily), nervousness, or new or worsening anxiety.

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

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 Plegridy.

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 Plegridy to anyone else, even if they appear to have the same condition as you.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Plegridy.

Plegridy 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.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- Yellowing of your skin or the whites of your eyes (jaundice)
- Itching all over
- Feeling sick, being sick (nausea and vomiting), loss of appetite
- Tiredness, sleepiness, confusion
- Bleeding more easily than normal, easy bruising of the skin
- Dark coloured urine, and pale stools
- Depression, thoughts of hurting yourself or suicide, new mood changes
- Symptoms of an allergic reaction such as 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.

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

Tell your doctor, nurse or pharmacist as soon as possible if you experience any of the following:

- Seizure (fit)
- Severe swelling, weakness, shortness of breath, lethargy or confusion

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

Flu-like symptoms

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 Plegridy during the first month of treatment to help reduce these symptoms. These side effects generally occur less often as therapy continues.

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

1. Consider the timing of your Plegridy injection. The start and end of flu-like symptoms are different for every patient. On average, flu-like symptoms begin approximately 10 hours after injection and last for about 17 hours.
2. Take paracetamol or ibuprofen half an hour before your Plegridy injection. Speak to your doctor or pharmacist about how much to take and how long to take it.
3. If you have a fever, drink plenty of water to keep you hydrated.

Injection site reactions

You may get reactions around the place you inject. These usually get less over time. Reactions such as redness, itching or pain are very common. Swelling, bruising, warmth or rash at the injection site is common.

To reduce injection site reactions, read and follow the advice given in the "Instructions for Use" at the end of the pack insert.

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

- Headache
- Muscle pain
- Pain in your joints, arms, legs or neck (arthralgia)
- Fever, chills, feeling cold
- Feeling weak and tired (asthenia)
- Feeling or being sick (nausea or vomiting)
- Itchy skin (pruritus)

- Increase in body temperature

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

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 (such as decreased blood cell counts, or changed liver function) can only be found when your doctor does tests from time to time to check your progress.

After using Plegridy

Storage

Keep your Plegridy in its original pack until it is time to use it.

Keep Plegridy in the refrigerator at 2°C to 8°C. Do not freeze.

If necessary, you can keep Plegridy out of the refrigerator for up to 30 days as long as it is kept away from light. If out of the refrigerator, store the carton in a cool dry place where the temperature stays between 2°C to 25°C.

Do not use any Plegridy that has been out of the refrigerator for more than 30 days (refer to Disposal below).

Do not store Plegridy 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 Plegridy 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

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 Plegridy or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

The Plegridy pre-filled syringe Titration Pack holds 2 ready to use syringes. Each Titration Pack for Plegridy syringe contains a clear, colourless liquid (0.5 mL) containing either 63 or 94 micrograms of peginterferon beta-1a.

The Plegridy pre-filled syringe Administration Dose Pack holds 2 ready to use syringes. Each Administration Dose Pack syringe contains a clear, colourless liquid (0.5 mL) containing 125 micrograms of peginterferon beta-1a.

Every syringe has a pre-attached needle and is ready to inject.

The Plegridy pre-filled pen Titration Pack holds 2 ready to use pens. Each Titration Pack for Plegridy pen contains a clear, colourless liquid (0.5 mL) containing either 63 or 94 micrograms of peginterferon beta-1a.

The Plegridy pre-filled pen Administration Dose Pack holds 2 ready to use pens. Each Administration Dose Pack pen contains a clear, colourless liquid (0.5 mL) containing 125 micrograms of peginterferon beta-1a.

Every pen has a pre-attached needle and is ready to inject.

Ingredients

Plegridy is available in 3 strengths: 63 micrograms, 94 micrograms, and 125 micrograms.

Active Ingredient:

- peginterferon beta-1a (rch)

It also contains:

- Sodium acetate trihydrate
- Glacial acetic acid
- L-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, or by telephoning 1800 852 289 in Australia or 0800 852 289 in NZ.

Supplier

Plegridy is supplied in Australia by:

Biogen Australia Pty Ltd
 ABN 30 095 760 115
 Level 3
 123 Epping Road
 North Ryde NSW 2113
 Australia

It is supplied in New Zealand by:

Biogen NZ Biopharma Limited
 Auckland

Australian registration numbers

Plegridy 63 microgram/0.5 mL and 94 microgram/0.5 mL:

AUST R 214198 (pre-filled syringe)
 AUST R 214200 (pre-filled pen)

Plegridy 125 microgram/0.5 mL:

AUST R 214199 (pre-filled syringe)
 AUST R 214197 (pre-filled pen)

Date of preparation

This leaflet was prepared in July 2018.

PLEGRIDY® is a registered trademark of Biogen MA Inc.