

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PLEGRIDY?

PLEGRIDY contains the active ingredient peginterferon beta-1a (rch). PLEGRIDY is used to treat people with relapsing forms of Multiple Sclerosis (MS).

For more information, see Section [1. Why am I using PLEGRIDY?](#) in the full CMI.

2. What should I know before I use PLEGRIDY?

Do not use if you have ever had an allergic reaction to PLEGRIDY or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PLEGRIDY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PLEGRIDY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PLEGRIDY?

- PLEGRIDY dose is gradually increased. The recommended starting dose is a single injection of PLEGRIDY 63 micrograms, followed by a single injection of PLEGRIDY 94 micrograms two weeks later. Full dose is 125 micrograms.
- PLEGRIDY is injected under the skin (subcutaneously) every 14 days (two weeks).

More instructions can be found in Section [4. How do I use PLEGRIDY?](#) in the full CMI.

5. What should I know while using PLEGRIDY?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, MS nurse or pharmacist you visit that you are using PLEGRIDY.• Tell your doctor if you are pregnant or plan to become pregnant, or if you want to breastfeed.• If you are about to have any blood tests, tell your doctor that you are using PLEGRIDY, as it may interfere with the results of some tests.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine unless your doctor tells you to.• Do not use PLEGRIDY if you have severe depression or think about committing suicide.• Do not use PLEGRIDY if you are already pregnant.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how PLEGRIDY affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Alcohol may increase the risk of liver injury.
Looking after your medicine	<ul style="list-style-type: none">• Keep 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. PLEGRIDY can be kept out of the refrigerator between 2°C to 25°C for up to 30 days as long as it is kept away from light.

For more information, see Section [5. What should I know while using PLEGRIDY?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache, muscles or joints pain, feeling sick or having flu, feeling cold or tired, nausea, vomiting, itch, injection site reactions.

Serious side effects may include seizure, allergic reaction, liver injury, depression, thoughts of hurting yourself or suicide.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PLEGRIDY® (PLEGG-rih-dee)

Active ingredient(s): *peginterferon beta-1a (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PLEGRIDY. **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 PLEGRIDY.**

Where to find information in this leaflet:

- [1. Why am I using PLEGRIDY?](#)
- [2. What should I know before I use PLEGRIDY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PLEGRIDY?](#)
- [5. What should I know while using PLEGRIDY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PLEGRIDY?

PLEGRIDY contains the active ingredient **peginterferon beta-1a (rch)**. PLEGRIDY belongs to a group of medicines called interferons.

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.

2. What should I know before I use PLEGRIDY?

Warnings

Do not use PLEGRIDY if:

- you are allergic to interferon beta or peginterferon, or any of the 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

- Always check the ingredients to make sure you can use this medicine.
- If you have severe depression or think about committing suicide
- If you are already pregnant

Check with your doctor if you:

have any other medical conditions such as:

- allergies to any other medicines, foods, preservatives or dyes.
- 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.
- take any medicines for any other condition

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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 are breastfeeding or intend 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.

3. What if I am taking other medicines?

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.

Some medicines may interfere with PLEGRIDY and affect how it works.

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

- medicines to treat epilepsy

- medicines to treat depression

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

4. How do I 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

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.

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).

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

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.

When to use PLEGRIDY

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 inject PLEGRIDY Pen

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

Self-injection needs to be taught and practiced. 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.

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

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.

If you forget to use PLEGRIDY

PLEGRIDY should be used regularly at the same time every 14 days. If you miss your dose at the usual time, 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 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 use too much PLEGRIDY

If you think that you have used too much PLEGRIDY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia, or 0800 POISON or 0800 764 766 in New-Zealand), 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.

5. What should I know while using PLEGRIDY?

Things you should do

Call your doctor straight away if you:

- **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.
- **If you experience signs of pulmonary arterial hypertension such as difficulty breathing or increased tiredness, immediately tell your doctor.**

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 Plegridy.

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.

Remind any doctor, dentist or pharmacist you visit that you are using PLEGRIDY.

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 should not do

- Do not stop using PLEGRIDY or change the dosage, without checking with your doctor.
- Do not give PLEGRIDY to anyone else, even if they appear to have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PLEGRIDY affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the risk of liver injury.

Looking after your medicine

- 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).

Heat and dampness can destroy some medicines.

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.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

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.

If you no longer need to use this medicine or it is out of date, or is damaged or looks differently than it should, take it to any pharmacy for safe disposal.

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

PLEGRIDY helps most people with MS but it may have unwanted effects in a few 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, MS nurse or pharmacist to answer any further questions you may have about side effects.

Less serious side effects

Less serious side effects	What to do
Nervous system-related: <ul style="list-style-type: none">• Headache• Feeling weak and tired (asthenia) Muscles and joints related: <ul style="list-style-type: none">• Muscle pain• Pain in your joints, arms, legs or neck (arthralgia) Skin related: <ul style="list-style-type: none">• Itchy skin (pruritus) Digestion system related: <ul style="list-style-type: none">• Feeling or being sick (nausea or vomiting) Non-specific effect on the body: <ul style="list-style-type: none">• Fever, chills, feeling cold	Speak to your doctor or MS nurse if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Liver-related <ul style="list-style-type: none">• 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 Psychiatric-related: <ul style="list-style-type: none">• Depression, thoughts of hurting yourself or suicide• New mood changes Allergic reaction related: <ul style="list-style-type: none">• 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. Nervous system-related: <ul style="list-style-type: none">• Seizure (fit)• Weakness• Tiredness (lethargy)• Confusion Lung-related: <ul style="list-style-type: none">• difficulty breathing• increased tiredness	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 or pharmacist if you notice anything else that may be making you feel unwell.

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.

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 PLEGRIDY contains

Active ingredient (main ingredient)	peginterferon beta-1a (rch)
Other ingredients (inactive ingredients)	Sodium acetate trihydrate Glacial acetic acid L-arginine hydrochloride Polysorbate 20 Water for injections
Potential allergens	None

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

What PLEGRIDY 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.

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)

Who distributes PLEGRIDY

PLEGRIDY is supplied in Australia by:

Biogen Australia Pty Ltd

Level 4

2 Banfield Road

Macquarie Park NSW 2113

Australia

It is supplied in New Zealand by:

Biogen NZ Biopharma Limited

Auckland

New Zealand

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