

ZINBRYTA®

(zin-BRY-tuh)

daclizumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zinbryta. It does not contain all the available information. It does not take the place of talking to your 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 Zinbryta and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zinbryta 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 Zinbryta is used for

What Zinbryta is used for

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

- Slow the usual progression of disability
- Reduce the risk of relapse

Zinbryta is available only with a doctor's prescription. Your first prescription should be written following a recommendation from a neurologist.

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

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

Your doctor may have prescribed it for another reason.

Zinbryta has not been tested in clinical trials in people with MS who are below 18 years of age or 65 years and over.

How it works

The active substance in Zinbryta is daclizumab. Zinbryta slows down the progression of physical disability in people

with relapsing forms of MS and decreases the number of flare-ups (relapses) in patients with Multiple Sclerosis (MS) by reducing the inflammation in the central nervous system (CNS).

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'.

Before you use Zinbryta

Zinbryta may cause serious liver problems. Your doctor will carry out blood tests to check your liver function. You may also be tested for serious infections, such as tuberculosis or hepatitis B or C, before you begin treatment with Zinbryta. Additional blood tests will be required throughout treatment and after its completion (see While you are using Zinbryta).

When you must not use it

Do not use Zinbryta if you have liver problems.

Do not use Zinbryta if you have or have had autoimmune-related liver problems including autoimmune hepatitis.

Do not use Zinbryta if you have an allergy to:

- daclizumab
- 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 Zinbryta after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Do not use this medicine if you notice any of the following:

- If the pen/syringe is cracked or broken.
- If the solution is cloudy or you can see particles floating in it.
- If the solution is any colour other than colourless to slightly yellow.

If it has expired or is damaged or looks different 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 liver problems. Zinbryta may cause serious liver problems.**
- **have depression or a history of depression or suicidal thoughts**
- **have a serious infection, such as pneumonia**
- **have tuberculosis or have lived in a country where tuberculosis is common**
- **have or have had skin problems including eczema or psoriasis.**

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding or plan 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 Zinbryta.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

If you need to receive a vaccine, seek your doctor's advice first. Seasonal flu vaccines have been shown to be effective when given to patients taking Zinbryta. However, it is not known if Zinbryta may affect your response to other vaccines (live vaccines).

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

How to use Zinbryta

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

Zinbryta 150mg is injected subcutaneously (under the skin) every month.

- You can inject into your thigh, stomach (abdomen), or back of your upper arm.

- Try to keep to a regular schedule to help you remember your injection. For example, inject on the first Monday of each month.

You will also receive a blood test to test your liver function every month.

It is very important that you do not miss this blood test.

Try to keep to a scheduled day for your blood test. Contact your doctor if you think you may have missed a blood test.

How to use it

Injecting yourself

Your doctor or nurse should train you on how to inject your Zinbryta before you use it for the first time. You can then inject Zinbryta yourself. Read and follow the advice given in the instructions on how to inject yourself in the 'Instructions For Use, How to inject Zinbryta' leaflet.

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

How long to use it

Continue taking Zinbryta for as long as your doctor tells you. Do not make changes unless your doctor tells you. If your doctor has told you to stop taking your medicine, do not restart until your doctor tells you to.

If you forget to use it

Zinbryta is injected monthly.

Try to keep to a particular day of the month to help remember your injection.

In case you miss a dose and it is within 2 weeks of the missed dose, take that dose as soon as you can and then stay on your original monthly dosing schedule.

If it is more than 2 weeks from the missed dose, skip the missed dose and take your next dose as planned on your next scheduled day.

Do not use two injections to make up for a missed injection.

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 Zinbryta.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Zinbryta

Things you must do

Zinbryta may cause serious liver problems.

Your doctor will carry out blood tests to check your liver function before you begin treatment with Zinbryta, every month during treatment and up to 4 months after stopping treatment (since side effects may occur after treatment).

- **It is important that you have these regular blood tests.**

You will be given a Patient Alert Card with further information. Keep the Patient Alert Card with you during treatment and up to 4 months after stopping treatment with Zinbryta. When you have any medical treatment, even if it is not for your MS, show the Patient Alert Card to your doctor.

If you have abnormal liver test results you may have to stop using Zinbryta temporarily or permanently. Your doctor will advise you on this.

If you experience any of the following, contact your healthcare provider or doctor immediately:

- unexplained nausea (feeling sick to your stomach)
- vomiting (being sick)
- stomach pain

- increased tiredness
- loss of appetite (anorexia)
- your skin or the whites of your eyes turn yellow
- dark (tea-coloured) urine

These symptoms may suggest problems with your liver. If you do develop liver problems your doctor may interrupt your treatment with Zinbryta and refer you to a liver specialist.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using or have used Zinbryta. Tell your doctor if you are going to be vaccinated.

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

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

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

It may interfere with the results of some tests.

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

Things you must not do

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

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

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 you are taking Zinbryta.

Zinbryta 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 of the 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, nurse or pharmacist if you notice any of the following and they worry you:

- Infections of the airways, such as colds (Nasopharyngitis, upper respiratory tract infection)
- Flu (Influenza)
- Sore throat, tonsillitis (Pharyngitis, Laryngitis)
- Runny nose (Rhinitis)
- Lung infections (Bronchitis, Pneumonia)
- Skin rashes, including inflamed, irritated, itchy, dry or peeling skin (Dermatitis, Eczema, Psoriasis)
- Skin infection (Folliculitis, Acne)
- Decreases in the amount of certain cells (lymphocytes) in your blood
- Increases in body temperature or fever
- Increases in liver enzymes in the blood (these will show up in blood tests)
- Inflamed or enlarged lymph nodes (Lymphadenopathy, Lymphadenitis)
- Depression
- Diarrhoea
- Anaemia (Symptoms may include feeling weak or tired, or appearing pale).

The above list includes the more common side effects of Zinbryta. Tell your doctor if you have any side effect that bothers you or that does not go away.

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

Liver problems

If you get any of these symptoms:

- unexplained nausea (feeling sick to your stomach)
- vomiting (being sick)
- stomach pain
- increased tiredness
- loss of appetite (anorexia)
- your skin or the whites of your eyes turn yellow
- dark (tea-coloured) urine

Contact your doctor. They may be signs of a serious liver problem.

Blood Tests

Your doctor will carry out blood tests before starting treatment, every month during treatment and up to 4 months after stopping treatment with Zinbryta. If your test results show a problem with your liver, your doctor may interrupt or stop your treatment and refer you to a liver specialist.

It is very important that you have these regular blood tests, even if you are feeling well.

Please refer to the Zinbryta Patient Alert Card for more information about these side-effects.

Other important side effects:

- **Skin reactions:**

Zinbryta may cause skin reactions including severe rash. Contact your doctor if you develop a wide-spread rash.

- **Depression:**

Some people taking Zinbryta may develop depression. Contact your doctor right away if you experience irritability (getting upset easily), depression (feeling unusually sad, feeling hopeless or bad about yourself), nervousness, anxiety, or thoughts of hurting yourself or suicide.

- **Infections:**

Zinbryta may increase your risk of developing a serious infection such as a respiratory tract infection (pneumonia, bronchitis).

- **Low red blood cell counts (autoimmune haemolytic anaemia):**

Some people taking Zinbryta may develop a condition that lowers red blood cell counts. Symptoms can include paleness, increased tiredness, dark urine, shortness of breath, or the whites of the eyes or the skin turn yellow.

These could be signs of a serious condition. Contact your doctor immediately if you experience any of these symptoms.

- **Intestinal problems (colitis):**

Some people taking Zinbryta may develop an inflammation of the bowel (colitis). Symptoms can include diarrhoea that does not go away, stomach pain, fever or blood in your stools.

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.

Ask your doctor to answer any questions you may have.

After using Zinbryta

Storage

Keep your Zinbryta in its original pack to protect from light. Keep the pack closed until you need to use a new pen / syringe.

Keep Zinbryta in the refrigerator at 2°C to 8°C. Do not freeze or expose to high temperatures.

If a refrigerator is not available, Zinbryta pens/syringes can be stored at room temperature (up to 30°C) in the original pack

for up to 30 days. Make sure the time Zinbryta is out of the refrigerator is no more than 30 days. If Zinbryta has been outside of the refrigerator for more than a total of 30 days or if you are not sure how long Zinbryta has been at room temperature, throw the pen/syringe out (see Disposal). Do not place Zinbryta back into the refrigerator after warming to room temperature.

Do not use your pre-filled pen/syringe if it has been dropped or is visibly damaged.

Do not store Zinbryta 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.

Keep it 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

Ask your pharmacist how to dispose of used pens/syringes and any unused medicines.

If your doctor tells you to stop using Zinbryta 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

Zinbryta is a colourless to slightly yellow, clear to opalescent liquid contained within a pre-filled pen /pre-filled syringe. Each pack contains one or three pre-filled pen(s)/pre-filled syringe(s) with a pre-attached needle, ready to inject.

Ingredients

Each pen/syringe of Zinbryta contains 150 mg daclizumab in 1 mL of solution.

It also contains:

- Sodium succinate
- Succinic acid
- Sodium chloride
- Polysorbate 80
- Water for injections

Further information

You can obtain more information from your doctor, MS Nurse, pharmacist or the MS Society in your State, or by telephoning 1800 852 289.

Supplier

Zinbryta is supplied in Australia by:

Biogen Australia Pty Ltd

Level 3

123 Epping Road

North Ryde NSW 2113

Australia

Australian registration numbers

ZINBRYTA daclizumab 150 mg/mL solution for injection
Pre-filled syringe AUST R 243872

ZINBRYTA daclizumab 150 mg/mL solution for injection
Pre-filled pen AUST R 243873

Not all presentations are available.

Date of preparation

This leaflet was prepared in July 2017.