



Information for people living with multiple sclerosis

**IMPORTANT NOTICE**

On 2 March 2018 Biogen and AbbVie announced the voluntary worldwide withdrawal of Zinbryta® (daclizumab) due to safety concerns. Patients with queries should speak with their treating neurologist.

# Treatment

## Zinbryta® (daclizumab)

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# Zinbryta<sup>®</sup> (daclizumab)

There is a range of disease-modifying therapies approved for people living with multiple sclerosis in Australia. These therapies, also called immunotherapies, work to reduce disease activity in the central nervous system and reduce the frequency and severity of relapses in people living with multiple sclerosis.

## What is Zinbryta<sup>®</sup> and how does it work?

Zinbryta<sup>®</sup> is used for the management of relapsing forms of multiple sclerosis. Zinbryta<sup>®</sup> treatment has been shown in clinical trials<sup>1</sup> to:

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

The active substance in Zinbryta<sup>®</sup> is daclizumab. It targets particular cells in the immune system to reduce their activity which is believed to reduce inflammation in the brain and spinal cord and reduce the risk of relapses.

Zinbryta<sup>®</sup> has not been tested in clinical trials in people living with multiple sclerosis who are below the age of 18 or above the age of 65.

## How is Zinbryta<sup>®</sup> administered?

Zinbryta<sup>®</sup> 150mg is supplied in a pre-filled pen/ pre-filled syringe with a pre-attached needle, ready to inject. Zinbryta<sup>®</sup> is injected subcutaneously (under the skin) every month. The injection can be into the thigh, stomach (abdomen) or back of the upper arm.

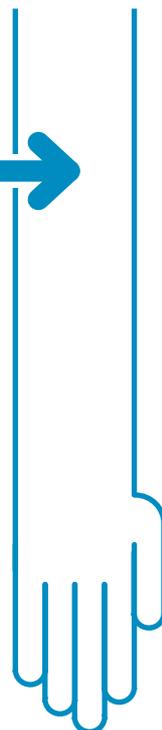
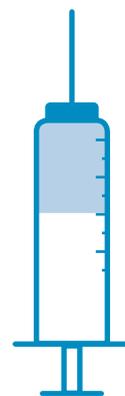
You will also receive a blood test to test your liver function prior to commencing treatment with Zinbryta<sup>®</sup> and repeat blood tests every month. These regular blood tests are important, even if you are feeling well.

It is very important that you remember your injection and that you do not miss the blood test. Try to keep a regular schedule so that you remember your injection and blood test.

Your doctor or nurse should train you on how to inject Zinbryta<sup>®</sup> before you use it for the first time. You can then inject Zinbryta<sup>®</sup> yourself. Read and follow the advice given in the instructions accompanying the medicine.

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

**150** x1  
milligrams per month



# Zinbryta<sup>®</sup> (daclizumab)

## Before you take Zinbryta<sup>®</sup>

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

Zinbryta<sup>®</sup> may cause serious liver problems and should not be used in people with existing liver conditions. Your doctor will carry out blood tests to check your liver function. You may also be tested for infections such as tuberculosis or hepatitis B or C, before you begin your treatment with Zinbryta<sup>®</sup>. Additional blood tests will be required throughout treatment and for up to four months after stopping treatment with Zinbryta<sup>®</sup>.

Before you start to take Zinbryta<sup>®</sup>, you should tell your doctor if you: have any allergies, liver problems, depression, infections, tuberculosis (TB) or have lived in a country where TB is common, skin problems, become pregnant or are breastfeeding, or plan to become pregnant or breastfeed, are taking any other medicines including vitamins, herbal supplements or natural therapies, or need to receive a vaccine such as flu vaccine.

## While you are taking Zinbryta<sup>®</sup>

### How long to take it

Continue taking Zinbryta<sup>®</sup> 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 doctors tells you to.

### If you forget to take it

Zinbryta<sup>®</sup> is injected monthly. Try to keep a particular day of the month to help you remember – for example, inject on the first Monday of each month. If you miss a dose and it is within two weeks of the missed dose, take that dose as soon as you can and then stay on your original monthly schedule.

If it is more than two weeks from the missed dose, skip the missed dose and take your next dose as planned on your original monthly schedule. 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 tips.

### If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (13 11 26) for advice. Go to your nearest hospital if you think you or anyone else may have taken too much Zinbryta<sup>®</sup>, even if there are no signs of discomfort or poisoning – you may need urgent medical attention.

### Things you must do

- Tell any other doctors, dentists or pharmacists that treat that you are taking this medicine
- If you are undergoing surgery, tell the surgeon and anaesthetist that you are taking this medicine
- If you become pregnant, tell your doctor immediately
- If you are about to have blood tests, tell your doctor that you are taking this medicine
- If you are about to be started on any new medicine, remind you doctor and pharmacist you are taking Zinbryta<sup>®</sup>
- Tell your doctor if you are going to be vaccinated
- Be careful driving or operating machinery until you know how this medicine affects you



# Zinbryta<sup>®</sup> (daclizumab)

You will be given a Patient Alert Card with further information. Keep the Patient Alert Card with you during treatment and up to four months after stopping treatment with Zinbryta<sup>®</sup>. When you have any medical treatment, even if it is not for your multiple sclerosis, show the Patient Alert Card to your doctor.

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

If you experience unexplained nausea, vomiting, stomach pain, increased tiredness, loss of appetite, your skin or the whites of your eyes turn yellow, or dark (tea-coloured) urine, contact your healthcare provider or doctor immediately.

## What are the potential side effects of Zinbryta<sup>®</sup> treatment?

Zinbryta<sup>®</sup> helps most people living with multiple sclerosis, but it may have side effects in some people. Liver side-effects can be serious if not detected and treated early, which is why the monthly blood test is very important while taking Zinbryta<sup>®</sup>.

Other common side effects of Zinbryta<sup>®</sup> (identified in 5% or more of the people taking Zinbryta<sup>®</sup> in the clinical trials) are as follows – however, you may not experience any of them.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you or you do not feel well while taking this medicine: infections of the airways, such as colds (nasopharyngitis, upper respiratory

tract infection), flu (influenza), sore throat, tonsillitis (pharyngitis, laryngitis), runny nose (rhinitis) or lung infections (bronchitis, pneumonia), skin rashes, including inflamed, irritated, itchy, dry or peeling skin (dermatitis, eczema, psoriasis) or skin infections (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), and depression, diarrhoea or anaemia.

Other side effects may also occur in some patients – tell your doctor if you notice anything else that is making you feel unwell.

## How much does Zinbryta<sup>®</sup> cost?

Zinbryta<sup>®</sup> has been approved by the Therapeutic Goods Administration and is available through the Pharmaceutical Benefits Scheme (PBS). Please discuss with your neurologist whether Zinbryta<sup>®</sup> is the right treatment for you.

If you are eligible for medications through the PBS, you will need to pay a contribution fee each time your prescription is dispensed. The Federal Government pays for the remaining cost. The amount of the contribution fee depends upon whether or not you have a pension or concession card. The amount of this fee is set each year by the Federal Government.

Further information about the PBS, your entitlements and details regarding the PBS safety net (which protects patients and their families requiring a large number of PBS items) is available through the Medicare Australia website at: [www.medicare.gov.au](http://www.medicare.gov.au)

If you are not eligible for Zinbryta<sup>®</sup> through the PBS, for example if you are a visitor from overseas, your neurologist may write a private prescription. In this instance you will have to pay the full cost to the pharmacy that dispenses your medication. You will need to request a quote from your pharmacist for the price of any medication which is not subsidised by the PBS.

## General information

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

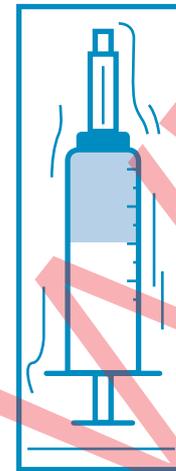
Keep Zinbryta<sup>®</sup> in the refrigerator at 2–8°C. Do not freeze or expose to high temperatures.

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

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

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

In Australia Zinbryta<sup>®</sup> is manufactured by:  
 Biogen Australia Pty Ltd  
 Level 3, 123 Epping Road  
 North Ryde NSW 2113  
 Phone: 02 8875 3900



**2–8°C**

Storage temperature

## For more information on multiple sclerosis and other multiple sclerosis treatments

- Speak to your neurologist about what treatment best suits your individual circumstances.
- MS nurses can also provide information, training and ongoing support in managing your immunotherapy.
- For information about multiple sclerosis, multiple sclerosis treatment and to find contact details for your state MS organisation visit [www.ms.org.au](http://www.ms.org.au)
- MS Research Australia provides information on the latest research and clinical trials at [www.msra.org.au](http://www.msra.org.au)

### References

1. Zinbryta<sup>®</sup> Approved Product Information, September 2016  
[www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-02547-1](http://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-PI-02547-1)

### Note

MS does not recommend any specific disease-modifying treatment for people living with multiple sclerosis. Decisions about any treatments, taking into consideration the potential benefits and side effects for each individual's circumstances, should be made in careful consultation with the person's neurologist.

The information supplied in this document is collated from material provided by the relevant pharmaceutical company, MIMS ([www.mims.com.au](http://www.mims.com.au)) and MS Research Australia.