Zinbryta
(daclizumab beta)

Acknowledgment form

This acknowledgement form provides information on the risk of serious liver problems with Zinbryta. Please read the form carefully and discuss the content with your doctor to ensure you are fully informed of and understand the information provided.

Zinbryta may cause serious liver problems, which can be unpredictable and could be life-threatening or potentially result in death. Serious liver problems can occur at any time during treatment or several months after stopping treatment. It is important to tell your doctor if:

- **You currently have liver problems (in this case you should not take Zinbryta).**
- **You have other immune system disorders in addition to Multiple Sclerosis (MS).**
- **You are taking other medicines that potentially may cause liver injury including non-prescription products and herbal supplements.**

If you are considering treatment with Zinbryta you should:

- discuss with your doctor the benefits and the risks associated with this treatment, in particular the risk of serious liver problems;
- read the patient card given to you by your doctor;
- read the package leaflet which is included in each box of Zinbryta.

The patient card and package leaflet contain important safety information about the risk of serious liver problems.

If you decide to receive treatment with Zinbryta, you should keep the patient card with you to remind you of the important safety information, in particular any signs and symptoms you may develop which could possibly indicate serious liver problems. If you notice any of these signs and symptoms, you should contact your doctor immediately.

If appropriate, you should show the patient card to your partner or caregiver, or to any other healthcare professional who is not your regular doctor.

If you do not have the patient card then please ask your doctor to provide it to you.

The package leaflet should be read each time that you receive a new pack of Zinbryta because it may have new information that is important to your treatment.

If you start treatment with Zinbryta your doctor will perform blood tests of your liver function, before starting treatment, at least monthly during treatment and up to 6 months after stopping treatment with Zinbryta. It is very important that you have these regular blood tests. If certain test results reach levels which are above three times the normal limit, or if you do not undergo your scheduled blood tests, your doctor may decide to stop treatment with Zinbryta.

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To be signed and dated by the patient

☐ I confirm I have discussed the risk of serious liver problems with my doctor and I understand the information that has been provided to me.

☐ I confirm I have received a copy of the patient card.

☐ I confirm I have received a copy of this acknowledgement form.

Patient name

Patient signature

Date (dd/mm/yyyy)

Signature of treating doctor

☐ I confirm I have discussed the content of this acknowledgement form with my patient on the basis of the current summary of product characteristics for Zinbryta.

Physician name

Physician signature

Date (dd/mm/yyyy)

A copy of the acknowledgement form should be provided to the patient

▼ **This medicine is subject to additional monitoring.**
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/ risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via MHRA (UK) Yellow Card Scheme.
Website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.
If in Ireland, report via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; Email: medsafety@hpra.ie.

Adverse events should also be reported to Biogen on 0800 008 7401 (UK) or 1800 812 719 (Ireland).
E-mail: MedInfoUKI@biogen.com.

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