TYRUKO (natalizumab)
TREATMENT DISCONTINUATION FORM

SANDOZ

This medicine is subject to additional monitoring. This will allow quick identification of new safety information..

This form should be read carefully before discontinuing treatment with TYRUKO. Please follow the advice in this form to ensure that you are fully informed of, and understand the continued risk of PML (progressive multifocal leukoencephalopathy) for up to 6 months following discontinuation of NATALIZUMAB.

Before starting treatment with TYRUKO you should have received an Alert Card from your doctor. This Alert Card should be kept for 6 months after discontinuation of treatment as it has important information about PML for your reference.

PML is a rare brain infection that has occurred in patients who have been given NATALIZUMAB, and which may lead to severe disability or death. PML has been reported up to 6 months after discontinuation of NATALIZUMAB.

Signs include:
- Changes in mental ability and concentration
- Behavioural changes
- Weakness on one side of the body
- Vision problems
- New neurological symptoms that are unusual for you

Symptoms of PML may be similar to an MS relapse. Therefore, if you believe your MS is getting worse or if you notice any new symptoms for up to 6 months after stopping NATALIZUMAB treatment, it is very important that you speak to your doctor as soon as possible.

During the 6 months following treatment discontinuation of NATALIZUMAB, your doctor will monitor you and will decide when you should receive MRI imaging. In general, you will continue to receive 3-6 month MRI imaging if you have either of the following combination of PML risk factors:

- You have antibodies to the JC virus, have taken NATALIZUMAB for more than 2 years and previously taken an immunosuppressant (a medicine that reduces the activity of your body's immune system) at any time before starting NATALIZUMAB
- You have never taken an immunosuppressant therapy before starting NATALIZUMAB, but have taken NATALIZUMAB for more than 2 years and have a high anti-JCV antibody index (increased amount of antibody in your blood)

If you do not fall into one of the above groups, then you will continue to receive routine MRIs as prescribed by your doctor.

Should you have any questions about the above information, please ask your doctor.

If you do not have the Alert Card that you received when starting TYRUKO, then please ask your doctor for a new card.

You should keep the Alert Card with you to remind you of the important safety information, in particular any symptoms you may develop which could possibly indicate PML, if appropriate, you should show the Alert Card to your partner or caregiver.

Patient's Name (print) _____

Patient's Signature _____ **Date** _____

Doctor's Name (print) _____

Doctor's Signature _____ **Date** _____

MLR ID: 284730

Date of MHRA Approval: January 2024

Reporting of side effects:

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.yellowcard.mhra.gov.uk.
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Artwork Proof Box:

Variation:	Initial Educational Material Registration + RFI 3
Proof no:	001.3
Date prepared:	05/12/2023
Font size:	9.5pt
Fonts:	Helvetica
Dimensions:	210 x 297 mm
Technical data:	
SKUs:	00000000
SZ codes:	SZ0000000000
Item codes:	00000000
Pharma codes:	00000000
Novartis data if applicable:	
Version:	00000000
Print Proof date:	00000000
AQWA#:	00000000
Production site:	00000000
Technical num:	00000000
Old Comp num:	00000000

Technical Colours:

	Legend:

Colours:

	Pantone 541

SANDOZ

Signature Panel: