# TYSABRI
(natalizumab)

# MEDICATION GUIDE

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

TYSABRI®
(natalizumab)

# TYSABRI (natalizumab)
# Treatment Initiation Form

# Before Starting Treatment with **TYSABRI** (natalizumab) you Should:

Lorem This form should be read carefully before starting treatment with TYSABRI (natalizumab). Please follow the advice in this form to ensure that you are fully informed of, and understand the risk of PML (progressive multifocal leukoencephalopathy), IRIS (Immune reconstitution Inflammatory Syndrome) and other important adverse effects of TYSABRI (natalizumab).

- Read the Package Leaflet which is included in each box of TYSABRI (natalizumab)
- Read the Alert Card given to you by your doctor
- Discuss with your doctor the benefits and the risks associated with this treatment

The Package Leaflet and the Alert Card contain important safety information about PML, a rare brain infection that has occurred in patients who have been given TYSABRI (natalizumab), and which may lead to severe disability or death.

JC virus is a common virus which infects many people but does not normally cause noticeable illness.

PML is associated with an uncontrolled increase of the JC virus in the brain, although the reason for this increase in some patients treated with TYSABRI (natalizumab) is unknown.

**The risk of PML with** TYSABRI (natalizumab) **is higher:**

- If you have antibodies to the JC virus in your blood
- The longer that you are on treatment with TYSABRI (natalizumab, especially if you have been on treatment for more than two years
- If you have taken an immunosuppressant (a medicine that reduces the activity of your body's immune system) at any time before starting TYSABRI (natalizumab) treatment.
- Your doctor should discuss the potential risk of developing PML with you before you start treatment with TYSABRI (natalizumab).
- Your doctor may test your blood to check if you have antibodies to the JC virus before you start treatment with TYSABRI (natalizumab).
- Your doctor may repeat the test while you are on TYSABRI (natalizumab) treatment to check if anything has changed. The risk of PML is higher if you have all the risk factors described above, or if you have not taken an immunosuppressant medication prior to starting TYSABRI (natalizumab) and have higher levels of antibodies to the JC virus and you have been on TYSABRI (natalizumab) for more than 2 years.
- Your doctor will monitor you more closely if you are at higher risk for PML.

**You should discuss with your doctor if** TYSABRI (natalizumab) **is the most suitable treatment for you before you start taking** TYSABRI (natalizumab) **and when you have been taking** TYSABRI (natalizumab) **for more than two years.**

In patients with PML, a reaction known as IRIS (Immune Reconstitution Inflammatory Syndrome) is likely to occur after treatment for PML, as TYSABRI (natalizumab) is removed from your body.

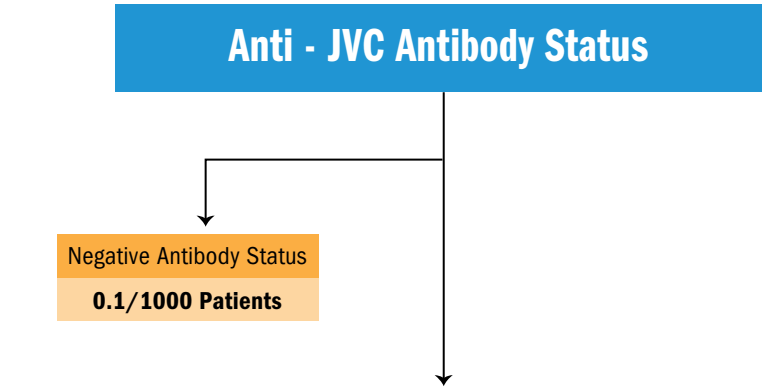
IRIS may lead to your condition getting worse, including worsening of brain function. The Package Leaflet should be read each time that you take TYSABRI (natalizumab) because it may have new information that is important to your treatment.

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.
If you do not have the Package Leaflet or the Alert Card, then please ask your doctor to provide them to you before you initiate your TYSABRI (natalizumab) treatment.

**[Patient's name, signature and date of signature, and Doctor's name, signature, and date of signature].**

TYSABRI (natalizumab)

# PML Risk Estimate:




**Positive Antibody Status**

| NataLizumab Exposure | PML risk estimates per 1000 patients | | | | |
|---|---|---|---|---|---|
| | Patients without prior IS use | | | | Patients with prior IS use |
| | No index value | Antibody index ≤ 0.9 | Antibody index > 0.9 ≤1.5 | Antibody index > 1.5 | |
| 1 - 12 months | 0.1 | 0.1 | 0.1 | 0.2 | 0.3 |
| 13 - 24 months | 0.6 | 0.1 | 0.3 | 0.9 | 0.4 |
| 25 - 36 months | 2 | 0.2 | 0.8 | 3 | 4 |
| 37 - 48 months | 4 | 0.4 | 2 | 7 | 8 |
| 49 - 60 months | 5 | 0.5 | 2 | 8 | 8 |
| 61 - 72 months | 6 | 0.6 | 3 | 10 | 6 |

# Patients Who Are Anti-JCV Antibody Negative

Based on global data, if you do not have antibodies to JCV your chance of getting PML is 0.1/1000 (or 1 in 10,000) patients.

# Patients Who Are Anti-JCV Antibody Positive

If you do have antibodies to JCV, your risk of developing PML will vary depending on the duration of treatment with TYSABRI (natalizumab) the level of anti-JCV antibodies in your blood and whether you have received prior treatment with an immunosuppressant medication.

Your doctor will discuss the potential risk before you start treatment.

**To report any adverse events, please contact:**

Saudi Food and Drug Authority (National Pharmacovigilance Center)

Online: http://ade.sfda.gov.sa

Email: npc.drug@sfda.gov.sa

Telephone: 19999

Biogen Technical Scientific office - Branch of Biogen International GmbH – Kingdome of Saudi Arabia:

Email: Safety.Saudi@biogen.com

PV Hotline: +966 552885028

This material is approved by the Saudi food & drug authority.
For extra copies please send an email with the required amount & contact number to: Safety.Saudi@biogen.com

TYSABRI (natalizumab)

# TYSABRI (natalizumab)
## Treatment Continuation Form



TYSABRI® (natalizumab)

# **TYSABRI**(natalizumab) Treatment Continuation Form

This form should be read carefully before continuing TYSABRI (natalizumab) treatment for more tha 2 years. Although you have been receiving TYSABRI (natalizumab) for 2 years, it is important that you are reminded that the risk of PML increases beyond this time.

Please follow the advice in this form to ensure that you are fully informed of, and understand the risk of PML (progressive multifocal leukoencephalopathy), IRIS (Immune reconstitution Inflammatory Syndrome) and other important adverse effects of TYSABRI (natalizumab).

**Before continuing treatment with** TYSABRI (natalizumab) **you should:**

- Read the Package Leaflet which is included in each box of TYSABRI (natalizumab)
- Read the Alert Card given to you by your doctor
- Discuss with your doctor the benefits and the risks associated with this treatment

The Package Leaflet and the Alert Card contain important safety information about PML, a rare brain infection that has occurred in patients who have been given TYSABRI (natalizumab), and which may lead to severe disability or death.

PML is associated with an uncontrolled increase of the JC virus in the brain, although the reason for this increase in some patients treated with TYSABRI (natalizumab) is unknown.

JC virus is a common virus which infects many people but does not normally cause noticeable illness.

**The risk of PML with** TYSABRI (natalizumab) **is higher:**

- If you have antibodies to the JC virus in your blood
- The longer that you are on treatment with TYSABRI (natalizumab), especially if you have been on treatment for more than two years
- If you have taken an immunosuppressant (a medicine that reduces the activity of your body's immune system) at any time before starting TYSABRI (natalizumab) treatment.
- Your doctor should discuss the potential risk of developing PML with you before you start treatment with TYSABRI (natalizumab).
- Your doctor may test your blood to check if you have antibodies to the JC virus before you start treatment with TYSABRI (natalizumab).
- Your doctor may repeat the test while you are on TYSABRI (natalizumab) treatment to check if anything has changed. The risk of PML is higher if you have all the risk factors described above, or if you have not taken an immunosuppressant medication prior to starting TYSABRI (natalizumab) and have higher levels of antibodies to the JC virus and you have been on TYSABRI (natalizumab) for more than 2 years.
- Your doctor will monitor you more closely if you are at higher risk for PML.

**You should discuss with your doctor if** TYSABRI (natalizumab) **is the most suitable treatment for you before you start taking** TYSABRI (natalizumab) **and when you have been taking** TYSABRI (natalizumab) **for more than two years.**

In patients with PML, a reaction known as IRIS (Immune Reconstitution Inflammatory Syndrome) is likely to occur after treatment for PML, as TYSABRI (natalizumab) is removed from your body.

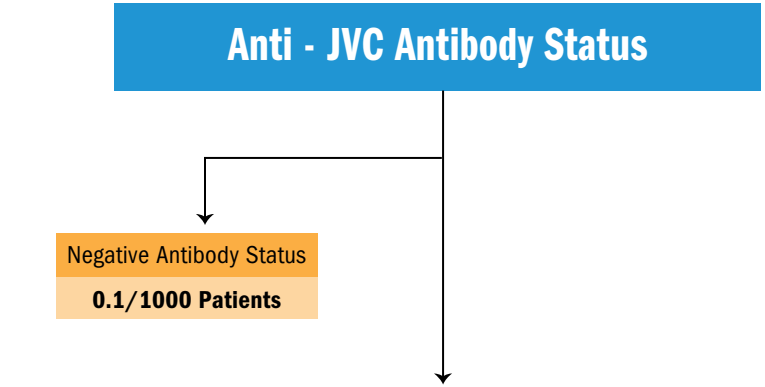
IRIS may lead to your condition getting worse, including worsening of brain function. The Package Leaflet should be read each time that you take TYSABRI (natalizumab) because it may have new information that is important to your treatment.

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.
If you do not have the Package Leaflet or the Alert Card, then please ask your doctor to provide them to you before you initiate your TYSABRI (natalizumab) treatment.

**[Patient's name, signature and date of signature, and Doctor's name, signature, and date of signature].**

TYSABRI (natalizumab)

# PML Risk Estimate:

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# Patients Who Are Anti-JCV Antibody Positive

If you do have antibodies to JCV, your risk of developing PML will vary depending on the duration of treatment with TYSABRI (natalizumab), the level of anti-JCV antibodies in your blood and whether you have received prior treatment with an immunosuppressant medication.

Your doctor will discuss the potential risk before you start treatment.

**To report any adverse events, please contact:**

Saudi Food and Drug Authority (National Pharmacovigilance Center)

Online: http://ade.sfda.gov.sa

Email: npc.drug@sfda.gov.sa

Telephone: 19999

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TYSABRI (natalizumab)

# TYSABRI (natalizumab)

## Treatment Discontinuation Form



TYSABRI (natalizumab)

# TYSABRI(natalizumab) Treatment Discontinuation Form

This form should be read carefully before discontinuing treatment with TYSABRI (natalizumab).

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 TYSABRI (natalizumab).

**This form should be read carefully before discontinuing treatment with TYSABRI (natalizumab).**
**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 TYSABRI (natalizumab).**

**Before starting treatment with TYSABRI (natalizumab) 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 TYSABRI (natalizumab), and which may lead to severe disability or death.

PML has been reported up to 6 months after discontinuation of TYSABRI (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 TYSABRI (natalizumab) treatment, it is very important that you speak to your doctor as soon as possible



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

- You have antibodies to the JC virus, have taken TYSABRI (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 TYSABRI (natalizumab).
- You have never taken an immunosuppressant therapy before starting TYSABRI (natalizumab), but have taken TYSABRI (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 TYSABRI (natalizumab), 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, signature and date of signature, and Doctor's name, signature, and date of signature].**

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TYSABRI (natalizumab)

## Reference:

TYSABRI SC (natalizumab) Summary of Product Characteristics. Sep2021.
TYSABRI IV (natalizumab) SmPC Saudi Arabia February 2021
TYSABRI IV (NATALIZUMAB)-PATIENT INFORMATION LEAFLET- Feb 2021
TYSABRI SC (NATALIZUMAB)-PATIENT INFORMATION LEAFLET- September 2021

Biogen-181211 Preparation Date : Sept 2022