TYRUKO

PATIENT ALERT CARD

SANDOZ

Tyruko▼(natalizumab)

MLR ID: 284725

Date of MHRA approval: January 2024

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

This alert card contains important safety information that you need to be aware of before, during and after stopping treatment with TYRUKO.

- Show this card to any doctor involved with your treatment, not only to your neurologist.
- Please read the TYRUKO 'Patient Leaflet' carefully before you start using this medicine.
- Keep this card with you during TYRUKO treatment and 6 months after the last dose of TYRUKO, since side effects may occur even after you have stopped treatment with TYRUKO.
- Show this card to your partner or caregivers. They might see symptoms of PML that you might not notice, such as changes in mood or behaviour, memory lapses, speech and communication difficulties. You should remain aware of symptoms that might arise for up to 6 months after stopping TYRUKO treatment.

Marketing Authorisation Holder:

Sandoz Limited.
Park View,
Riverside Way,
Watchmoor Park,
Camberley,
Surrey,
GU15 3YL

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, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting side effects, you can help provide more information on the safety of this medicine.

Contact Details

Patient Name:

Treating Doctor:

Name:

Phone Number:

Start date of NATALIZUMAB treatment:

Prior to treatment with TYRUKO

- You should not be treated with TYRUKO if you have a serious problem with your immune system.
- You should not take any other long-term medicines for your multiple sclerosis while receiving TYRUKO.

During treatment with TYRUKO

Progressive Multifocal Leukoencephalopathy (PML)

PML, a rare brain infection, has occurred in patients who have been given TYRUKO. PML usually leads to severe disability or death.

The risk of PML appears to increase with treatment duration, especially beyond 2 years.

The 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 while you are on TYRUKO treatment or for up to 6 months after stopping TYRUKO treatment, it is very important that you speak to your doctor as soon as possible. PML symptoms generally develop more slowly than those associated with an MS relapse (over days or weeks), and may be similar to your MS symptoms.

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.

Management of PML requires immediately stopping TYRUKO treatment

Serious Infections

Other serious infections may occur with TYRUKO. Speak to your doctor as soon as possible if you think you have developed a severe, persistent infection, for example a persistent fever.

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