MEDISON

We are **Always Ahead** | We **Grow as One** | We **Care**

ינואר 2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הריני להודיעכם על עדכון שם התכשיר ועדכון העלון לרופא של התכשיר:

טייסברי תוך ורידי 300 מ"ג **TYSABRI I.V 300 MG**

CONCENTRATE FOR SOLUTION FOR INFUSION

מרכיב פעיל : **natalizumab**

התוויה מאושרת :

Tysabri is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations.
The safety and efficacy of Tysabri beyond two years are unknown.
Because Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability Tysabri is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, alternate multiple sclerosis therapies.
Safety and efficacy in patients with chronic progressive multiple sclerosis have not been studied.

להלן העדכונים בעלון לרופא המהווים החמרות:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[…]

Excipient with known effect
Each vial contains 2.3 mmol (or 52 mg) sodium and 3 mg polysorbate 80
(see section 4.4 for further information).

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion.
Colourless, clear to slightly opalescent solution with a pH of 5.8 – 6.4 and an osmolality of 268 – 308 mOsm/kg.

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3. PHARMACEUTICAL FORM

[…]

Patient Alert Card

The marketing of Tysabri is subject to a Risk management plan (RMP) including a 'Patient Alert Card'. The 'Patient Alert Card', emphasizes important safety information that the patient should be aware of before, during and after stopping treatment with Tysabri. Please explain to the patient the need to review the card before starting treatment.

4.2 Posology and method of administration

[…]

Special populations

Elderly

This medicinal product is not recommended for use in patients aged over 65 years due to a lack of data in this population.

4.4 Special warnings and precautions for use

[…]

Anti-JCV antibody testing

[…]

Patients should not be tested for anti- JCV antibodies within 2 weeks of PLEX due to removal of antibodies from the serum, or within 6 months of IVIg (i.e. 6 months = 5~~x~~ half-~~life~~ lives for immunoglobulins).

[…]

MRI screening for PML

[…]

~~No studies have been performed to evaluate the efficacy and safety of natalizumab when switching patients from DMTs with an immunosuppressant effect. It is unknown if patients switching from these therapies to this treatment have an increased risk of PML, therefore these patients should be monitored more frequently (i.e. similarly to patients switching from immunosuppressants to natalizumab).~~

[…]

Prior treatment with immunosuppressive or immunomodulatory therapies

Patients with a treatment history of immunosuppressant medications are at increased risk for PML.

Data from an observational study demonstrated that there is no increased risk of PML for the group of patients switching to natalizumab from fingolimod, dimethyl fumarate, or teriflunomide when compared to the group of patients switching from either beta interferon or glatiramer acetate.

No studies have been performed to evaluate the ~~efficacy and~~ safety of natalizumab ~~the medicinal product~~ when switching patients from DMTs ~~with an immunosuppressant effect~~ other than beta interferon, glatiramer acetate, fingolimod, dimethyl fumarate and teriflunomide. It is unknown if patients switching from ~~these~~ other therapies to ~~this~~

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~~medicinal product~~ natalizumab have an increased risk of PML compared to those switching from the above-mentioned DMTs, therefore these patients should be monitored more frequently (i.e. similarly to patients switching from immunosuppressants to natalizumab ~~this medicinal product, see MRI screening for PML~~).

[…]

Polysorbate 80 (E 433) content

This medicinal product contains 3 mg of polysorbate 80 in each vial. Polysorbates may cause allergic reactions.

Sodium content

Before dilution, this medicinal product contains 52 mg sodium per vial of medicinal product, equivalent to 2.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult. When diluted in 100 ml sodium chloride 9 mg/ml (0.9%), this medicinal product contains 406 mg sodium per dose. To be taken into consideration in case patients are on a controlled sodium diet.

4.8 Undesirable effects

[…]

Table 1: Adverse reactions

MedDRA System Organ Class	Frequency of Adverse Reactions				
	Very Common	*Common*	*Uncommon*	*Rare*	*Not known*
[…]					
Skin and subcutaneous tissue disorders		Pruritus Rash Urticaria		Angioedema	
Musculoskeletal and connective tissue disorders	Arthralgia				

[…]

~~*Malignancies*~~

~~No differences in incidence rates or the nature of malignancies between natalizumab and placebo-treated patients were observed over 2 years of treatment. However, observation over longer treatment periods is required before any effect of natalizumab on malignancies can be excluded (see section 4.3).~~

[…]

Tysabri Observational Program (TOP, IMA-06-02)

~~Interim analysis of results (as of May 2015) from the ongoing~~ The Tysabri Observational Program (TOP, IMA-06-02) was~~),~~ a ~~phase 4,~~ multicentre, single-arm study ~~(n =5,770) demonstrated that~~ initiated in 2007 to assess real-world safety and effectiveness outcomes in MS patients ~~switching from beta interferon (n = 3,255) or glatiramer acetate (n = 1,384) to~~ treated with Tysabri, ~~showed a sustained, significant~~

~~decrease in annualised relapse rate (p < 0.0001). Mean EDSS scores remained stable over 5 years.~~
~~Consistent~~ with ~~efficacy results observed~~ patient follow-up data for ~~patients switching from beta interferon or glatiramer acetate~~ up to ~~Tysabri, for~~ approximately 15 years. The study generated data from 6,319 patients in 17 countries, including 1,145 patients ~~switching from fingolimod (n = 147)~~ with up to ~~this medicinal product, a significant decrease in annualised relapse rate (ARR) was observed, which remained stable over 2 years, and mean EDSS scores remained similar from baseline to Year 2. The limited sample size and shorter duration of natalizumab exposure for this subgroup of patients should be considered when interpreting these data~~10 years of exposure and 102 patients with up to 15 years of exposure.

Overall, the safety findings of the TOP analyses were consistent with the known safety profile of natalizumab. Patients showed reductions in pre-treatment annualised relapse rate (ARR) regardless of the number of prior relapses, baseline EDSS, prior immunosuppressants use, or the number of DMTs used prior to natalizumab initiation. In the overall population, the ARR was 0.17 (95% CI: 0.17, 0.18) over the course of 15 years of follow up. Mean EDSS scores were similar from baseline (3.5, SD = 1.61) to year 15 (3.4, SD = 1.97) in patients treated with natalizumab.

A total of 5,635 patients had received another DMT prior to natalizumab initiation. The patients switching from beta interferon, glatiramer acetate or fingolimod had similar effectiveness outcomes to the overall natalizumab-treated population.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Immunosuppressants, monoclonal antibodies, ATC code ~~LO4AG03~~L04AG03

העלון לרופא נמצא בקישור, וכן מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,

מדיסון פארמה בע"מ

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