MEDISON
Delivering Innovative Healthcare

רופא/ה, רוקח/ת נכבדים,

הריני להודיעכם כי העלון של התכשיר עודכן:

TYSABRI טייסברי

concentrate for solution for infusion

מרכיב פעיל

natalizumab **300 mg/15ml**

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.

נעשו עדכונים והחמרות בעלון לרופא בסעיפים הבאים:

4.4 Special warnings and precautions for use

MRI screening for PML

Based on a retrospective analysis of natalizumab-treated patients since its approval, no difference was observed on 2-year survival after PML diagnosis between patients who received PLEX and those who did not. ~~For other considerations on the management of PML, see the Physician Informaion and Management Guidelines.~~

PML and IRIS (Immune Reconstitution Inflammatory Syndrome)

IRIS occurs in almost all TYSABRI PML patients after withdrawal or removal of the medicinal product~~, e.g. by plasma exchange (see section 5.2).~~ IRIS is thought to result from the restoration of immune function in patients with PML, which can lead to serious neurological complications and may be fatal. Monitoring for development of IRIS~~, which has occurred within days to several weeks after plasma exchange in TYSABRI treated patients with PML,~~ and appropriate treatment of the associated inflammation during recovery from PML should be undertaken ~~(see the Physician Information and Management Guidelines for further information).~~

[...]

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4.8 Undesirable effects

[...]

MedDRA System Organ Class	Adverse reaction	Frequency category
Infections and infestations	Urinary tract infection	Very common~~Common~~
	Nasopharyngitis	Very common~~Common~~
Immune system disorders	Urticaria	Common
	Hypersensitivity	Uncommon
Nervous system disorders	Headache	Very common~~Common~~
	Dizziness	Very common~~Common~~
	Progressive Multifocal Leukoencephalopathy (PML)	Uncommon
Gastrointestinal disorders	Vomiting	Common
	Nausea	Very common~~Common~~
Musculoskeletal and connective tissue disorders	Arthralgia	Very common~~Common~~
General disorders and administration site conditions	Rigors	Common
	Pyrexia	Common
	Fatigue	Very common~~Common~~

[...]

5.2 Pharmacokinetic properties

[...]

~~The effect of plasma exchange on natalizumab clearance and pharmacodynamics was evaluated in a study of 12 MS patients. Estimates of the total natalizumab removal after 3 plasma exchanges (over a 5-8 day interval) was approximately 70-80%. This compares to approximately 40% seen in earlier studies in which measurements occurred after natalizumab discontinuation over a similar period of observation. The impact of plasma exchange on the restitution of lymphocyte migration and ultimately its clinical usefulness is unknown.~~

[...]

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

בברכה,

שרון עמיר
רוקחת ממונה

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