

רופא/ה נכבד/ה  
רוקח/ת נכבד/ה,

הריני להודיעכם כי העלון לרופא של התכשיר עודכן:

**Tysabri****טייסברי**

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:

**4.6 Fertility, pregnancy and lactation**

[...]

Pregnancy

There are no adequate and well-controlled studies of natalizumab therapy in pregnant women.

Thrombocytopenia and anaemia in infants born to women exposed to natalizumab during pregnancy were reported in the postmarketing setting. Monitoring of platelet counts haemoglobin, and **haematocritis** recommended in neonates born to women exposed to natalizumab during pregnancy.

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**4.8 Undesirable effects**

<i>General disorders and administration site conditions</i>	Fatigue	Pyrexia Chills Infusion site reaction Injection site reaction	Face oedema		
<u>Investigations</u>		<u>Hepatic enzyme increased</u> <u>Drug specific antibody present</u>			
<u>Injury, poisoning and procedural complications</u>	<u>Infusion related reaction</u>				
<i>Skin and subcutaneous tissue disorders</i>		Pruritus Rash Urticaria		Angioedema	
<i>Vascular disorders</i>		Flushing			
<i>Nervous system disorders</i>	Dizziness Headache				
<i>Musculoskeletal and connective tissue disorders</i>	Arthralgia				

MedDRA System Organ Class	Frequency of Adverse Reactions				
	<i>Very Common</i>	<i>Common</i>	<i>Uncommon</i>	<i>Rare</i>	<i>Not known</i>
<i>Infections and infestations</i>	Nasopharyngitis Urinary tract infection	Herpes infection	Progressive multifocal leukoencephalopathy	Herpes ophthalmic	Meningoencephalitis herpetic JC virus granule cell neuropathy Necrotising herpetic retinopathy
<i>Immune system disorders</i>		<u>Hypersensitivity</u>	<u>Anaphylactic reaction</u>		

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MedDRA System Organ Class	Frequency of Adverse Reactions				
	<i>Very Common</i>	<i>Common</i>	<i>Uncommon</i>	<i>Rare</i>	<i>Not known</i>
<u>lymphatic system disorders</u>			Immune thrombocytopenic purpura (ITP) Eosinophilia	anaemia Nucleated red cells	
<u>Immune system disorders</u>		Hypersensitivity	Anaphylactic reaction Immune reconstitution inflammatory syndrome		
<u>Nervous system disorders</u>	Dizziness Headache				
<u>Vascular disorders</u>		Flushing			
<u>Respiratory, thoracic and mediastinal disorders</u>		Dyspnoea			
<u>Gastrointestinal disorders</u>	Nausea	Vomiting			
<u>Hepatobiliary disorders</u>				Hyperbilirubinaemia	Liver injury
<u>Investigations</u>		Hepatic enzyme increased Drug specific antibody present			
<u>Injury, poisoning and procedural complications</u>	Infusion related reaction				
<u>Respiratory, thoracic and mediastinal disorders</u>		Dyspnoea			
<u>Gastrointestinal disorders</u>	Nausea	Vomiting			

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<i>Skin and subcutaneous tissue disorders</i>		Pruritus Rash Urticaria		Angioedema	
<i>Vascular disorders</i>		Flushing			
<i>Nervous system disorders</i>	Dizziness Headache				
<i>Musculoskeletal and connective tissue disorders</i>	Arthralgia				

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: **Pharmacotherapeutic group: Immunosuppressants, selective immunosuppressants, ATC code: L04AA23**

**Immunosuppressante selective immu**monoclonal, ATC code LO4AG03

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

בברכה,

מדיון פארמה בע"מ

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