הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 7 באוקטובר 2015

שם תכשיר באנגלית: Intron A 10 MIU solution for injection or infusion

מספר רישום: 137.87.31717.00

שם בעל הרישום: חברת מרק שארפ ודוהם (ישראל-1996) בע"מ

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
Combination of Intron A with telbivudine.		**Contraindications**
Other CNS effects including aggressive behaviour (sometimes directed against others such as homicidal ideation), bipolar disorders, mania, confusion and alterations of mental status have been observed with alfa interferons. Patients should be closely monitored for any signs or symptoms of psychiatric disorders. If such symptoms appear, the potential seriousness of these undesirable effects must be borne in mind by the prescribing physician and the need for adequate therapeutic management should be considered. If psychiatric symptoms persist or worsen, or suicidal or homicidal ideation is identified, it is recommended that treatment with Intron A be discontinued, and the patient followed, with psychiatric intervention as appropriate.		**Special warnings and precautions for use**
Patients with substance use/abuse: HCV infected patients having a co-occurring substance use disorder (alcohol, cannabis, etc) are at an increased risk of developing psychiatric disorders or exacerbation of already existing psychiatric disorders when treated with alfa interferon. If treatment with alfa interferon is judged necessary in these patients, the presence of psychiatric co-morbidities and the potential for other substance use should be carefully assessed and adequately managed before initiating therapy. If necessary, an inter-disciplinary approach including a mental health care provider or addiction specialist should be considered to evaluate, treat and follow the patient. Patients should be closely monitored during therapy and even after treatment discontinuation. Early intervention for re-emergence or development of psychiatric disorders and substance use is recommended.		
Adverse experiences including prolongation of coagulation markers and liver abnormalities Moderate to severe adverse experiences may require modification of the patient's dose regimen, or in some cases, termination of Intron A therapy. Intron A increases the risk of liver decompensation and death in patients with cirrhosis. Discontinue treatment with Intron A in patients with chronic hepatitis who develop prolongation of coagulation markers which might indicate liver decomposition. Any patient developing liver function abnormalities during treatment with Intron A must be monitored closely and treatment discontinued if signs and symptoms progress.		

Liver enzymes and hepatic function should be closely monitored in cirrhotic patients.		
Ocular adverse events Ocular adverse events (see section 4.8) including retinal haemorrhages, cotton wool spots, serous retinal detachment, and retinal artery or vein obstruction have been reported in rare instances after treatment with alfa interferons.		
Cases of Vogt-Koyanagi-Harada (VKH) syndrome have been reported in patients with chronic hepatitis C treated with interferon. This syndrome is a granulomatous inflammatory disorder affecting the eyes, auditory system, meninges, and skin. If VKH syndrome is suspected, antiviral treatment should be withdrawn and corticosteroid therapy discussed (see section 4.8).		
Concomitant chemotherapy Administration of Intron A in combination with other chemotherapeutic agents (e.g., Ara-C, cyclophosphamide, doxorubicin, teniposide) may lead to increased risk of toxicity (severity and duration), which may be life-threatening or fatal as a result of the concomitantly administered medicinal product. The most commonly reported potentially life-threatening or fatal adverse events include mucositis, diarrhoea, neutropaenia, renal impairment, and electrolyte disturbance. Because of the risk of increased toxicity, careful adjustments of doses are required for Intron A and for the concomitant chemotherapeutic agents (see section 4.5). When Intron A is used with hydroxyurea, the frequency and severity of cutaneous vasculitis may be increased.		
A clinical trial investigating the combination of telbivudine, 600 mg daily, with pegylated interferon alfa-2a, 180 micrograms once weekly by subcutaneous administration, indicates that this combination is associated with an increased risk of developing peripheral neuropathy. The mechanism behind these events is not known (see telbivudine SPC). Moreover, the safety and efficacy of telbivudine in combination with interferons for the treatment of chronic hepatitis B has not been demonstrated. Therefore, the combination of Intron A with telbivudine is contraindicated (see section 4.3).		**Interaction with other medicinal products and other forms of interaction**
Sepsis, Vogt-Koyanagi-Harada syndrome, acute hypersensitivity reactions including urticaria, angioedema, bronchoconstriction, anaphylaxis, Homicidal ideation, mental status change, mania, bipolar disorders, Peripheral neuropathy, coma, Serous retinal detachment, Congestive heart failure, pericardial effusion, Pulmonary fibrosis, Pulmonary arterial hypertension, Periodontal disorder NOS, dental disorder NOS. Cases of pulmonary arterial hypertension (PAH) have been reported with interferon alfa products, notably in patients with risk factors for PAH (such as portal hypertension, HIV-infection, cirrhosis). Events were reported at various time points typically several months after starting treatment with interferon alfa. Moderate and usually reversible pancytopenia has been reported.		**Undesirable effects**