

Copaxone® 20 mg/ml solution for injection, single-use pre-filled syringe containing 1.0 ml of a solution consisting of 20 mg glatiramer acetate, equivalent to 18 mg glatiramer base, list of excipients: Mannitol, water for injections. Prescription medicine. Therapeutic indications: Copaxone is indicated for the treatment of patients who have experienced a well defined first clinical episode and are determined to be at high risk of developing clinically definite multiple sclerosis (CDMS). Copaxone is indicated for the reduction in frequency of relapses in ambulatory patients, (i.e. who can walk unaided) with relapsing, remitting multiple sclerosis (MS). In clinical trials this was characterised by at least two attacks of neurological dysfunction over the preceding two-year period. Copaxone is not indicated in primary or secondary progressive MS. Contraindications: hypersensitivity to glatiramer acetate or mannitol, pregnant women. Paediatric Use: children and adolescents: No prospective, randomised, controlled clinical trials or pharmacokinetic studies have been conducted in children or adolescents. However, limited published data suggest that the safety profile in adolescents from 12 to 18 years of age receiving Copaxone 20 mg subcutaneously every day is similar to that seen in adults. There is not enough information available on the use of Copaxone in children below 12 years of age to make any recommendations for its use. Therefore, Copaxone should not be used in this population. Copaxone should only be administered subcutaneously. Copaxone should not be administered by intravenous or intramuscular routes. Undesirable effects: In all clinical trials, injection-site reactions were seen to be the most frequent adverse reactions and were reported by the majority of patients receiving Copaxone. The most commonly reported injection-site reactions, which were more frequently reported in Copaxone vs. placebo-treated patients, were erythema, pain, mass, pruritus, oedema, inflammation and hypersensitivity. A reaction associated with at least one or more of the following symptoms: vasodilatation, chest pain, dyspnoea, palpitation or tachycardia has been described as the Immediate Post-Injection Reaction. This reaction, reported in clinical trials for 31% of Copaxone patients compared to 13% on placebo, may occur within minutes of a Copaxone injection. All adverse reactions from four controlled clinical trials (512 patients treated with Copaxone and 509 patients treated with placebo), which were more frequently reported in Copaxone vs. placebo treated patients are presented below. *More than 2% (> 2/100) higher incidence in the Copaxone treatment group than in the placebo group. Adverse reactions without the *symbol represents a difference of less than or equal to 2%. Very common (>1/10): infection, influenza, anxiety*, depression, headache, vasodilatation*, dyspnoea*, nausea*, rash*, arthralgia, back pain*, asthenia, chest pain*, injection site reactions*, pain*. Common (>1/100, ≤1/10): bronchitis, gastroenteritis, Herpes simplex, otitis media, rhinitis, tooth abscess, vaginal candidiasis*, benign neoplasm of skin, neoplasm, lymphadenopathy*, hypersensitivity, anorexia, weight increased*, nervousness, dysgeusia, hypertonia, migraine, speech disorder, syncope, tremor*, diplopia, eye disorder*, ear disorder, palpitations*, tachycardia*, cough, rhinitis seasonal, anoctal disorder, Constipation, Dental Caries, Dyspepsia, Dysphagia, Faecal Incontinence, Vomiting*, liver function test abnormal, ecchymosis, hyperhidrosis, pruritus, skin disorder*, urticaria, neck pain, micturition urgency, pollakiuria, urinary retention, chills*, face oedema*, injection site atrophy includes terms which relate to localized lipotrophy at the injection sites, local reaction*, oedema peripheral, oedema, pyrexia. Uncommon (>1/1.000, ≤1/100): abscess, cellulitis, furuncle, Herpes zoster, pyelonephritis, skin cancer, leukocytosis, leukopenia, splenomegaly, thrombocytopenia, lymphocyte morphology abnormal, goitre, hyperthyroidism, alcohol intolerance, gout, hyperlipidaemia, blood sodium increased, serum ferritin decreased, abnormal dreams, confusional state, euphoric mood, hallucination, hostility, mania, personality disorder, suicide attempt, Carpal tunnel syndrome, cognitive disorder, convulsion, dysgraphia, dyslexia, dystonia, motor dysfunction, myoclonus, neuritis, neuromuscular blockade, nystagmus, paralysis, peroneal nerve palsy, stupor, visual field defect, cataract, corneal lesion, dry eye, eye haemorrhage, eyelid ptosis, mydriasis, optic atrophy, extrasystoles, sinus bradycardia, tachycardia paroxysmal, varicose vein, apnoea, choking sensations, epistaxis, hyperventilation, laryngospasms, Lung disorder, colitis, colonic polyp, enterocolitis, eruption, oesophageal ulcer, periodontitis, rectal haemorrhage, salivary gland enlargement, cholelithiasis, hepatomegaly, angioedema, contact dermatitis, erythema nodosum, skin nodule, arthritis, bursitis, flank pain, muscle atrophy, osteoarthritis, haematuria, nephrolithiasis, urinary tract disorder, urine abnormality, abortion, breast engorgement, erectile dysfunction, pelvic prolapse, Priapisms, prostatic disorder, smear cervix abnormal, testicular disorder, vaginal haemorrhage, vulvovaginal disorder, cyst, hangover, hypothermia, inflammation, injection site necrosis, mucous membrane disorder, post vaccination syndrome. rare (>1/10.000, <1/1.000) reports of anaphylactoid reactions were collected from MS patients treated with Copaxone in uncontrolled clinical trials and from post-marketing experience with Copaxone. 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Teva & sanofi-aventis Symposium

INVITATION

9 September 2009, 14:30 - 15:30
Congress Center Düsseldorf

MS TREATMENT NOW AND TOMORROW: WHY, WHO, WHEN AND HOW DO WE MAKE THE RIGHT DECISION?

Chairman: *Xavier Montalban*

Evidence for early to long term benefits of glatiramer acetate

Peter Rieckmann

Making the right treatment decision - when do treatment benefits outweigh the risks?

Mark Tullman



Dear Colleagues,

We are pleased to invite you to a satellite symposium entitled “*MS treatment now and tomorrow: Why, who, when and how do we make the right decision?*” that will take place during the 25th Congress of theECTRIMS.

Multiple sclerosis (MS) is a lifelong, immune-mediated chronic progressive disorder characterised by recurrent relapses and accumulation of physical disability. The management of MS has been transformed by the availability of disease modifying treatments (DMTs) and also symptomatic treatments. Experience with the first line therapeutic options such as glatiramer acetate and interferons show these therapies to be effective and safe both in the short and in the long-term, in preventing or at least modifying a significant portion of the disease activity.

More recently, the focus has shifted to early treatment of clinically isolated syndrome patients. Data from studies in CIS patients, such as the glatiramer acetate PreCISe trial, have provided important information regarding the optimal time to begin treatment, and give a clearer rationale to support early intervention.

With an improved understanding of the disease pathology, basic research and drug development are evolving at an unprecedented pace. The future of MS treatment is poised to change significantly with the introduction of new emerging oral or low frequency injectable therapeutic options now in phase III stage. Once approved, the clinician will be faced with many challenges regarding when, for whom and which therapy to initiate. This symposium will review current understanding of the management of MS, and present new insights and future considerations pertinent to therapeutic decision making.

We look forward to seeing you in Düsseldorf at this stimulating symposium.

Xavier Montalban - Chairman