

INFORMATION FOR AUTHORS SUBMISSION PROCESS

Before submitting a manuscript, please gather the following information:

- All Authors First Names, Middle Names/Initials, Last Names
- Author affiliations/Institutions
- Departments
- Phone and Fax Numbers
- Street Addresses
- E-mail Addresses
- Title and Running Title (you may copy and paste these from your manuscript) YOUR TITLE MUST BE UNDER 80 CHARACTERS (including spaces)

File Formats

- Manuscript files in Word or Text formats

Cover Letter

A cover letter is required and must state that the manuscript has not been published elsewhere, except in abstract form, and is not under simultaneous consideration by another journal.

Once a decision is made by the Editor on your manuscript, the Journal office will send you an Author Release form and a Conflict of Interest form only if your manuscript has been accepted for revision.

Abstracts

For articles that require abstracts either Structured (250 words) or Unstructured (150 words), see website for Manuscript Category specifications.

Articles with structured abstracts should be submitted under conventional headings of introduction, methods and materials, results, discussion, but other headings will be considered if more suitable.

Figures Ideal resolution/Minimum resolution

- Figures/Images in TIF, EPS, PDF, or JPG formats (must follow high resolution formats below)
- Line Bitmap 1200 dpi (ideal) 600 dpi (min)
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- Tables accepted in DOC format only.
- Type tables double-spaced on pages separate from the text.
- Provide a table number and title for each.
- Particular care should be taken in the preparation of tables to ensure that the data are presented clearly and concisely.
- Each column should have a short or abbreviated heading.
- Place explanatory matter in footnotes, not in the heading.
- Do not submit tables as photographs.

Acknowledgements

Acknowledgements, including recognition of financial support, should be typed on a separate page at the end of the text.

The SI system (système international d'unités) should be used in reporting all laboratory data, even if originally reported in another system.

References

- References should be numbered in the order of their citation in the text. Those cited only in tables and legends for illustrations are numbered according to the sequence established by the first identification in the text of a particular table or illustration.
- Titles of journals should be abbreviated according to the style used in Index Medicus.
- List all authors when there are six or fewer; for seven or more, list only the first three and add "et al".
- Provide the full title, year of publication, volume number and inclusive pagination for journal articles.
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- Avoid "personal communications" and, if necessary, include them in the body of the text, not among the references.
- Reference citations should not include unpublished presentations or other non-accessible material.
- Books or chapter references should also include the place of publication and the name of the publisher.

For Uniform Requirements for Sample References go to http://www.nlm.nih.gov/bsd/uniform_requirements.html.

Examples of correct forms of reference:

Journals

1. Rose ME, Huerbin MB, Melick J, et al. Regulation of interstitial excitatory amino acid concentrations after cortical contusion injury. *Brain Res.* 2002;935(1-2):40-6.

Chapter in a book

1. Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. *The genetic basis of human cancer*. New York: McGraw-Hill; 2002. p. 93-113.

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These guidelines apply to each author and their immediate families. Conflicts of interest are not necessarily wrong, nor do they necessarily change the scientific validity of research or opinion, but the Journal and readers should be aware of the conflict. If the Editor considers the conflict to compromise the validity of the paper, it will not be accepted for publication.

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INFORMATION FOR AUTHORS SUBMISSION PROCESS *(continued)*

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- Neuroimaging Highlights*
- Critically Appraised Topics (CATs)
- Brief Communications
- Reflections
- Obituary
- Letters to the Editor
- Medical Hypothesis
- Commentary
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Attention Residents - CNSF 2013 Congress News

For 2013, residents that are members of CNSF societies, are being offered an additional \$100 discount on Congress registration prior to the early bird deadline. Full Congress registration, which includes all sessions, plus pre-congress on June 11th, only \$395 + tax.

Make sure that your member dues are paid prior to registering in order to receive this special rate. Only available to CNSF Junior members and only available until April 30, 2013.

2013 Congress highlights include a Tuesday evening "Resident Career Networking Social". This is a wine and cheese event, organized by the society resident representatives.

Wednesday features two concurrent, all day, Resident Review courses. "Emergency Neurosurgery" and "Movement Disorders and Parkinson's Disease"

Program details and course outlines are available under the "Program" tab on our website at <http://congress.cnsfederation.org/>.

We encourage neurosurgery and neurology residents to participate in our Annual Canadian Congress. It provides the opportunity to network with colleagues and mentors from across the country, creating positive connections for future opportunities.

Join us at the Fairmont Queen Elizabeth in Montreal, June 11-14.



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ALZHEIMER'S PREVENTION & TREATMENT

Clinical Trials Investigator Fellowship

Available July 1, 2013



Alzheimer Society
ONTARIO

Toronto Memory Program is now accepting applications for the new Pfizer-Alzheimer Society of Ontario Dementia Trial Investigator Fellowship to commence July 1, 2013. This one year fellowship was created to address the need for Qualified Investigators in the field of clinical pharmacological research in dementia and will be of interest to those who wish to be involved in advancing treatment options in dementia. The successful applicant will acquire the practical experience in dementia research and dementia practice to assume the role of Principal Investigator at an independent trial site. The fellowship takes place at Toronto Memory Program, Canada's largest dementia clinical pharmacological research site.

Supervisor: Dr. Sharon Cohen, Behavioural Neurologist and PI.

The fellowship curriculum includes practical experience with:

- Clinical research regulations, guidelines, standards
- Principal Investigator responsibilities
- Study design; protocol development
- Research contracts, business development
- Clinical trial operations
- Clinical and research diagnostic criteria in dementia
- Standard of care in dementia clinical practice

To apply, applicants must be licensed, or eligible to be licensed, to practice medicine in Ontario and have completed training in any of the following: family medicine, neurology, geriatrics, psychiatry, or internal medicine.

Salary: \$70,000 (plus practice generated income)

Interested applicants should send:

- A letter of intent detailing your interest in this fellowship
- Current CV, signed and dated

Applications will remain confidential and can be sent to:

Dr. Sharon Cohen, Toronto Memory Program, 400 - 1 Valleybrook Dr., Toronto, ON M3B 2S7 or by email to: cohen@memorydisorders.ca

COPAXONE[®] (glatiramer acetate injection)

Treat from the start. Treat for the long run.

Prescribing Summary

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION: Immunomodulator

INDICATIONS AND CLINICAL USE

COPAXONE[®] is indicated for: the treatment of ambulatory patients with Relapsing Remitting Multiple Sclerosis (RRMS), to decrease the frequency of clinical exacerbations, to reduce the number and volume of active brain lesions identified on Magnetic Resonance Imaging (MRI) scans; for the treatment of patients who have experienced a single demyelinating event, accompanied by abnormal MRI scans and are considered to be at risk of developing Clinically Definite MS (CDMS), after alternative diagnoses are excluded, to delay the onset of definite MS, to decrease the number and volume of active brain lesions and overall disease burden (as identified by MRI scans). The safety and efficacy of COPAXONE[®] in chronic progressive MS have not been established.

with its use. Whether COPAXONE[®] can alter normal human immune responses, such as the recognition of foreign antigens is unknown. It is therefore possible that treatment with COPAXONE[®] may undermine the body's defenses against infections and tumor surveillance. Systematic assessments of these risks have not been done. Continued alteration of cellular immunity due to chronic treatment with glatiramer acetate might result in untoward effects.

Glatiramer acetate-reactive antibodies are formed in practically all patients exposed to daily treatment with the recommended dose. Studies in both the rat and monkey have suggested that immune complexes are deposited in the renal glomeruli. Furthermore, in a controlled clinical trial of 125 RRMS patients given glatiramer acetate 20 mg for 2 years, serum IgG levels reached at least 3 times baseline values in 80% of patients by 3 months of initiation of treatment. By 12 months of treatment, however, 30% of patients still had IgG levels at least 3 times baseline values, and 90% had levels above baseline by 12 months. The antibodies are exclusively of the IgG subtype — and predominantly of the IgG-1 subtype. No IgE type antibodies could be detected in any of the 94 sera tested. Nevertheless, anaphylaxis can be associated with the administration of almost any foreign substance and, therefore, this risk cannot be excluded.

Carcinogenesis and Mutagenesis: Preclinical studies to assess the carcinogenic potential of glatiramer acetate in mice and rats do not suggest any evidence of carcinogenic potential related to glatiramer acetate administered subcutaneously at dose levels of up to 30 mg/kg/day in rats and 60 mg/kg/day in mice (see TOXICOLOGY: Carcinogenicity). The relevance of these findings for humans is unknown (see PRECAUTIONS — Considerations Involving the Use of a Product Capable of Modifying Immune Responses).

Renal: The pharmacokinetics of COPAXONE[®] in patients with impaired renal function have not been determined.

Special Populations: Pregnant Women: There are no adequate and well-controlled studies in pregnant women. No evidence of reproductive toxicity was observed in preclinical studies (see TOXICOLOGY: Reproduction and Teratology). Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. During pre-marketing clinical trials with COPAXONE[®], seven women conceived while being treated with the active drug. One case was lost to follow-up. Three of the patients electively discontinued pregnancy. Three patients stopped treatment 1, 1.5 and 2 months after learning they were pregnant; all delivered healthy babies.

Nursing Women: It is not known whether this drug is excreted in human milk. Because nursing should be used during pregnancy only if clearly needed. During pre-marketing clinical trials with seven women conceived while being treated with the active drug. One case was lost to follow-up. Three of the patients electively discontinued pregnancy. Three patients stopped treatment 1, 1.5 and 2 months after learning they were pregnant; all delivered healthy babies.

Nursing Women: It is not known whether this drug is excreted in human milk. Because nursing should be used during pregnancy only if clearly needed. During pre-marketing clinical trials with seven women conceived while being treated with the active drug. One case was lost to follow-up. Three of the patients electively discontinued pregnancy. Three patients stopped treatment 1, 1.5 and 2 months after learning they were pregnant; all delivered healthy babies.

Pediatrics (< 18 years of age): The safety and effectiveness of COPAXONE[®] have not been studied in individuals below 18 years of age.

Geriatrics (> 65 years of age): COPAXONE[®] has not been studied in the elderly (> 65 years of age).

Monitoring and Laboratory Tests: Data collected pre- and post-market do not suggest a need for routine laboratory monitoring.

ADVERSE REACTIONS

Adverse Drug Reaction Overview: In the 4 placebo-controlled clinical trials, the most common adverse events associated with the use of COPAXONE[®] occurring at an incidence of at least 10% were (in order of descending frequency): injection-site reactions, dyspnea, urticaria, vasodilation, and chest pain.

In the placebo-controlled clinical trials approximately 5% discontinued treatment due to an adverse event compared to 1% for placebo-treated patients. The adverse events most commonly associated with COPAXONE[®] were (in order of descending frequency): injection-site reactions, dyspnea, urticaria, vasodilation, sensitivity. Treatment discontinuation due to a serious adverse event considered by investigators to be related to COPAXONE[®] treatment included a case of life-threatening serum sickness.

Immediate Post-Injection Reaction: Approximately 14% of Multiple Sclerosis patients exposed to COPAXONE[®] in the 4 placebo-controlled studies reported a post-injection reaction immediately following

identified on Magnetic Resonance Imaging (MRI) scans, for the treatment of patients who have experienced a single demyelinating event, accompanied by abnormal MRI scans and are considered to be at risk of developing Clinically Definite MS (CDMS), after alternative diagnoses are excluded, to delay the onset of definite MS, to decrease the number and volume of active brain lesions and overall disease burden (as identified by MRI scans). The safety and efficacy of COPAXONE[®] in chronic progressive MS have not been established.

CONTRAINDICATIONS

COPAXONE[®] (glatiramer acetate) is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol.

Safety Information

WARNINGS AND PRECAUTIONS

The only recommended route of administration of COPAXONE[®] (glatiramer acetate) injection is the subcutaneous route. COPAXONE[®] should not be administered by the intravenous route.

Cardiovascular: Symptoms of Potentially Cardiac Origin: Approximately 13% of COPAXONE[®] patients in the multicenter controlled trials (compared to 5% of placebo patients) experienced at least one episode of what was described as transient chest pain (see ADVERSE REACTIONS: Chest Pain). While some of these episodes occurred in the context of the Immediate Post-Injection Reaction (see ADVERSE REACTIONS: Immediate Post-Injection Reaction), many did not. The pathogenesis of this symptom is unknown. Patients in controlled clinical trials were free of significant cardiovascular problems (New York Heart Association Class I and II) and thus the risks associated with COPAXONE[®] treatment for Multiple Sclerosis patients with comorbid cardiovascular disease are unknown.

COPAXONE[®] has been associated with an Immediate Post-Injection Reaction consisting of a constellation of symptoms appearing immediately after injection that could include flushing, chest pain, tachycardia, anxiety,

mechanism, and whether several similar episodes seen in a given patient have identical mechanisms is unknown. In fact, whether or not this constellation of symptoms actually represents a specific syndrome is unknown. During the post-marketing period, there have been reports of patients with similar symptoms who received emergency medical care (see WARNINGS AND PRECAUTIONS: Symptoms of Potentially Cardiac Origin).

Chest Pain: Approximately 13% of glatiramer acetate patients in the 4 placebo-controlled studies (compared to 5% of placebo patients) experienced at least one episode of what was described as transient chest pain. While some of these episodes occurred in the context of the Immediate Post-Injection Reaction described above, many did not. The temporal relationship of the chest pain to an injection of glatiramer acetate was not always known, although the pain was transient (usually lasting only a few minutes), often unassociated with other symptoms, and expected to have no important clinical sequelae. Some patients experienced more than one episode, and episodes usually began at least 1 month after the initiation of treatment. The pathogenesis of this symptom is unknown. Patients in controlled trials were free of significant cardiovascular disease (New York Heart Association Class I or II); therefore, the risks associated with glatiramer acetate treatment

medical treatment.

General: Patients should be instructed in aseptic reconstitution and self-injection administration of COPAXONE[®] (glatiramer acetate), including a control over the information. The first injection should be performed under the supervision of a care professional. Patient understanding and use of aseptic self-injection techniques should be periodically reevaluated. Patients should be cautioned against the reuse of needles and syringes and instructed on the safe disposal of used needles and syringes. A puncture-resistant container for disposal of used needles and syringes should be provided. Patients should be instructed on the safe disposal of full, used vials.

Localized Adverse Reactions Associated with Subcutaneous Use: At injection sites, severe pain, necrosis have been reported during clinical trials in COPAXONE[®] patients. These reactions may occur after treatment onset (sometimes as early as several days) and are not known to be related to the drug. Patients should be instructed in the use of aseptic self-injection techniques and to rotate injection sites and

DOSAGE AND ADMINISTRATION

COPAXONE® should only be prescribed by (or following consultation with) clinicians who are experienced in the diagnosis and management of Multiple Sclerosis. The only recommended route of administration of COPAXONE® (glatiramer acetate) injection is the subcutaneous route. COPAXONE® should not be administered by the intravenous route.

Recommended Dose and Dosage Adjustment: The recommended dose of COPAXONE® (glatiramer acetate injection) for the treatment of Clinically Isolated Syndrome and Relapsing Remitting MS is a daily injection of 20 mg given subcutaneously. Please see the Part III – Consumer Information – pre-filled syringe for instructions on the preparation and injection of COPAXONE®.

Missed Dose: If a dose is missed it should be taken as soon as possible. If, however, it is closer to the time of the next dose, skip the missed dose and resume at the usual dosing schedule.

Avoid giving 2 injections in the same 12-hour period.

SUPPLEMENTAL PRODUCT INFORMATION
ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions: Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates. The adverse reaction data in this section is derived from 4 pivotal, double-blind, placebo-controlled clinical trials which were conducted during pre-marketing and post-marketing periods in a total of 512 patients treated with glatiramer acetate and 509 patients treated with placebo for up to 36 months. Three trials were conducted in RRMS. The fourth trial was in patients presenting with a first clinical event and MRI features suggestive of MS and included 243 patients treated with glatiramer acetate and 238 patients treated with placebo. All adverse events were recorded by the clinical investigators, using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse events, similar types of events were grouped into standardized categories using MedDRA dictionary terminology. The following table lists treatment-emergent signs and symptoms that occurred in at least 2% of patients treated with glatiramer acetate in the placebo-controlled trials. These signs and symptoms were numerically more common in patients treated with glatiramer acetate than in patients treated with placebo.

Table 1: Controlled Trials – Incidence of Glatiramer Acetate Adverse Reactions ≥2% and More Frequent than Placebo

MedDRA Version 10.0		GA 20 mg (n=512) % of Patients	Placebo (n=509) % of Patients
Blood and Lymphatic System Disorders	Lymphadenopathy	7.2	2.9
Cardiac Disorders	Palpitations	7.6	3.3
	Tachycardia	4.7	1.6
Eye Disorders	Eye Disorder	3.3	1.2
	Diplopia	2.9	1.8
Gastrointestinal Disorders	Nausea	14.5	10.4
	Vomiting	7.4	4.3
	Constipation	7.0	6.3
	Dyspepsia	6.6	6.5
	Dysphagia	2.3	1.2
	Fecal Incontinence	2.3	2.0
General Disorders and Administration Site Conditions	Injection-Site Erythema	46.1	10.6
	Injection-Site Pain	36.3	17.1
	Injection-Site Mass	25.8	5.9
	Injection-Site Pruritus	24.4	2.8
	Asthenia	23.8	23.2
	Injection-Site Edema	20.9	4.5
	Pain	18.9	16.7
	Chest pain	12.5	4.9
	Injection-Site Inflammation	8.2	1.6
	Injection-Site Reaction	8.2	1.4
	Pyrexia	6.4	5.7
	Injection-Site Hypersensitivity	4.1	0.0
	Local Reaction	3.7	1.4
	Face Edema	3.3	0.6
	Edema Peripheral	3.3	2.4
	Chills	2.9	0.4
	Injection-Site Atrophy*	2.0	0.0
	Injection-Site Fibrosis	2.0	0.6
Immune System Disorders	Hypersensitivity	3.3	1.8
Infections and Infestations	Infection	31.8	30.8
	Influenza	15.4	14.5
	Rhinitis	7.4	5.9
	Bronchitis	6.4	5.7
	Gastroenteritis	6.3	4.3
	Vaginal Candidiasis	4.9	2.6
	Otitis Media	3.7	2.9
	Herpes Simplex	2.5	1.8
	Tooth Abscess	2.3	2.2
Metabolism and Nutrition Disorders	Weight Increased	2.9	0.8
	Anorexia	2.3	2.2
Musculoskeletal and Connective Tissue Disorders	Back Pain	13.5	11.2
	Arthralgia	10.4	9.4
	Neck Pain	4.5	3.9

* "Injection-site atrophy" comprises terms relating to localized lipatrophy at injection site.

MedDRA Version 10.0		GA 20 mg (n=512) % of Patients	Placebo (n=509) % of Patients
Nervous System Disorders	Headache	30.9	29.1
	Hypertonia	7.8	7.3
	Tremor	4.1	1.8
	Migraine	3.7	2.4
	Syncope	3.1	1.8
Psychiatric Disorders	Depression	13.1	12.0
	Anxiety	11.1	8.8
	Nervousness	2.3	1.0
Renal and Urinary Disorders	Micturition Urgency	5.1	4.3
	Pollakiuria	4.7	4.5
Respiratory, Thoracic and Mediastinal Disorders	Dyspnea	13.3	2.8
	Cough	6.6	5.3
Skin and Subcutaneous Tissue Disorders	Rash	13.7	9.0
	Hyperhidrosis	6.6	4.7
	Pruritus	5.1	4.3
	Ecchymosis	3.5	3.3
	Urticaria	3.1	1.6
	Skin Disorder	2.9	0.8
Vascular Disorders	Vasodilatation	18.0	4.7

Data on adverse events occurring in the controlled clinical trials were analyzed to evaluate gender-related differences. No clinically significant differences were identified. In these clinical trials 96% of patients were Caucasian. This percentage reflects the higher representation of Caucasian in the MS population, even though it does not reflect the exact world racial distribution among MS patients. In addition, the vast majority of patients treated with COPAXONE® were between the ages of 18 and 45. Consequently, inadequate data are available to perform an analysis of the incidence of adverse events related to clinically relevant age subgroups. Laboratory analyses were performed on all patients participating in the clinical program for COPAXONE®. Clinically significant changes in laboratory values for hematology, chemistry, and urinalysis were similar for both COPAXONE® and placebo groups in blinded clinical trials. No patient receiving COPAXONE® withdrew from any placebo-controlled trial due to abnormal laboratory findings which were assessed as possibly related to glatiramer acetate.

Other Adverse Events Observed During All Clinical Trials: In the pre-marketing clinical trials, approximately 900 individuals have received at least one dose of COPAXONE® (glatiramer acetate) in controlled and uncontrolled clinical trials. Total patient exposure to COPAXONE® in clinical trials ranged from 6 months (693 patients) to 2 years (306 patients), with a subset of patients continuing to 10 years (n=108) and some patients to an average of 13.6 years (n=100) in open-label extensions at a daily dose of 20 mg. During these trials, all adverse events were recorded by clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse events, similar types of events were grouped into a smaller number of standardized categories using COSTART II dictionary terminology. All reported events that occurred at least twice and potentially important events occurring once, are included except those already listed in the previous table, those too general to be informative, trivial events, and other events which occurred in at least 2% of treated patients and were present at equal or greater rates in the placebo group. Events are further classified within body system categories and enumerated in order of decreasing frequency using the following definitions: **Frequent** adverse events are defined as those occurring in at least 1/100 patients; **Infrequent** adverse events are those occurring in 1/100 to 1/1000 patients. **Body as a whole:** Frequent: Injection-site edema, injection-site atrophy, abscess and injection-site hypersensitivity. **Infrequent:** Injection-site hematoma, injection-site fibrosis, moon face, cellulitis, generalized edema, hernia, injection-site abscess, serum sickness, suicide attempt, injection-site hypertrophy, injection-site melanosis, lipoma, and photosensitivity reaction. **Cardiovascular:** Frequent: Hypertension. **Infrequent:** Hypotension, mid-systolic click, systolic murmur, atrial fibrillation, bradycardia, fourth heart sound, postural hypotension and varicose veins. **Digestive:** Frequent: Dry mouth, stomatitis, burning sensation on tongue, cholecystitis, colitis, esophageal ulcer, esophagitis, gastrointestinal carcinoma, gum hemorrhage, hepatomegaly, increased appetite, melena, mouth ulceration, pancreas disorder, pancreatitis, rectal hemorrhage, tenesmus, tongue discoloration and duodenal ulcer. **Endocrine:** Frequent: Goiter, hyperthyroidism, and hypothyroidism. **Gastrointestinal:** Frequent: Bowel urgency, oral moniliasis, salivary gland enlargement, tooth caries, and ulcerative stomatitis. **Hemic and Lymphatic:** Infrequent: Leukopenia, anemia, cyanosis, eosinophilia, hematocrit, lymphedema, pancytopenia, and splenomegaly. **Metabolic and Nutritional:** Infrequent: Weight loss, alcohol intolerance, Cushing's syndrome, gout, abnormal healing, and xanthoma. **Musculoskeletal:** Infrequent: Arthritis, muscle atrophy, bone pain, bursitis, kidney pain, muscle disorder, myopathy, osteomyelitis, tendon pain, and tenosynovitis. **Nervous:** Frequent: Abnormal dreams, emotional lability and stupor. **Infrequent:** Aphasia, ataxia, convulsion, circumoral paresthesia, depersonalization, hallucinations, hostility, hypokinesia, coma, concentration disorder, facial paralysis, decreased libido, manic reaction, memory impairment, myoclonus, neuralgia, paranoid reaction, paraplegia, psychotic depression and transient stupor. **Respiratory:** Frequent: Hyperventilation, hay fever. **Infrequent:** Asthma, pneumonia, epistaxis, hypoventilation, and voice alteration. **Skin and Appendages:** Frequent: Eczema, herpes zoster, pustular rash, skin atrophy and warts. **Infrequent:** Dry skin, skin hypertrophy, dermatitis, furunculosis, psoriasis, angioedema, contact dermatitis, erythema nodosum, fungal dermatitis, maculopapular rash, pigmentation, benign skin neoplasm, skin carcinoma, skin striae, and vesiculobullous rash. **Special Senses:** Frequent: Visual field defect. **Infrequent:** Dry eyes, otitis externa, ptosis, cataract, corneal ulcer, mydriasis, optic neuritis, photophobia, and taste loss. **Urogenital:** Frequent: Amenorrhea, hematuria, impotence, menorrhagia, suspicious Papanicolaou smear, urinary frequency and vaginal hemorrhage. **Infrequent:** Vaginitis, flank pain (kidney), abortion, breast engorgement, breast enlargement, breast pain, carcinoma cervix in situ, fibrocystic breast, kidney calculus, nocturia, ovarian cyst, priapism, pyelonephritis, abnormal sexual function, and urethritis.

Post-Marketing Adverse Drug Reactions

Adverse Events Reported Post-Marketing and Not Previously Noted in Clinical Trials: Post-marketing experience has shown an adverse event profile similar to that presented above. Reports of adverse reactions occurring under treatment with COPAXONE® (glatiramer acetate) in either ongoing phases of clinical trials or from spontaneous reports, that have been received since market introduction and that may have or not have causal relationship to the drug include the following: **Body as a Whole:** Sepsis, SLE syndrome, hydrocephalus, enlarged abdomen, injection-site hypersensitivity, allergic reaction, anaphylactoid reaction, bacterial infection, fever, infection. **Cardiovascular:** Thrombosis, peripheral vascular disease, pericardial effusion, myocardial infarct, deep thrombophlebitis, coronary occlusion, congestive heart failure, cardiomyopathy, cardiomegaly, arrhythmia, angina pectoris, tachycardia. **Digestive:** Tongue edema, stomach ulcer hemorrhage, liver function abnormality, liver damage, hepatitis, eructation, cirrhosis of the liver, cholelithiasis, diarrhea, gastrointestinal disorder. **Hemic and Lymphatic:** Thrombocytopenia, lymphoma-like reaction, acute leukemia. **Metabolic and Nutritional:** Hypercholesterolemia. **Musculoskeletal:** Rheumatoid arthritis, generalized spasm. **Nervous:** Myelitis, meningitis, CNS neoplasm, cerebrovascular accident, brain edema, abnormal dreams, aphasia, convulsion, neuralgia, anxiety, foot drop, nervousness, speech disorder, vertigo. **Respiratory:** Pulmonary embolus, pleural effusion, carcinoma of lung, hay fever, laryngismus. **Skin and Appendages:** Herpes simplex, pruritis, rash, urticaria. **Special Senses:** Glaucoma, blindness, visual field defect. **Urogenital:** Urogenital neoplasm, urine abnormality, ovarian carcinoma, nephrosis, kidney failure, breast carcinoma, bladder carcinoma, urinary frequency. **Localized Adverse Reactions Associated with Subcutaneous Use:** At injection sites, localized lipatrophy and, rarely, injection-site necrosis have been reported during post-marketing experience. Lipatrophy may occur after treatment onset (sometimes as early as several months) and may be permanent. There is no known therapy for lipatrophy. To assist in possibly minimizing these events the patient should be advised to follow proper injection technique and to rotate injection areas and sites on a daily basis (See Part III – Consumer Information).

DRUG INTERACTIONS

Interactions between COPAXONE® and other drugs have not been fully evaluated. Results from existing clinical trials do not suggest any significant interactions of COPAXONE® with therapies commonly used in MS patients. This includes the concurrent use of corticosteroids for up to 28 days. COPAXONE® has not been formally evaluated in combination with Interferon beta. However, 246 patients who failed on or who did not tolerate therapy with Interferon beta and were later treated with COPAXONE® within the framework of an open clinical trial did not report any serious or unexpected adverse events thought to be related to treatment.

OVERDOSAGE

Overdose with COPAXONE® has been reported in three patients. One patient injected four doses (80 mg total) of COPAXONE® at once. No sequelae were noted. Two other patients, a 28-year old male and a 37-year old female, were given 3 injections of 20 mg of COPAXONE® at one half hour intervals by error. Neither patient evidenced any change in blood pressure, heart rate, or temperature. Telephone follow-up several hours later produced no report of adverse experiences from either patient. The maximum COPAXONE® dose reported in an overdose case is 80 mg glatiramer acetate injection.

For management of a suspected overdose, contact your Regional Poison Centre.

Based on Product Monograph dated July 7, 2011. Product Monograph available on request.



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Congress Agenda
as of February 1, 2013

**2013 Canadian Neurological Sciences Federation Annual Congress
June 12-14, 2013 • Fairmont Queen Elizabeth Hotel, Montreal, Quebec**

*Pre-Congress June 11, 2013 *SIG - Special Interest Groups*

Tuesday, June 11, 2013

9:00 am - 5:00 pm	Epilepsy (UCB)	<i>Martin del Campo</i>
6:00 pm - 8:00 pm	Neurocritical Care-Brain Death Workshop SIG	<i>Jeanne Teitelbaum, Draga Jichici</i>
6:00 pm - 8:00 pm	Movement Disorders SIG	<i>David Grimes, Oksana Suchowersky</i>
6:00 pm - 8:00 pm	Epilepsy Video SIG	<i>Seyed Mirsattari</i>
6:00 pm - 8:00 pm	Headache: Migraine & Friends SIG	<i>Elizabeth Leroux</i>
6:00 pm - 8:00 pm	Neuromuscular SIG	<i>Mike Nicolle, Kristine Chapman</i>

Wednesday, June 12, 2013

9:00 am - 5:00 pm	Neurosurgery Residents: Emergency Neurosurgery	<i>Max Findlay, Roberto Diaz</i>
9:00 am - 5:00 pm	Neurology Residents: Movement Disorders and Parkinson's Disease	<i>Pierre J. Blanchet, Nailyn Rasool, Serena Orr</i>
9:00 am - 12:00 pm	Stroke	<i>Alex Poppe, Sylvain Lanthier</i>
9:00 am - 12:00 pm	Hot Topics in Child Neurology	<i>Asif Doja</i>
9:00 am - 12:00 pm	Minimally Invasive Neurosurgery	<i>Kesh Reddy</i>
12:15 pm - 1:45 pm	Co-Developed Symposium TBD	
12:15 pm - 1:45 pm	Scotiabank Lunch n' Learn TBD	
2:00 pm - 5:00 pm	Headache	<i>Sian Spacey</i>
2:00 pm - 5:00 pm	Neuromuscular	<i>Mike Nicolle, Kristine Chapman</i>
2:00 pm - 5:00 pm	Neurocritical Care	<i>Jeanne Teitelbaum, Draga Jichici</i>
5:00 pm - 7:30 pm	Exhibitors' Reception	

Thursday, June 13, 2013

8:30 am - 11:00 am	Grand Plenary	
11:15 am - 12:15 pm	Child Neurology Day: CACN Abstract	<i>Michelle Demos, Craig Campbell</i>
11:15 am - 12:15 pm	CNSS Abstract	
11:15 am - 12:15 pm	CNS/ CSCN Abstract	
12:15 pm - 1:45 pm	Co-Developed TBA	
12:15 pm - 1:45 pm	Lunch n' Learn	
2:00 pm - 5:00 pm	Canadian Neurosurgical Innovations & Discoveries	<i>Brian Toyota</i>
2:00 pm - 5:00 pm	Child Neurology Day	<i>Michelle Demos, Craig Campbell</i>
2:00 pm - 5:00 pm	Epilepsy	<i>Jorge Burneo</i>
2:00 pm - 5:00 pm	EEG	<i>Seyed Mirsattari</i>
2:00 pm - 5:00 pm	MASS: Minimal Access Spine Surgery	<i>Eric Massicotte</i>
2:00 pm - 5:00 pm	Promises of Stem Cells in the Neurosciences	<i>Peter Dirks</i>
5:00 pm - 6:30 pm	Digital Poster Author Standby	

Friday, June 14, 2013

8:00 am - 11:00 am	Platform Sessions	
11:15 am - 1:00 pm	Grand Rounds	
1:00 pm - 2:15 pm	Digital Poster Author Standby	
2:15 pm - 5:15 pm	Difficult Cases in Neurosurgery	<i>Joseph Megyesi</i>
2:15 pm - 5:15 pm	Multiple Sclerosis	<i>Paul Giacomini, Catherine Larochelle</i>
2:15 pm - 5:15 pm	Neurovascular & Interventional Neuroradiology	<i>Gary Redekop</i>
2:15 pm - 5:15 pm	Genetics of Neurological & Neuro Degenerative Syndromes	<i>Matt Farrer</i>
2:15 pm - 5:15 pm	Neuro-Ophthalmology	<i>Jason Barton</i>

