

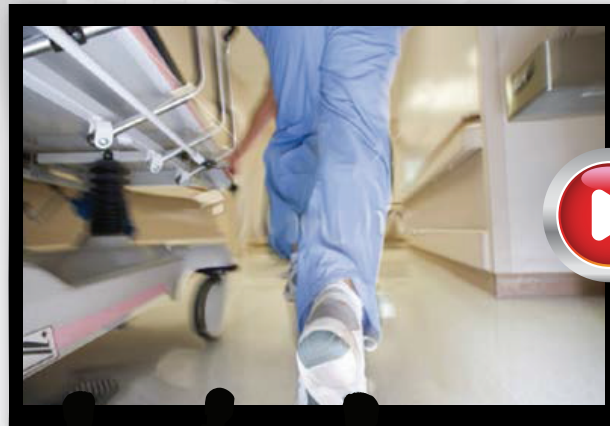


Join us
this fall!

ER Direct Luncheon Series

ACS and Thrombosis in the Emergency Setting

Coming to
12 Canadian
Cities...
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through CAEP.ca!



Program Highlights

ER Direct program is created with the intention to deliver the most recent updates on ACS and stroke/AF diagnosis and first line treatment. The program is relevant to all types of emergency settings: hospital-affiliated, community, and rural. Attendees will benefit from this interactive CME program, where four local expert panelists review case-based videos and facilitate the program through discussion and audience polling questions. Two of the clinical cases demonstrate challenges of first line emergency care for ACS (STEMI and NSTEMI) including accurate early diagnosis and appropriate antiplatelet treatment. The third case features an atrial fibrillation patient treated with novel anticoagulants and readmitted with an internal bleed.

For more information about this program, please visit: www.erdirect.ca

Research is important in all areas of emergency medicine. As such, physicians and fellows working in diverse academic, non-academic, community, and rural settings are encouraged to electronically submit Research Grant applications.

PRE-REQUISITE FOR SUBMITTING PROPOSALS

- The Principal Investigator (PI) and Supervisor (for Residents and Fellows only) must be current CAEP members at the time of application
- The PI must be < 8 years beyond postgraduate training
- A letter from Resident's/Fellow's Supervisor must be included with the proposal

APPLICATION PROCESS

Grants are submitted electronically. More information on the competition and the full submission instructions will be posted on the CAEP Research Page (www.caep.ca/research).

Proposals must be single-spaced text (excluding references and appendices) using size 12 font. Submissions will include:

- Structured Research Abstract
- Research In Depth
- Timeline and Impact
- References
- Research Data Collection Tool
- Detailed Budget and Justification
- Curriculum Vitae of the Principal Investigator ONLY
- Accompanying Letter from the Responsible Supervisor

A Cover Letter is not required.

GRANT REVIEW PROCESS

Grants are peer reviewed by 3 CAEP Grant Reviewers using a standardized evaluation form. Reviewers are blinded to the author's name and institutional affiliations. Reviewers will not review grants from their own province and strict conflict of interest declarations are provided to each reviewer. Reviewers consider:

- Relevancy to emergency medicine
- Methodological quality
- Originality of the topic and methodology
- Level of training
- Ability to complete the proposed study

Notification of acceptance will be transmitted via email no later than January 31, 2014.

FUNDING PROVISIONS

Funding support to an individual project will not exceed \$5000. Funding cannot be a supplement to other funding sources and shall not be used for meeting registration, travel or equipment purchases.



Large enough to be cutting edge, small enough to be remarkable.

Located in Simcoe, Ontario, **Norfolk General Hospital** provides exceptional health care to a municipality of approximately 69,000 people. Our area of focus provides a continuum of service throughout the life span of the people we serve, including Emergency, Critical Care, Obstetrics as well as on-site 24-hour per day emergency coverage.

Supporting approximately 29,000 cases per year, our modern 9,000 square foot Emergency Department and McMaster University teaching site is staffed by a combination of ED and family physicians. The workload model includes AFA remuneration. The following full-time, part-time, and locum practice opportunities are available:

- **Emergency Physicians**
- **Hospitalists**
- **Family Medicine Physicians**

Simcoe is less than one hour away from most major centres, including Hamilton and London, and only 90 minutes from the Greater Toronto Area. Situated in Norfolk County (Ontario's South Coast), Simcoe is not far from Lake Erie and the 88 miles of shoreline that includes long stretches of sandy beach.

Contact **Carolynn Beam, Physician Liaison** at 519-426-0130 extension 1259 or via email at cbeam@ngh.on.ca to arrange your personalized tour today!

For more information about NGH and these positions, please visit www.ngh.on.ca.

www.ngh.on.ca

CAEP | ACMU ROADSHOWS

CME That Travels

AIME: Airway Interventions & Management in Emergencies

September 25, 2013 - Whistler BC

November 7, 2013 - Vancouver BC

November 8, 2013 - Vancouver BC

EDTU: Emergency Department Targeted Ultrasound

October 5, 2013 - Edmonton AB

October 6, 2013 - Edmonton AB

MSK: Musculoskeletal Injuries in Adults & Children in the ED

September 26, 2013 - Whistler BC

TOX: Hot Talks - Cool Tox

October 17, 2013 - Saskatoon SK

November 15, 2013 - Perth ON

November 6, 2013 - Vancouver BC

December 11, 2013 - Montreal QC

REGISTER NOW AT CAEP.CA

* Roadshow dates are subject to change without notice. Additional roadshows are always being scheduled. Check CAEP website often for the most current CME schedule.

EMERGENCY PHYSICIANS

Permanent Full and Part Time Opportunities

Belleville General Hospital, Trenton Memorial Hospital, and North Hastings Hospital

QUINTE HEALTH CARE

The four hospitals of Quinte Health Care (QHC) provide primary and secondary services to a population of 160,000 in Hastings and Prince Edward Counties. The region, which has become one of Canada's most desired locations to live, includes a number of diverse and culturally rich urban and rural communities within an area defined by both its pastoral settings and its proximity to a multitude of waterways.

Opportunities

Belleville General

The Belleville General Emergency Department sees over 38,000 cases annually, and members receive outstanding remuneration based on our AFA. The ER physicians have access to state of the art diagnostic equipment including ER Ultrasound, a 64 multi-slice CT scanner and an MRI. As of June 2013 the Belleville General Emergency Department will move to a newly constructed facility simply unrivalled in the region.

North Hastings

Physicians can enjoy comprehensive ER medicine in a rural setting. The North Hastings ER department has over 14,000 visits annually. Opportunity also exists to combine family medicine and ER work. A variety of payment options are available for either full-time or part-time work.

Trenton Memorial

The Department of Emergency Medicine at Quinte Health Care Trenton Memorial site consists of a dynamic team of physicians. Trenton Memorial sees over 34,000 cases annually and is paid an hourly rate based on their AFA. There is an on-site CT Scanner and access to an MRI at the Belleville General site.

Candidates

We are looking for additional emergency physicians with CCFP (EM) or FRCPC designations and/or extensive emergency medicine experience. Applicants must be current with ACLS, ATLS, and PALS certifications and be eligible for licensure in the Province of Ontario.

Interested candidates please contact:

Bree Ricketts-Gaber
p: 613-969-7400 or 1-800-483-2811 x 2600
bricketts@qhc.on.ca



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When donating to CAEP Research, your money is directed to serious researchers who make a difference in emergency medicine, with relevant and critical research proposals.

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CAEP | Canadian Association
of Emergency Physicians
ACMU | Association canadienne
des médecins d'urgence

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WINNIPEG REGIONAL HEALTH AUTHORITY

EMERGENCY PROGRAM

HEALTH SCIENCES CENTRE, WINNIPEG, MANITOBA, CANADA

SITE MEDICAL DIRECTOR

The Winnipeg Regional Health Authority ("WRHA") Emergency Program is seeking to fill a full-time position (.4 administration and .6 Clinical) with an outstanding individual who will provide forward-thinking leadership in the WRHA Emergency Program as the Site Medical Leader at the Health Science Centre ("HSC").

The ideal candidate would be an experienced and respected Emergency Medicine physician with outstanding clinical, mentorship, administration and leadership skills. This is a challenging and exciting opportunity for a qualified individual to provide medical leadership, ensure effective and efficient delivery of quality care, and participate in the planning and coordination of the Emergency Department's clinical activities within the region-wide Emergency Program. Candidate should have the ability to communicate, see connections, and establish purposeful working relationships with colleagues throughout the region.

The Health Sciences Centre (HSC) is one of six hospitals within the WRHA and the largest Health Care Centre in the Province of Manitoba. It is the designated Trauma Centre for the Province as well as the centre for transplants, burns, neurosciences with a referral base of over a million people. The WRHA has a strong affiliation with the University of Manitoba, Faculty of Medicine, and residents from all programs – including robust training programs for FRCP-EM and CCFP-EM. The pathology that presents to the HSC emergency department provides excellent opportunities for teaching and research, along with an exciting and challenging clinical practice.

Winnipeg is located in the heart of North America and home to over 760,000 people known for their friendly, welcoming spirit. It is a growing and vibrant city that has an innovative arts scene, year round festivals, bountiful tantalizing restaurants, fabulous shopping and a dynamic music, and sports scene. It is home to charming neighborhoods, beautiful tree-lined streets, and an abundance of outdoor spaces and parks, all of which can be enjoyed year round with 2,300 hours of sunlight annually and up to 16 hours of sunlight in the summer. Come experience it for yourself! www.tourismwinnipeg.com/teamwinnipeg/top-reasons-to-choose-winnipeg

Remuneration for this key position is competitive.

Candidate must be eligible for registration with the College of Physicians and Surgeons of Manitoba and have CCFP (EM) or FRCPC certification in Emergency Medicine.

SUBMIT APPLICATIONS TO:

Physician Recruitment
4th Floor, 650 Main Street
Winnipeg, MB R3B 1E2
physicianrecruitment@wrha.mb.ca



Winnipeg Regional
Health Authority
Office régional de la
santé de Winnipeg
*Caring for Health
À l'écoute de notre santé*

wrha.mb.ca

FULL TIME POSITIONS

CALGARY EMERGENCY DEPARTMENT

The Department of Emergency Medicine (Alberta Health Services – Calgary Zone) is now accepting applications for full time emergency physicians. Flexible start dates are available, beginning throughout 2013.

The Calgary Department of Emergency Medicine encompasses two emergency medicine residency programs and four hospital sites seeing over 260,000 patients per year. The fourth site, the South Health Campus opened in January 2013 and has one of Canada's most advanced Emergency Departments. In addition to a full spectrum of high acuity clinical medicine, trauma and cardiac care, we have active programs in human patient simulation and EM ultrasound, and Calgary is the home of STARS (Shock Trauma Air Rescue Society), one of North America's longest operating rotary wing aero medical systems. The Calgary Department of Emergency Medicine has a growing academic program with research and teaching opportunities.

Calgary is a vibrant, multicultural city (population 1.2 million) near the Rocky Mountains, Banff National Park and Lake Louise with a full range of recreational, sports and cultural opportunities. Alberta emergency physicians are among the highest paid in North America, and enjoy a flexible work/life balance while working in a highly supportive, collegial environment.

Requirements: CCFP (EM), ABEM or FRCPC training and certification is required, as well as eligibility for licensure in the province of Alberta.

Interested applicants should forward their curriculum vitae, cover letter and have 3 letters of recommendation sent to:

Scott H. Banks, MBA, CHRP, CITP
Zone Department Manager, Emergency Medicine
Foothills Medical Centre
Room C231, 1403 -29th St NW
Calgary, AB T2N 2T9

Email: scott.banks@albertahealthservices.ca





Fellowship in Resuscitation

Queen's University and the Kingston Resuscitation Institute are offering Fellowship training in Resuscitation and Reanimation. Started in 2008, the program runs from July 1 to June 30 and will consider emergency residents interested in overlap during the 4th year of a 5-year training program.

Students experience a spiral curriculum with three arms: the Science of Resuscitation Medicine; Medical Education and Simulation; and Leadership and Crisis Resource Management. For more information visit:

www.resuscitationinstitute.org/index.cfm/courses/resuscitation-fellowship/

or contact Dr. Daniel Howes: howesd@kgh.kari.net



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A quarter of a million visitors come to Western Maryland each year - the smart ones figure out a way to stay. Enjoy the good life that Western Maryland has to offer - scenic beauty; outdoor activities; friendly, safe communities and life at a pace you can enjoy.

Western Maryland's mountains and nearby state parks are great for camping, hiking, fishing, boating, canoeing, hunting, swimming, and biking. Within a quick 2 hour drive enjoy the cultural events in Washington, D.C., Baltimore and Pittsburgh.

FOR MORE INFORMATION CONTACT:

REBECCA COWMAN
301-944-0040
rcowman@emergencydocs.com

We are seeking experienced **Emergency Medicine Physicians** to join the MEP team at the **Western Maryland Regional Medical Center (WMRMC)**. Enjoy the benefits of working with MEP:

- Productivity Based Compensation
- Comprehensive Benefits Package
- Leadership/Ownership Opportunities
- **VISA's ARE ACCEPTED!**
- 60k Sign-On Bonus
- Level III Trauma Center



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Thunder Bay Regional Health Sciences Centre
Emergency Department

Full Time and Locum Positions



The Thunder Bay Regional Health Sciences Centre Emergency Department (ED) averages approximately 300 patient visits per day and is one of Canada's busiest EDs. Our ED is an academic centre, training medical students and residents, including CCFP(EM) candidates, through our affiliation with the Northern Ontario School of Medicine. Our facility is a designated regional trauma centre, and has intensive care, cath lab, stroke, and in-patient pediatric services.

Start dates are flexible. Please contact us to learn more about this exciting career opportunity. Interested applicants should forward their curriculum vitae to:

Michael Chang,
MD CCFP (EM)
Emergency Physician
Co-Director,
Recruitment/Retention

980 Oliver Road,
Thunder Bay,
ON. P7B 6V4

Telephone: 807-684-6115
Fax: 807-684-5828

changm@tbh.net

It is a great place to practice the full scope of Emergency Medicine.

Beautiful and friendly Thunder Bay (pop. 110,000) is located on the northern shore of Lake Superior in North Western Ontario. We offer fantastic opportunities for outdoor recreation including sailing, kayaking, fishing, hiking, cross-country and downhill skiing.

Thunder Bay Emergency Physicians are among the highest paid in Canada. We are a supportive and collegial group dedicated to quality patient care, medical education, and a good work/life balance.



healthy together

Allerject™

Voice-assisted Auto Injector
Epinephrine: 0.3 mg/0.3 mL / 0.15 mg/0.15 mL



Prescribing Summary



Patient Selection Criteria

THERAPEUTIC CLASSIFICATION

Catecholamine/Sympatomimetic

INDICATIONS AND CLINICAL USE

ALLERJECT™ 0.3 mg (0.3 mL Epinephrine Injection, USP, 1:1000) and ALLERJECT™ 0.15 mg (0.15 mL Epinephrine Injection, USP, 1:1000) are indicated for the emergency treatment of anaphylactic reactions in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Selection of the appropriate dosage strength is determined according to patient body weight. ALLERJECT™ is intended for immediate self-administration for the emergency treatment of severe allergic reactions (Type I), including anaphylaxis associated with: • foods (e.g., peanuts, tree nuts, shellfish, fish, milk, eggs, and wheat) • stinging insects (e.g., Order Hymenoptera, including bees, wasps, hornets, yellow jackets, and fire ants) and biting insects (e.g., mosquitoes and black flies) • medications • latex • idiopathic anaphylaxis • exercise-induced anaphylaxis • other allergens. Epinephrine is the drug of choice for the emergency treatment of severe allergic reactions. The strong vasoconstrictor action of epinephrine, through its effect on alpha adrenergic receptors, quickly counteracts vasodilation and increased vascular permeability which can lead to loss of intravascular fluid volume and hypotension during anaphylactic reactions. ALLERJECT™ is designed as emergency supportive therapy only and not as a replacement or substitute for subsequent medical or hospital care, nor are they intended to supplant insect venom hyposensitization. After injection seek immediate medical attention. All individuals receiving emergency epinephrine must be immediately transported to hospital, ideally by ambulance, for evaluation and observation.

Clinical Signs and Symptoms of Anaphylaxis

Anaphylaxis is a serious, acute, allergic reaction that may cause death. It has a sudden onset and generally lasts less than 24 hours. Because anaphylaxis is a generalized reaction, a wide variety of clinical signs and symptoms may be observed. One to 2% of the general population are estimated to be at risk for anaphylaxis from food allergies and insect stings, with a lower reported prevalence for drugs and latex. People with asthma are at particular risk. **Symptoms of anaphylaxis may include:** **Oral:** pruritus of lips, tongue, and palate, edema of lips and tongue; metallic taste in the mouth. **Cutaneous:** flushing, pruritus, urticaria, angioedema, morbilliform rash, and pilor erecti. **Gastrointestinal:** nausea, abdominal pain, vomiting, and diarrhea. **Respiratory:** **Laryngeal:** pruritus and “tightness” in the throat, dysphagia, dysphonia, hoarseness, wheezing, and cough. **Nasal:** nasal pruritus, congestion, rhinorrhea, sneezing, and sensation of itching in the external auditory canals. **Cardiovascular:** feeling of faintness, syncope, chest pain, dysrhythmia, hypotension. **Note:** Hypotension is a sign of anaphylaxis. Patients should be treated in the early stages of anaphylaxis to prevent hypotension from developing. **Other:** periorbital pruritus, erythema and edema, conjunctival erythema, and tearing; lower back pain and uterine contractions in women; aura of “doom”. The severity of previous anaphylactic reactions does not determine the severity of future reactions, and subsequent reactions could be the same, better, or worse. The severity may depend on the degree of sensitivity, the dose of allergen, and other factors. Research shows that fatalities from anaphylaxis are often associated with failure to use epinephrine or a delay in the use of epinephrine treatment. Epinephrine should be administered as early as possible after the onset of symptoms of a severe allergic response. Patients requiring epinephrine will not always have predictable reactions. Adequate warning signs are not always present before serious reactions occur. It is recommended that epinephrine be given at the start of any reaction associated with a known or suspected allergen contact. In patients with a history of severe cardiovascular collapse on exposure to an allergen, the physician may advise that epinephrine be administered immediately after exposure to that allergen, and before any reaction has begun. Epinephrine may prove to be life saving when used as directed immediately

following exposure to an allergen. In most patients, epinephrine is effective after 1 injection. However, symptoms may recur and further injections may be required to control the reaction. Epinephrine can be re-injected every 5 to 15 minutes until there is resolution of the anaphylaxis or signs of adrenaline excess (such as palpitations, tremor, uncomfortable apprehension and anxiety). All individuals receiving emergency epinephrine must be immediately transported to hospital, ideally by ambulance, for evaluation and observation. Repeat attacks have occurred hours later without additional exposure to the offending allergen. Therefore, it is recommended that a patient suffering from an anaphylactic reaction be observed in an emergency facility for an appropriate period because of the possibility of either a “biphasic” reaction (a second reaction) or a prolonged reaction. At least a four hour period of observation is advised, although this time may vary. The attending physician will take into consideration such factors as the severity of the reaction, the patient’s response and history and the distance from the hospital to the patient’s home. Anaphylactic reactions typically follow a uniphasic course; however, 20% will be biphasic in nature. The second phase usually occurs after an asymptomatic period of 1 to 8 hours, but may occur up to 38 hours (mean 10 hours) after the initial reaction. About one third of the second phase reactions are more severe, one third are as severe, and one third are less severe. The second-phase reactions can occur even following administration of corticosteroids. **Following treatment of anaphylaxis, the patient must stay within close proximity to a hospital or where he or she can call 911 for the next 48 hours.** Protracted anaphylaxis, which is frequently associated with profound hypotension and sometimes lasts longer than 24 hours, is minimally responsive to aggressive therapy, and has a poor prognosis.

CONTRAINDICATIONS

There are no absolute contraindications to the use of epinephrine in a life-threatening allergic situation.



Safety Information

WARNINGS AND PRECAUTIONS

General: Patients with a history of anaphylaxis are at risk for subsequent episodes and even death. All patients who have had one or more episodes of anaphylaxis should have injectable epinephrine with them or with their parent or caregiver at all times, and should wear some form of medical identification bracelet or necklace. Epinephrine injection is not intended as a substitute for medical attention or hospital care. In conjunction with the administration of epinephrine, the patient should seek appropriate medical care. More than two sequential doses of epinephrine should only be administered under direct medical supervision. Antihistamines and asthma medications must not be used as first line treatment for an anaphylactic reaction. Following the resolution of an anaphylactic episode and discharge from hospital, the patient should immediately obtain and fill a new ALLERJECT™ auto-injector prescription. **Injection site ALLERJECT™ should ONLY be injected into the anterolateral aspect of the thigh. Patients should be advised that ALLERJECT™ is not intended for intravenous injection.** Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration. **Patients should be advised that ALLERJECT™ is not intended for injection into the buttock.** Injection into the buttock may not provide effective treatment of anaphylaxis; advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis. **Patients should be advised that ALLERJECT™ is not intended for injection into digits, hands or feet.** Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Treatment of such inadvertent administration should consist of vasodilation, in addition to further appropriate treatment of anaphylaxis. The presence of a condition listed below is not a contraindication to epinephrine administration in an acute, life-threatening situation. Therefore, patients with these conditions, or any other person who might be in a position to administer epinephrine to a patient with these conditions experiencing anaphylaxis, should be instructed about the circumstances under which epinephrine should be used: **Cardiovascular** Epinephrine use should be avoided in patients with cardiogenic, traumatic, or hemorrhagic shock; cardiac dilation; and/or cerebral arteriosclerosis. Epinephrine should be used with caution in patients with cardiac arrhythmias, coronary artery or organic heart disease, hypertension, or in patients who are on medications that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. Patients with

hypertension or hyperthyroidism are prone to more severe or persistent effects.

Endocrine and Metabolism Patients with diabetes may develop increased blood glucose levels following epinephrine administration. **Neurologic** Epinephrine use should be avoided in patients with organic brain damage. Patients with Parkinson's disease may notice a temporary worsening of symptoms after treatment with epinephrine. **Ophthalmologic** Epinephrine use should be avoided in patients with narrow-angle glaucoma. **Respiratory** There is a significantly increased risk of respiratory symptoms in patients with concomitant asthma, especially if poorly controlled. These patients are at increased risk of death from anaphylaxis. Fatalities may also occur from pulmonary edema resulting from peripheral constriction and cardiac stimulation. **Sensitivity** This product contains sodium metabisulfite, a substance which may cause allergic-type reactions including anaphylactic symptoms or mild to severe asthmatic episodes in certain susceptible persons. Nevertheless, epinephrine is the drug of choice for serious allergic reactions and the presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations, even if the patient is sulfite-sensitive. **Reproduction** No studies have been conducted to determine epinephrine's potential effect on fertility. **Special Populations Pregnant Women:** Although there are no adequate and well-controlled studies in pregnant women, epinephrine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. **Pediatrics (patients 15-30 kg):** There are no data to suggest a difference in safety or effectiveness of epinephrine between adults and children in this weight group. **Geriatrics (patients > 65 years of age):** Elderly patients with hypertension, coronary artery disease or cardiac arrhythmias are particularly at risk for epinephrine overdose. More careful monitoring and avoidance of epinephrine overdose is recommended for these patients.

ADVERSE REACTIONS

Adverse reactions of epinephrine include transient, moderate anxiety; feelings of over stimulation; apprehensiveness; restlessness; tremor; weakness; shakiness; dizziness; sweating; tachycardia; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. Ventricular arrhythmias may follow administration of epinephrine. While these symptoms occur in some patients treated with epinephrine, they are likely to be more pronounced in patients with hypertension or hyperthyroidism. These signs and symptoms usually subside rapidly, especially with bed rest. Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include elderly individuals, pregnant women, and patients with diabetes. Patients with coronary artery disease are prone to more severe or persistent effects, and may experience angina. Excessive doses cause acute hypertension. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs. The potential for epinephrine to produce these types of adverse reactions does not contraindicate its use in an acute life-threatening allergic reaction.

DRUG INTERACTIONS

There are no known contraindications to the use of epinephrine in a life-threatening allergic reaction. **Drug-Drug Interactions** Epinephrine should be used with caution in patients who are on medications that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics. In such patients, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. Caution is advised in patients receiving cardiac glycosides or diuretics, since these agents may sensitize the myocardium to beta-adrenergic stimulation and make cardiac arrhythmias more likely. The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, sodium levothyroxine, and certain antihistamines, notably chlorpheniramine, triprolidine, and diphenhydramine. The cardio-stimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol. Anaphylaxis may be made worse by beta blockers because these drugs decrease the effectiveness of epinephrine. The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine. Phenothiazines may also reverse the pressor effects of epinephrine. Deaths have been reported in asthmatic patients treated with epinephrine following the use of isoproterenol, orciprenaline, salbutamol, and long acting beta agonists. **Drug-Lifestyle Interactions** Cocaine sensitizes the heart to catecholamines (as does uncontrolled hyperthyroidism), and epinephrine use in these patients should be cautious.

If you suspect you have a serious or unexpected reaction to this drug, you may notify Health Canada by telephone at 1-866-234-2345 or sanofi-aventis Canada Inc. at 1 800 265-7927.



Administration

DOSAGE AND ADMINISTRATION

A health professional should review the patient instructions and operation of ALLERJECT™, in detail, with the patient or caregiver. Epinephrine is essential for the treatment of anaphylaxis. Patients who are at risk of or with a history of severe allergic reactions (anaphylaxis) should be carefully instructed about the circumstances under which epinephrine should be used. The prescriber should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is indicated. With severe persistent anaphylaxis episode, repeat injections of epinephrine may be necessary. More than two sequential doses of epinephrine should only be administered under direct medical supervision. **Voice-assisted auto injector** The voice-assisted auto injector is designed to accurately deliver the required dosage of epinephrine for immediate self-administration for the emergency treatment of severe allergic reactions (Type I), including anaphylaxis. The injector has been designed to be easy-to-use, portable and ergonomic in order to assist patients with complying with recommendations that epinephrine should be available at all times and administered without delay in an allergic emergency. The device also includes several features to mitigate use-related hazards, such as a retractable needle system, a safety tab mechanism, and an electronic voice and visual prompt system that assist the user through the injection process. **Dosing Considerations** Selection of the appropriate dosage strength (ALLERJECT™ 0.3 mg or ALLERJECT™ 0.15 mg) is determined according to patient body weight. A physician who prescribes ALLERJECT™ 0.3 mg or ALLERJECT™ 0.15 mg auto-injector should take appropriate steps to ensure that the patient thoroughly understands the indications and use of the device. The physician should review with the patient, in detail, the CONSUMER INFORMATION section and operation of the auto-injector. ALLERJECT™ 0.3 mg auto-injector contains 0.76 mL of solution but delivers a single dose of 0.3 mL only, with 0.46 mL remaining in the unit, after activation. The remaining volume cannot be used. ALLERJECT™ 0.15 mg auto-injector contains 0.76 mL of solution but delivers a single dose of 0.15 mL only, with 0.61 mL remaining in the unit, after activation. The remaining volume cannot be used. Inject ALLERJECT™ intramuscularly into the anterolateral aspect of the thigh, through clothing if necessary. **Do not inject into the buttock. Recommended Dose and Dosage Adjustment** **ALLERJECT™ 0.3 mg:** ALLERJECT™ 0.3 mg delivers 0.3 mg epinephrine injection (0.3 mL, 1:1000) and is intended for patients who weigh 30 kg or more. **ALLERJECT™ 0.15 mg:** ALLERJECT™ 0.15 mg delivers 0.15 mg epinephrine injection (0.15 mL, 1:1000) and is intended for patients who weigh 15 to 30 kg. Each ALLERJECT™ contains a single dose of epinephrine. Since the doses of epinephrine delivered from ALLERJECT™ are fixed, consider using other forms of injectable epinephrine if doses lower than 0.15 mg are deemed necessary. **Administration** ALLERJECT™ instructional and safety systems should be thoroughly reviewed with patients and caregivers prior to use. The epinephrine solution in the viewing window of ALLERJECT™ should be inspected visually for particulate matter and discoloration. Replace ALLERJECT™ if the epinephrine solution appears cloudy, discolored, contains particles, if the RED safety guard has previously been removed, or the expiration date has passed. Epinephrine is light sensitive and should be stored in the outer case provided to protect it from light.

Product Monograph or full Prescribing Information can be found at: <http://www.sanofi.ca> or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-855-405-4321.

SUPPLEMENTAL PRODUCT INFORMATION OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre. Epinephrine is rapidly inactivated in the body, and treatment following overdose with epinephrine is primarily supportive. If necessary, pressor effects may be counteracted by rapidly acting vasodilators or alpha-adrenergic blocking drugs. If prolonged hypotension follows such measures, it may be necessary to administer another pressor drug. Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Overdosage sometimes also results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations. Epinephrine overdosage can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol. If an epinephrine overdose induces pulmonary edema that interferes with respiration, treatment consists of a rapidly acting alpha-adrenergic blocking drug and/or intermittent positive-pressure respiration. Premature ventricular contractions may appear within 1 minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block.

Manufactured for sanofi-aventis Canada Inc., Laval, Quebec, Canada H7V 0A3



PRESCRIBING SUMMARY

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION: Antidote (Powder for solution for infusion)

INDICATIONS AND CLINICAL USE: Cyanokit[®] contains hydroxocobalamin, an antidote indicated for the treatment of known or suspected cyanide poisoning. Cyanokit[®] is to be administered together with appropriate decontamination and supportive measures.

Identifying patients with cyanide poisoning: Cyanide poisoning may result from inhalation, ingestion, or dermal exposure to various cyanide containing compounds, including smoke from closed space fires. Sources of cyanide poisoning include hydrogen cyanide and its salts, cyanogens, including cyanogenic plants, aliphatic nitriles, or prolonged exposure to sodium nitroprusside. The presence and extent of cyanide poisoning are often initially unknown. There is no widely available, rapid, confirmatory cyanide blood test. Treatment decisions must be made on the basis of clinical history and signs and symptoms of cyanide intoxication. If clinical suspicion of cyanide poisoning is high, Cyanokit[®] should be administered without delay.

Table 1. Common Signs and Symptoms of Cyanide Poisoning

Symptoms	Signs
<ul style="list-style-type: none"> • Headache • Confusion • Dyspnea • Chest tightness • Nausea 	<ul style="list-style-type: none"> • Altered Mental Status (e.g., confusion, disorientation) • Seizures or Coma • Mydriasis • Tachypnea/Hyperpnea (early) • Bradypnea/Apnea (late) • Hypertension (early)/Hypotension (late) • Cardiovascular collapse • Vomiting • Plasma lactate concentration ≥ 8 mmol/L

In some settings, panic symptoms, including tachypnea and vomiting, may mimic early cyanide poisoning signs. The presence of altered mental status (confusion and disorientation) and/or mydriasis is suggestive of true cyanide poisoning, although these signs can occur with other toxic exposures as well.

Smoke inhalation: Not all smoke inhalation victims will necessarily have cyanide poisoning, and may present with burns, trauma, and exposure to additional toxic substances making a diagnosis of cyanide poisoning particularly difficult. Prior to the administration of Cyanokit[®], smoke-inhalation victims should be assessed for the following:

- exposure to fire smoke in an enclosed area
- soot present around mouth, nose and/or oropharynx
- altered mental status

Use with Other Cyanide Antidotes: The safety of administering other cyanide antidotes simultaneously with Cyanokit[®] has not been established. If the decision is made to administer another cyanide antidote with Cyanokit[®], these medicinal products must not be administered concurrently in the same intravenous line (see **DOSAGE AND ADMINISTRATION**).

Geriatrics (≥ 65 years of age): Approximately 50 known or suspected cyanide victims aged 65 or older received hydroxocobalamin in clinical studies. In general, the safety and effectiveness of hydroxocobalamin in these patients was similar to that of younger patients. No adjustment of dose is required in elderly patients.

Pediatrics (< 18 years of age): Limited safety and efficacy data are available for pediatric patients. In infants to adolescents, the dose of Cyanokit[®] is 70 mg/kg (see **DOSAGE AND ADMINISTRATION**).

CONTRAINDICATIONS: None.

SPECIAL POPULATIONS: For use in special populations, see **WARNINGS AND PRECAUTIONS**, Special Populations.

Safety Information

WARNINGS AND PRECAUTIONS

General: Emergency Patient Management – In addition to Cyanokit[®] treatment of cyanide poisoning must include immediate attention to airway patency, adequacy of oxygenation and hydration, cardiovascular support, and management of any seizure activity. Consideration should be given to decontamination measures based on the route of exposure. Cyanokit[®] does not substitute for oxygen therapy and must not delay the set up of the above measures.

Cardiovascular: Transient, generally asymptomatic, increase in blood pressure may occur in patients receiving hydroxocobalamin. The maximal increase in blood pressure has been observed toward the end of infusion.

Immune: Known hypersensitivity to hydroxocobalamin or vitamin B₁₂ must be taken into benefit-risk consideration before administration of Cyanokit[®], since hypersensitivity reactions may occur in patients receiving hydroxocobalamin. Allergic reaction may include anaphylaxis, chest tightness, edema, urticaria, pruritus, dyspnea and rash.

Renal: Based on its vasopressor effect, hydroxocobalamin may cause vasoconstriction of the renal vasculature. Since no more than two injections of hydroxocobalamin are to be administered it is unlikely that this will have any effect in patients with normal renal function; the outcome in patients with impaired renal function is unknown.

Sexual Function/Reproduction: No animal studies on male and female fertility and early embryonic development to implantation have been performed. Developmental toxicity including teratogenicity was observed in animal studies at doses that correspond approximately to the maximum recommended human dose (see **TOXICOLOGY**). Hydroxocobalamin levels were detected in urine for some patients up to 35 days following treatment with Cyanokit[®] indicating that elimination of Cyanokit[®] from the body may not be completed after 35 days. Based on these data, it is recommended to practice adequate methods of contraception for 2 months following Cyanokit[®] treatment.

Skin: Photosensitivity – Hydroxocobalamin absorbs visible light in the UV spectrum. It therefore has potential to cause photosensitivity. While it is not known if the skin redness predisposes to photosensitivity, patients should be advised to avoid direct sun while their skin remains discoloured.

Special Populations

Pregnant Women: Animal studies have shown teratogenic effects following daily exposure throughout organogenesis (see **TOXICOLOGY**). There are no adequate and well-controlled studies in pregnant women. However, treatment of maternal/fetal cyanide poisoning may be life-saving. The effect of Cyanokit[®] on labour and delivery is unknown.

Nursing Women: It is not known whether hydroxocobalamin is excreted in human milk. Because of the unknown potential for adverse reactions in nursing infants, discontinue nursing after Cyanokit[®] treatment.

Renal Impairment: The safety and effectiveness of Cyanokit[®] have not been studied in patients with renal impairment. Hydroxocobalamin and cyanocobalamin are eliminated unchanged by the kidneys. Oxalate crystals have been observed in the urine of both healthy subjects given hydroxocobalamin and patients treated with hydroxocobalamin following suspected cyanide poisoning.

Hepatic Impairment: The safety and effectiveness of Cyanokit[®] have not been studied in patients with hepatic impairment.

Monitoring and Laboratory Tests

Effects on blood cyanide assay: Hydroxocobalamin will lower blood cyanide concentrations. While determination of blood cyanide concentration is not required and must not delay treatment with hydroxocobalamin, it may be useful for documenting cyanide poisoning. If a cyanide blood level determination is planned, it is recommended to draw the blood sample before initiation of treatment with Cyanokit[®].

Interference with burn assessment: Because of its deep red colour, hydroxocobalamin has the potential to induce a red colouration of the skin and therefore may interfere with burn assessment. However, skin lesions, edema, and pain are highly suggestive of burns.

Interference with laboratory tests: Because of its deep red colour, hydroxocobalamin has the potential to interfere with determination of laboratory parameters (e.g., clinical chemistry, hematology, coagulation, and urine parameters) (Table 2). In vitro tests indicate that the extent and duration of the interference is dependent on numerous factors such as the dose of hydroxocobalamin, analyte, analyte concentration,

methodology, analyzer, concentrations of cobalamins-(III) including cyanocobalamin and partially the time between sampling and measurement. Based on in vitro studies and pharmacokinetic data obtained in healthy volunteers the following table describes interference with laboratory tests that may be observed following a 5 g dose of hydroxocobalamin. Interference following a 10 g dose can be expected to last up to an additional 24 hours. The extent and duration of interference in cyanide-poisoned patients may differ according to the severity of intoxication. Results may vary considerably from one analyzer to another, therefore, caution is required when reporting and interpreting laboratory results.

Table 2. Laboratory Interference Observed with in vitro Samples of Hydroxocobalamin

Laboratory Parameter	No Interference Observed	Artificially Increased ^a	Artificially Decreased ^a	Unpredictable ^c	Duration of Interference
Clinical Chemistry	Calcium Sodium Potassium Chloride Urea Gamma glutamyl transferase (GGT)	Creatinine Total and conjugate bilirubin ^b Triglycerides Cholesterol Total protein Glucose Albumin Alkaline phosphatase	Alanine aminotransferase (ALT) Amylase	Phosphate Uric Acid Aspartate aminotransferase (AST) Creatine Kinase (CK) Creatine Kinase isoenzyme MB (CKMB) Lactate dehydrogenase (LDH)	24 hours with the exception of bilirubin (up to 4 days)
Hematology	Erythrocytes Hematocrit Mean corpuscular volume (MCV) Leukocytes Lymphocytes Monocytes Eosinophils Neutrophils Platelets	Hemoglobin (Hb) Mean corpuscular hemoglobin (MCH) Mean corpuscular hemoglobin concentration (MCHC) Basophils			12 – 6 hours
Coagulation				Activated partial thromboplastin time (aPTT) Prothrombin time (PT) Quick or INR	24 – 48 hours
Urinalysis		pH (with doses \geq 5 g) Glucose Protein Erythrocytes Leukocytes Ketones Bilirubin Urobilinogen Nitrite	pH (with equivalent doses of < 5 g)		48 hours up to 8 days; colour changes may persist up to 28 days

^a \geq 10% interference observed on at least 1 analyzer

^b Artificially decreased using the diazo method

^c Inconsistent results

Analyzers used: ACL Futura (Instrumentation Laboratory), AxSYM[®]/Architect[™] (Abbott), BM Coasys¹¹⁰ (Boehringer Mannheim), CellDyn 3700[®] (Abbott), Clinitek[®] 500 (Bayer), Cobas Integra[®] 700, 400 (Roche), Gen-S Coultronics, Hitachi 917, STA[®] Compact, Vitros[®] 950 (Ortho Diagnostics).

Interference with hemodialysis machines: Because of its deep red colour, hydroxocobalamin may cause hemodialysis machines to shut down due to an erroneous detection of a 'blood leak'. This should be considered before hemodialysis is initiated in patients treated with hydroxocobalamin.

ADVERSE REACTIONS (see **Supplemental Product Information** for full listing):

Adverse Drug Reaction Overview: Serious adverse reactions with hydroxocobalamin include allergic reactions and increases in blood pressure (see **WARNINGS AND PRECAUTIONS**). A total of 347 subjects were exposed to hydroxocobalamin in clinical studies. Of these 347 subjects, 245 patients had suspected exposure to cyanide at the time of hydroxocobalamin administration. The remaining 102 subjects were healthy volunteers who had not been exposed to cyanide at the time of hydroxocobalamin administration. Most patients will experience a reversible red colouration of the skin and mucous membranes that may last up to 15 days after administration of Cyanokit[®]. All patients will show a dark red colouration of the urine that is quite marked during the three days following administration. Urine colouration may last up to 35 days after administration of Cyanokit[®].

Post-Market Adverse Drug Reactions: The following adverse events have been reported in post-marketing surveillance. The relationship of these events to Cyanokit[®] use is not known. Smoke inhalation and cyanide exposure may have contributed to these events: abnormal laboratory tests, pulmonary edema, cardiac arrest, renal failure – in some cases requiring dialysis, and transient impairment of renal function. To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Health Canada by toll-free telephone: 1-866-234-2345.

DRUG INTERACTIONS (also see **Supplemental Product Information**): **Overview:** Due to its high molecular weight, hydroxocobalamin is unlikely to interact with or inhibit CYP450 enzymes at clinically relevant concentrations. It is therefore considered to have low potential to be involved in drug-drug interactions with drugs that are substrates of CYP450. Physical incompatibility (particle formation) and chemical incompatibility were observed with the mixture of hydroxocobalamin in solution with selected drugs that are frequently used in resuscitation efforts. Hydroxocobalamin is also chemically incompatible with sodium thiosulfate and sodium nitrite and has been reported to be incompatible with ascorbic acid. Therefore, these and other drugs should not be administered simultaneously through the same IV line as hydroxocobalamin (see **DOSAGE AND ADMINISTRATION**).

Drug-Drug Interactions: No formal drug-drug interaction studies with hydroxocobalamin have been done.

Drug-Food Interactions: No formal drug-food interaction studies with hydroxocobalamin have been done.

Administration

DOSAGE AND ADMINISTRATION: Dosing Considerations: Comprehensive treatment of acute cyanide intoxication requires support of vital functions. Cyanokit[®] should be administered in conjunction with appropriate airway, ventilatory and circulatory support. The safety of administering other cyanide antidotes simultaneously with Cyanokit[®] has not been established. If the decision is made to administer another cyanide antidote with Cyanokit[®], these medicinal products must not be administered simultaneously through the same intravenous line.

Recommended Dose and Dosage Adjustment: In adults, the initial dose of Cyanokit[®] is 5 g administered as an IV infusion. Depending on the severity of the poisoning and the clinical response, a second dose may be administered by IV infusion. The maximum recommended total dose is 10 g. In infants and adolescents, the initial dose of Cyanokit[®] is 70 mg/kg body weight not exceeding 5 g. Depending on the severity of the poisoning and the clinical response, a second dose may be administered by IV infusion. The maximum recommended total dose is 140 mg/kg body weight not exceeding 10 g (Table 3).

Table 3. Initial Dosing Guidelines in Infants and Adolescents

Body weight in kg	5	10	20	30	40	50	60
Initial dose in g	0.35	0.70	1.40	2.10	2.80	3.50	4.20
Initial dose in mL	14	28	56	84	112	140	168

Use in Renal and Hepatic Impairment: Although the safety and efficacy of hydroxocobalamin has not been studied in patients with renal or hepatic impairment, Cyanokit[®] is administered as emergency therapy in an acute, life-threatening situation only, and no dosage adjustment is required in these patients.

Administration: The initial dose of hydroxocobalamin for adults is 5 g (i.e., two 2.5 g vials or one 5 g vial) administered as an intravenous (IV) infusion over 15 minutes (approximately 15 mL/min). Depending upon the severity of the poisoning and the

clinical response, a second dose of 5 g may be administered by IV infusion for a total dose of 10 g. The rate of infusion for the second dose ranges from 15 minutes (for patients who are extremely unstable) to 2 hours depending on the patient's condition.

Table 4. Reconstitution

Dose per Vial	Volume of Diluent to be Added to Vial	Approximate Available Volume	Nominal Concentration per mL
2.5 g	100 mL	Approx. 100 mL	25 mg/mL
5 g	200 mL	Approx. 200 mL	25 mg/mL

2.5g Vial: Each 2.5 g vial is to be reconstituted with 100 mL of diluent using the supplied sterile transfer device. Sodium chloride 9 mg/mL (0.9%) solution for injection is the recommended diluent. Only when sodium chloride 9 mg/mL (0.9%) solution for injection is not available, Lactated Ringer solution or 5% glucose can also be used. The Cyanokit® 2.5 g vial is to be rocked or inverted for at least 30 seconds to mix the solution. It must not be shaken as shaking the vial may cause foam and therefore may make checking reconstitution less easy.

5 g Vial: Each 5 g vial is to be reconstituted with 200 mL of diluent using the supplied sterile transfer device. Sodium chloride 9 mg/mL (0.9%) solution for injection is the recommended diluent. Only when sodium chloride 9 mg/mL (0.9%) solution for injection is not available, Lactated Ringer solution or 5% glucose can also be used. The Cyanokit® 5 g vial is to be rocked or inverted for at least 60 seconds to mix the solution. It must not be shaken as shaking the vial may cause foam and therefore may make checking reconstitution less easy. Because the reconstituted solution is a dark red solution, some insoluble particles may not be seen. The intravenous infusion set provided in the kit must therefore be used as it includes an appropriate filter and is to be primed with the reconstituted solution. Repeat this procedure if necessary with the second vial.

Incompatibility Information: Physical incompatibility (particle formation) and chemical incompatibility were observed with the mixture of hydroxocobalamin in solution with selected drugs that are frequently used in resuscitation efforts. Hydroxocobalamin is also chemically incompatible with sodium thiosulfate and sodium nitrite and has been reported to be incompatible with ascorbic acid. Therefore, these and other drugs must not be administered simultaneously through the same IV line as hydroxocobalamin. Simultaneous administration of hydroxocobalamin and blood products (whole blood, packed red cells, platelet concentrate and/or fresh frozen plasma) through the same IV line is not recommended. However, blood products and hydroxocobalamin can be administered simultaneously using separate IV lines (preferably on contralateral extremities, if peripheral lines are being used).

Storage of Reconstituted Drug Product: Once reconstituted, hydroxocobalamin is stable for up to 6 hours at a temperature between 2°C and 40°C (35.6°F and 104°F). Do not freeze. Any reconstituted product not used by 6 hours should be discarded.

Supplemental Product Information

ADVERSE REACTIONS: Systematic collection of adverse events was not done in all clinical studies involving known or suspected cyanide-poisoning victims who were treated with hydroxocobalamin. The interpretation of causality in these studies is limited due to lack of a control group and due to circumstances of administration (e.g., use in fire victims).

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.*

Experience in Healthy Subjects: A double-blind, randomized, placebo-controlled, single-ascending dose (2.5, 5, 7.5, and 10 g) study was conducted to assess the safety, tolerability, and pharmacokinetics of hydroxocobalamin in 136 healthy adult subjects. Because of the dark red colour of hydroxocobalamin, the two most frequently occurring adverse reactions were chromaturia (red-coloured urine) which was reported in all subjects receiving a 5 g dose or greater; and erythema (skin redness), which occurred in most subjects receiving a 5 g dose or greater. Adverse reactions reported in at least 1% of the 5 g dose group and corresponding rates in the 10 g and placebo groups are shown in Table 5.

Table 5. Incidence of Adverse Reactions Occurring in ≥ 1% of Healthy Subjects in 5 g Dose Group and Corresponding Incidence in 10 g Dose Group and Placebo

	5 g Dose Group		10 g Dose Group	
	Hydroxocobalamin	Placebo	Hydroxocobalamin	Placebo
	N = 66	N = 22	N = 18	N = 6
Adverse Drug Reaction	n (%)	n (%)	n (%)	n (%)
Eye disorder				
Eye redness	2 (3)	0	1 (6)	0
Renal and Urinary Disorders				
Chromaturia (red coloured urine)	66 (100)	0	18 (100)	0
Pollakiuria (frequent urination)	1 (2)	0	0	0
Skin and subcutaneous tissue Disorders				
Erythema	62 (94)	0	18 (100)	0
Rash*	14 (21)	0	3 (17)	0
Immune Disorders				
Face edema	1 (2)	0	0	0
Pruritus	1 (2)	0	3 (17)	0
Urticaria	1 (2)	0	0	0
Investigations				
Blood amylase increased	1 (2)	0	0	0
Blood pressure increased	12 (18)	0	5 (28)	0
Lymphocyte percent decreased	5 (8)	0	3 (17)	0
Gastrointestinal disorders				
Abdominal discomfort	2 (3)	0	2 (11)	0
Flatulence	1 (2)	0	0	0
Loose stools	1 (2)	0	0	0
Nausea	4 (6)	1 (5)	2 (11)	0
Vomiting	2 (3)	0	0	0
Nervous System Disorders				
Dizziness	2 (3)	0	1 (6)	0
Headache	4 (6)	1 (5)	6 (33)	0
General disorders and administrative site conditions				
Chest discomfort	3 (5)	0	2 (11)	0
Discomfort	1 (2)	0	0	0
Feeling hot and/or cold	2 (3)	0	0	0
Infusion site reaction	4 (6)	0	7 (39)	0
Musculoskeletal and connective tissue disorders				
Joint/back pain	2 (3)	0	0	0
Psychiatric disorders				
Restlessness	2 (3)	0	0	0
Respiratory, thoracic and mediastinal disorders				
Dyspnea	1 (2)	0	0	0
Sore or dry throat	3 (5)	0	3 (17)	0

* Rashes were predominately acneiform

Less Common Adverse Drug Reactions Occurring at a rate of less than 1%

Eye disorders: Swelling, irritation.

Gastrointestinal disorders: Dyspepsia, diarrhea, dysphagia, hematochezia.

General disorders and administration site conditions: Peripheral edema.

Immune system disorders: Allergic reactions including angioneurotic edema and skin eruption (see **WARNINGS AND PRECAUTIONS**).

Nervous system disorders: Memory impairment.

Respiratory, thoracic and mediastinal disorders: Pleural effusion.

Vascular disorders: Hot flush.

Experience in Known and Suspected Poison Victims: Four open-label, uncontrolled, clinical studies (one of which was prospective and three of which were retrospective) were conducted in known or suspected cyanide-poisoning victims. A total of 245 patients received hydroxocobalamin treatment in these studies. Systematic collection of adverse events was not done in all of these studies and interpretation of causality is limited due to the lack of a control group and due to circumstances of administration (e.g., use in fire victims). Adverse reactions reported in these studies listed by system organ class included:

Cardiac disorders: Ventricular extrasystoles, an increase in heart rates, electrocardiogram repolarization abnormality.

Adverse reactions common to both the studies in known or suspected cyanide poisoning victims and the study in healthy volunteers are listed in the healthy volunteer section of the Product Monograph only and are not duplicated in this list.

Abnormal Hematologic and Clinical Chemistry Findings: Cyanokit® may cause red discoloration of the plasma, which may cause artificial elevation or reduction in the levels of certain laboratory parameters (see **WARNINGS AND PRECAUTIONS**). White blood cell counts (WBC) showed a slight and transient increase in mean values from baseline at 2 to 12 hours after treatment in healthy subjects, and small decreases in serum sodium levels were also observed. Changed values generally remained

within normal ranges. Other minor and transient changes in hematology and clinical chemistry findings were considered due to interference by hydroxocobalamin or due to individual variation.

DRUG INTERACTIONS: Drug-Herb Interactions: Interactions with herbal products have not been established.

Drug-Laboratory Interactions: Because of its deep red colour, hydroxocobalamin has been found to interfere with colourimetric determination of certain laboratory parameters (e.g., clinical chemistry, hematology, coagulation, and urine parameters). In vitro tests indicated that the extent and duration of the interference are dependent on numerous factors such as the dose of hydroxocobalamin, analyte, methodology, analyzer, hydroxocobalamin concentration, and partially on the time between sampling and measurement. Based on in vitro studies and pharmacokinetic data obtained in healthy volunteers, Table 2 describes laboratory interference that may be observed following a 5 g dose of hydroxocobalamin (see **WARNINGS AND PRECAUTIONS**). Interference following a 10 g dose can be expected to last up to an additional 24 hours. The extent and duration of interference in cyanide-poisoned patients may differ. Results may vary substantially from one analyzer to another; therefore, caution should be used when reporting and interpreting laboratory results.

OVERDOSAGE:

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

Limited data are available about overdose with Cyanokit®. Doses as high as 15 g have been administered without reported specific dose related adverse reactions. If overdose occurs, treatment is directed to the management of symptoms. Hemodialysis may be effective in such a circumstance, but is only indicated in the event of significant hydroxocobalamin-related toxicity. Because of its deep red colour, hydroxocobalamin may interfere with the performance of hemodialysis machines (see **WARNINGS AND PRECAUTIONS**, Monitoring and Laboratory Tests).

Product Monograph available on request.

References: 1. CYANOKIT® (Hydroxocobalamin) Product Monograph, EMD Serono, October, 2011.



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www.emdserono.ca
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CYANOKIT[®] 5 g
HYDROXOCOBALAMIN

*If you encounter a smoke inhalation victim,
they may have cyanide poisoning*

If you suspect cyanide poisoning, respond with Cyanokit[®]

Cyanokit[®] contains hydroxocobalamin, an antidote indicated for the treatment of known or suspected cyanide poisoning. Cyanokit[®] is to be administered together with appropriate decontamination and supportive measures!

- Designed for use at the scene or in the hospital¹
- Available in a 5 g vial¹

To order Cyanokit[®] or for more information,
call EMD Serono Customer Care at 1-800-387-9749

Warnings and Precautions: In addition to Cyanokit[®], treatment of cyanide poisoning must include immediate attention to airway patency, adequacy of oxygenation and hydration, cardiovascular support, and management of any seizure activity. Consideration should be given to decontamination measures based on the route of exposure. Cyanokit[®] does not substitute for oxygen therapy and must not delay the set up of the above measures.

Contraindications: None.

Adverse events: Systematic collection of adverse events was not done in all clinical studies involving known or suspected cyanide-poisoning victims who were treated with hydroxocobalamin. The interpretation of causality in these studies is limited due to lack of a control group and due to circumstances of administration (e.g., use in fire victims). The most common adverse events (>5%) in healthy subjects who received hydroxocobalamin are reversible red colouration of the skin and mucous membranes (erythema), marked dark red colouration of the urine (chromaturia), eye redness, rash (acneiform), pruritus, transient increase in blood pressure, decrease in the percentage of lymphocytes, abdominal discomfort, nausea, dizziness, headache, chest discomfort, injection site reaction, and sore or dry throat. Other less common adverse events (<5%) include: pollakiuria (frequent urination), face edema, urticaria, increase in blood amylase levels, flatulence, loose stools, vomiting, general discomfort, feeling hot and/or cold, joint/back pain, restlessness, dyspnea, eye swelling, eye irritation, dyspepsia, diarrhea, dysphagia, hematochezia, peripheral edema, memory impairment, pleural effusion, and allergic reactions including angioneurotic edema and skin eruption.

Please consult the Cyanokit[®] Product Monograph for further information.

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See prescribing summary on page A15

CPR & AED Training in Schools



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PAGES 255 - 316

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