Alberta Health Services	Diphtheria Antitoxin (Equine) Biological Page		
Section 7:	**Biological Product Information**		**Standard #: 07.202**
Created by:	Province-wide Immunization Program Standards and Quality		
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	DIPHTHERIA ANTITOXIN (equine)
Manufacturer	Institute of Immunology Inc., Croatia
Biological Classification	Antitoxin

Indications for Provincially Funded Vaccine	**Treatment of suspected** (based on clinical symptoms) **or confirmed diphtheria disease**.
	• Eligibility will be determined though discussion amongst the treating physician, the zone Medical Officer of Health (MOH) and Alberta Health Chief Medical Officer of Health
	  o The zone MOH/MOH designate must notify the Office of the Chief Medical Officer of Health (OCMOH) by the fastest means possible of all cases in which diphtheria antitoxin is required
	  o OCMOH is available on a 24 hour basis by pager at 780-638-3630
	  o Once eligibility has been determined, OCMOH will authorize release of the product through either the Provincial Vaccine Depot or the Alberta Health Services (AHS) Calgary Vaccine Depot. It is not routinely stocked outside of these two sites.
	• Special authorization, access and transport procedures must be followed. This includes:
	  o ensuring the biological is packed and transported under strict cold chain management guidelines from the vaccine depot to the hospital unit
	  o obtaining a signature for receipt of product from the treating physician
	  o completion of Special Access Program Form C by the treating physician in conjunction with the zone MOH (a Special Access Program form is included with the product or can be found at http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf3_pasf3-eng.php)
	  o returning the completed Special Access Program Form C to the MOH/MOH designate
	The zone MOH/MOH designate will review the Special Access Program Form C to ensure all fields are completed and then submit the completed form to AH
	Notes:
	• Diphtheria antitoxin is considered the mainstay of treatment for diphtheria; it will not neutralize diphtheria toxin that is already fixed to tissues, it will only neutralize circulating (unbound) diphtheria toxin and prevent the progression of disease. Antibiotic therapy is required to eradicate the organism, to stop toxin production and prevent transmission.
	  o For further information about the disease and reporting requirements refer to the Alberta Health Public Health Notifiable Disease Management Guidelines – Diphtheria.
	• Active immunization against diphtheria should occur during convalescence from diphtheria (three to four weeks after diphtheria antitoxin was administered) to complete the primary series unless serological testing indicates protective levels of diphtheria antitoxin; disease does not necessarily confer immunity
	• Diphtheria antitoxin is not recommended for prophylaxis of close, unimmunized contacts of diphtheria cases or diphtheria carriers

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Serology	Blood should be collected to identify the specific toxin before antitoxin is administered; however the administration of the antitoxin should not be withheld pending the test results (refer to the Alberta Health Public Health Notifiable Disease Management Guidelines – Diphtheria).
Schedule	• Diphtheria antitoxin should be administered as soon as possible after clinical diagnosis. • Treatment should not await laboratory confirmation of toxigenic *C. diphtheriae*. • Skin testing for hypersensitivity is recommended before administration of diphtheria antitoxin regardless of whether or not the individual has received equine antigens previously. o For information on skin testing and desensitization procedures, refer to Alberta Health Public Health Notifiable Disease Management Guidelines – Diphtheria, Annex A and B.
Preferred Use	N/A
Dose	The therapeutic dose is determined by the severity and duration of the disease and the age and body weight of the patient. **Notes:** • Diphtheria antitoxin is supplied in vials containing 10,000 I.U. each. • Additional doses may be considered based on the clinical presentation and the patient's response to treatment. • This is a treatment product administered under the direction of a physician in an acute care setting.
Route	• **Mild to moderate cases:** IM • **Severe cases:** IM and/or slow intravenous infusion o IV doses must be diluted with normal saline or 5% dextrose o Warm diphtheria antitoxin before injection (to not greater than 32º to 34ºC).
Contraindications/ Precautions	**Contraindications:** • None as this is a vital indication due to life-threatening condition. **Precautions:** • History of severe hypersensitivity reaction to this antitoxin. Use desensitization protocol if hypersensitivity exists and antitoxin urgently needed. If diphtheria is present, antitoxin must be given. • Patients should be assessed and tested for hypersensitivity to equine sera prior to administration of diphtheria antitoxin as it may trigger allergic reactions of varying degrees. Refer to Alberta Health Public Health Notifiable Disease Management Guidelines – Diphtheria, Annex A and B.
Possible Reactions	**Common:** • Fever, arthralgia, skin rash or lymphadenopathy may occur and are dose related. **Rare:** • Anaphylaxis with urticaria, respiratory distress and vascular collapse can occur with varying frequency within the first 24 hours following administration. • Patients previously treated with antitoxin of equine origin may present a higher incidence of reaction. • Antitoxin sickness may occur within 7 to 12 days after administration (incidence rate of approximately 10%). Typical symptoms include fever, skin rashes, edema of the skin, adenopathy and pains in the joints. Serum sickness is more likely to occur following repeat injections of equine serum. • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	• Pregnancy is not a contraindication to the use of diphtheria antitoxin when clearly indicated. • Intact IgG crosses the placenta from maternal circulation increasingly after 30 weeks.

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Lactation	• Breastfeeding is not a contraindication to diphtheria antitoxin when clearly indicated. • It is not known if antitoxin antibodies are excreted into breast milk (problems have not been documented).
Composition	Each 1 mL vial contains: • Not more than 170 mg immunoglobulin (equine) • 1000 I.U minimal antibody activity against *C.diphtheriae* • 0.027 mmol m-Cresol (preservative) • 0.150 mmol sodium chloride • Up to 1 mL sterile water for injection
Blood/Blood Products	Equine horse serum
Bovine/Porcine Products	None listed in the ingredient list
Latex	None listed in ingredient list
Interchangeability	N/A
Administration with Other Products	• Delay administration of products containing diphtheria toxoid for 3 to 4 weeks after diphtheria antitoxin administration to minimize the possibility of antigen-antibody antagonism. • No contraindication to other medications.
Appearance	Clear transparent solution
Storage	• Store at +2ºC to +8ºC. • Once the vial is opened, the preparation should be used immediately. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in the original packaging when possible to protect from light.
Vaccine Code	DA
Antigen Code	DA
Licensed for	Currently there is no licensed product made in Canada, and product is made available from Health Canada's Special Access Program (SAP).

Notes:

Related Resources:

- **AHS-Imm-07.202-R01 (July 18, 2014) Diphtheria Antitoxin (Equine) Information Sheet**

References:

1. Alberta Health and Wellness, Communicable Disease Control and Prevention. (2011, September). Public Health Notifiable Disease Management Guidelines – Diphtheria. In Public health notifiable disease management guidelines.
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5. Centers for Disease Control and Prevention. (2011, January). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report, 60(2).*
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7. Institute of Immunology Inc. Diphtheria antitoxin (equine). Product Leaflet.
8. National Advisory Committee on Immunization. (2012). *Canadian immunization guide* (Evergreen edition.). Ottawa, ON: Public Health Agency of Canada. http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-dip-eng.php