Diphtheria Antitoxin (equine)

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.202**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	July 18, 2014	**Published**	April 15, 2025

	Diphtheria Antitoxin Butantan Institute, Brazil	**Diphtheria Antitoxin VINS Bioproducts Limited, India**
Manufacturer	Butantan Institute, Brazil	VINS Bioproducts Limited, India
Classification	Antitoxin	
Authorization and Access	**Follow special authorization and access procedures.** • 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. • Available 24 hours a day from Alberta Health by calling OCMOH pager: 780-638-3630. ○ A Special Access Program (SAP) Form is included with the product and must be completed and returned to Alberta Health. **Note:** • Stocked in the Provincial Vaccine Depot and the Alberta Health Services (AHS) Calgary Vaccine Depot. • Both products are supplied in Alberta. They have different dosing and scheduling recommendations. Providers will receive the product that is readily available in their zone. Refer to the corresponding dosing and scheduling recommendations below.	

Indications for Provincially Funded Diphtheria Antitoxin Serum	Treatment of suspected (based on clinical symptoms) or confirmed disease. Bacteriologic confirmation is not required to initiate treatment.
	• Eligibility is determined though discussion amongst the treating physician, the zone Medical Officer of Health (MOH) and Alberta Health Chief Medical Officer of Health.
	  ○ Once eligibility has been determined, OCMOH will authorize release of the product through either the Provincial Vaccine Depot or the AHS Calgary Vaccine Depot. It is not routinely stocked outside of these 2 sites.
	• Follow special authorization, access and transport procedures.
	  ○ Ensure the biological is packed and transported under strict cold chain management guidelines from the Vaccine Depot to the facility.
	  ○ Obtain a signature for receipt of product from the treating physician.
	  ○ Complete the Special Access Program Form C by the treating physician in conjunction with the zone MOH.
	  ▪ A Special Access Program Form C 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).
	  ○ Return the completed Special Access Program Form C to the zone MOH/MOH designate.
	• The zone MOH/MOH designate will review the Special Access Program Form C to ensure all fields are complete and then submit the completed form to Alberta Health.
	Note:
	• Not recommended for prophylaxis of close contacts of diphtheria cases whether they are, immunized or not unimmunized.	

<table>
<tr><th></th><th>Diphtheria Antitoxin Butantan Institute, Brazil</th><th>Diphtheria Antitoxin VINS Bioproducts Limited, India</th></tr>
<tr><td></td><td colspan="2">• For further information about the disease and reporting requirements refer to the Alberta public health disease management guidelines: diphtheria.</td></tr>
<tr><td rowspan="3">Schedule</td><td colspan="2">Administer diphtheria antitoxin serum as soon as possible after clinical diagnosis. Do not wait for laboratory confirmation of toxigenic Corynebacterium diphtheriae.</td></tr>
<tr><td>Skin testing for serum hypersensitivity is recommended before administration of diphtheria antitoxin.
Note:
• This recommendation differs from the product leaflet.
• For hypersensitivity and desensitization procedures only, refer to US CDC Use of Diphtheria Antitoxin (DAT) for Possible Diphtheria Cases - Protocol, specifically sections 6.3 & 6.4, including Tables 3 & 4.</td><td>Skin testing for serum hypersensitivity is recommended before administration of diphtheria antitoxin.
• See the product leaflet for details.</td></tr>
<tr><td colspan="2">See product information and Appendix 1 and 2 of Alberta public health disease management guidelines: diphtheria.
Note:
• Diphtheria infection does not necessarily confer immunity.
• Individuals who have recovered should receive age-appropriate diphtheria-containing vaccine.
○ Administer vaccine three to four weeks after diphtheria antitoxin to minimize antigen-antibody antagonism.</td></tr>
<tr><td>Preferred Use</td><td colspan="2">N/A</td></tr>
<tr><td rowspan="2">Dose</td><td colspan="2">This treatment product is administered under the direction of a physician in an acute care setting.
Therapeutic dose is determined by severity of disease.
• Follow the dosage as outlined on the product leaflet.</td></tr>
<tr><td>Note:
• Diphtheria antitoxin is supplied in 10 mL vials containing 10,000 IU each.
• The product leaflet recommends 40,000 IU for mild cases and up to a maximum of 100,000 IU for severe cases.</td><td>Note:
• Diphtheria antitoxin is supplied in 10 mL vials containing 10,000 IU each.
• The product leaflet recommends 10,000 to 30,000 IU for mild to moderately severe cases and up to a maximum of 100,000 IU for severe cases.</td></tr>
<tr><td>Route</td><td colspan="2">Refer to the product leaflet accompanying the product.</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="2">Contraindications:
• None.
○ This is a vital indication due to a 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.
• Assess and test patients for hypersensitivity to equine sera prior to administration.</td></tr>
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	Diphtheria Antitoxin Butantan Institute, Brazil	Diphtheria Antitoxin VINS Bioproducts Limited, India
	○ It may trigger allergic reactions of varying severity. ○ Refer to product leaflet accompanying the product.	
Possible Reactions	**Common:** • Serum sickness (fever, itching, urticaria, rash, arthralgia, myalgia, adenopathy) may occur 5-24 days following administration. • Lymph gland enlargement 7-12 days following administration. • Allergic reactions of varying severity are more common in those previously treated with antitoxin of equine origin. ○ This includes skin pruritus, flushing, angioedema, morbilliform rash, tachycardia, rhinorrhea, sneezing, abdominal cramps, diarrhea, pain, swelling or redness, urticaria, cough, hoarseness, nausea, vomiting and asthma-like crisis. **Uncommon:** • Chills, sweating. **Rare:** • Anaphylaxis • Pallor, dyspnea, glottis edema • Respiratory failure with hypoxemia • Tachycardia, bradycardia, hypotension, which may progress to shock and syncope, loss of consciousness and persistent circulatory collapse • Neurological or renal compromise • Vasculitis • Unexpected or unusual side effects can occur. Refer to the product leaflet for more detailed information.	
Pregnancy	• May use during pregnancy. ○ Intact IgG crosses the placenta from maternal circulation increasingly after 30 weeks.	
Lactation	• May use for people who are lactating and feeding their milk to infants or children. ○ It is not known if antitoxin antibodies are excreted into breast milk.	
Composition	Each 1 mL contains: • $F(ab')_2$ equine-derived immunoglobulin fractions • phenol • saline solution.	Each 1 mL contains: • enzyme refined, equine Diphtheria antitoxic immunoglobulin fragments, not less than 1000 IU • cresol I.P/B.P (preservative): not more than 0.25% v/v • sodium chloride I.P/B.P • glycine I.P/B.P.
Blood/Blood Products	Contains equine horse serum.	
Bovine/Porcine Products	Does not contain bovine or porcine products.	
Latex	Does not contain latex.	
Interchangeability	N/A	
Administration with Other Products	Administer products containing diphtheria toxoid 3 to 4 weeks after diphtheria antitoxin to minimize the possibility of antigen-antibody antagonism.	
Preparation	Refer to product leaflet accompanying the product.	

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Appearance	Clear, transparent solution to slightly opalescent liquid which is colorless to pale yellow. Do not use the DAT if turbidity or precipitates are present.	

Storage	• Store at +2°C to +8°C.
	  ○ The product must be maintained in strict monitored cold chain until ready for use.
	• Once the vial is opened, use the preparation immediately.
	• Ship unused product back to the Provincial Vaccine Depot or the AHS Calgary Vaccine Depot.
	  ○ Ship under cold chain with at least twice daily documented storage temperatures.
	  ○ See the shipment package for further details.	

Vaccine Code	DA	
Antigen Code	DA	
Licensed for	There is no licensed product manufactured in Canada. Product is available from Health Canada's Special Access Program (SAP).	
Related Resources	Diphtheria Antitoxin (Equine) Information Sheet	

References

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