

10.0 Passive Immunization Protocols (in alphabetic order)

- **Botulism Anti-toxin (Batx)**
 - Botulism Anti-toxin Behring
Fact Sheet: Botulism Anti-toxin

- **Hepatitis B Immune Globulin (HBig)**
 - HyperHEP B™ S/D
Fact Sheet: Hepatitis B Immune Globulin

- **Immune Globulin (Ig)**
 - Gamastan S/D
Fact Sheet: Immune Globulin

- **Tetanus Immune Globulin (Tlg)**
 - HYPERTET® S/D
Fact Sheet: Tetanus Immune Globulin

Immunization Protocol for BAT[®]

Botulism Antitoxin (BAtx) Heptavalent (A, B, C, D, E, F, G)

Purpose	To provide information and guidance for the use of Botulism Antitoxin (BAtx) in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph or insert for specific information.
Objective	To reduce morbidity and mortality secondary to Botulism infection.
Indication	Nunavummiut are at risk for developing botulism if they are eating improperly prepared <i>igunaq</i> (fermented walrus) and other foods contaminated with <i>Clostridium botulinum</i> . Nunavut's publicly funded program is offered to all suspected and confirmed cases of botulism in Nunavut. See eligibility for further details.
Eligibility	All Nunavummiut with suspected or confirmed Botulism. BAtx requires an order from the attending physician responsible for the patient and approval from the Office of the Chief Medical Officer of Health (CMOH).
Product	BAT [®]
Vaccine Type	Immune Sera
Vaccine components	Equine (horse) botulism antitoxin for serotypes A, B, C, D, E, F, and G. Maltose, Polysorbate 80
Formats available	Single dose 50 ml vial.
Manufacturer	Emergent BioSolutions Canada Inc.
Administration	Intravenous (IV) injection – Review product monograph for specific administration guidelines.
Dose Series	This product is only to be given as directed by the Office of the CMOH. Review product monograph for specific dosing guidelines.
Booster Dose	Not Applicable
Vaccine interchangeability	Not Applicable
Contraindications	There are no absolute contraindications for BAtx, as it is necessary in life threatening cases of botulism.
Precautions and Additional Notes	<p>BAtx is composed of equine protein and has the potential risk of the patient developing anaphylactic reactions, pyretic reactions, or late reactions (serum sickness). There is an increased risk of reactions if the patient has a history of allergic reactions to horses, horse blood products, asthma, or hay fever in the past. There is also greater risk if the patient has previously received an equine-derived antivenom/antitoxin. Close monitoring of vital signs, as well signs and symptoms of adverse reactions should be observed for at least 2 hours after administration. Be prepared to treat for shock.</p> <p>Previous allergic reactions to equine protein is not a contraindication, however consider administering BAtx in combination with medications for the prevention of shock for individuals with a history of allergic reactions horse protein. Also consider administering in a setting with appropriate monitoring; equipment and medication (including epinephrine); and staff trained in management of hypersensitivity, anaphylaxis, and shock.</p>
Vaccine Supply and Distribution	Review section on vaccine ordering in the policy and procedure section of the Nunavut Formulary.

Storage	<p>BAT[®] should be stored at a temperature of +2° C to +8° C and must not be used after the expiry date shown on the pack and container.</p> <p>*Please note: The Canadian labelling recommends this product be stored frozen. As this is not possible in Nunavut, the date of expiry has been recalculated to expire earlier, based on manufacturer guidelines when the product is thawed and stored in the fridge. Each vial will have an adjusted expiry date assigned by the GN Pharmacy, which reflects the change in storage.</p>
Consent	The General Immunization Consent Form must be reviewed and signed by the client or parent/guardian prior to administration.
Anaphylaxis	Review the principles of the emergency management of anaphylaxis in the Nunavut Immunization Manual Section 3 (3.7). Further information can be found in: Anaphylaxis: Initial Management in Non-Hospital Settings , in the Canadian Immunization Guide.
Side Effects	<p>Anaphylactoid/anaphylactic reactions: onset within minutes to hours after start of therapy. Symptoms include urticaria, nausea, headache, bronchospasm, and shock.</p> <p>Pyretic reactions: onset 1 to 2 hours after start of therapy. Symptoms include fever, chills, and arterial hypertension.</p> <p>Late reactions (serum sickness): onset 5 to 24 days after start of therapy. Symptoms include pruritus, urticaria, fever, arthralgia, and neurological disorders (eg. inflammation of the nerves).</p>
Reportable Adverse Events/Side Effects	Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC. Review section 3.5 in the Nunavut Immunization Manual. Available online at: https://www.gov.nu.ca/sites/default/files/3.0_practice_guidelines_-_april_20_2018_0.pdf
Vaccine Coverage and Reporting	Under development.
Documentation	All immunizations given should be documented on the Immunization Card, chart, personal immunization record, and electronic record (where applicable).
Materials and Resources	<p>Botulism Protocol - Available online at: https://www.gov.nu.ca/sites/default/files/nu_communicable_diseases_manual_-_complete_2018-april19.pdf</p> <p>Botulism Antitoxin Fact Sheet</p>
References	<ol style="list-style-type: none"> 1. BAT[®] Product Monograph. Emergent BioSolutions Canada Inc. May 9, 2017. 2. Public Health Agency of Canada. Canadian Immunization Guide – Evergreen Edition (2018). Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Fiche de renseignements

L'antitoxine botulinique

Qu'est-ce que le botulisme?

Le botulisme est une maladie rare, mais grave, causée par une toxine qui affecte le système nerveux et qui peut causer la paralysie.

Les Nunavummiuts courent le risque de contracter le botulisme s'ils mangent de l'*igunaq* (viande de morse fermentée) mal préparé ou d'autres produits alimentaires contaminés.

Qui devrait recevoir l'antitoxine botulinique?

Toutes les personnes âgées de plus d'un an dont la contamination au botulisme est soupçonnée ou confirmée.

Qu'est-ce que l'antitoxine botulinique et comment l'administre-t-on?

L'antitoxine botulinique est un médicament utilisé pour traiter le botulisme chez les personnes ayant été exposées à la bactérie. Elle est fabriquée à partir de l'antisérum (protéine) provenant de chevaux ayant une immunité (une protection) contre le botulisme. Elle est administrée directement dans la circulation sanguine par cathéter intraveineux.

L'antitoxine botulinique protège-t-elle contre le botulisme?

L'antitoxine botulinique peut empêcher la maladie de s'aggraver et elle réduit le risque de complications et de décès.

L'antitoxine botulinique est-elle sécuritaire?

Oui.

À l'occasion, les personnes font de la fièvre, ont des frissons ou une pression artérielle élevée 1 à 2 heures après la réception de l'antitoxine.

Dans de rares cas, les personnes recevant l'antitoxine subissent de graves réactions telles qu'un choc anaphylactique ou d'autres réactions allergiques. Une telle réaction peut survenir dans quelques minutes à quelques heures suivant la

réception du médicament.

Dans certains cas, les personnes ont une réaction appelée « maladie sérique », pouvant survenir 5 à 24 jours suivant la réception de l'antitoxine. La maladie sérique peut se manifester sous forme d'urticaire, de démangeaisons, de fièvre ou de douleur articulaire ou névralgique.

Quels sont les risques auxquels on s'expose en ne prenant pas l'antitoxine botulinique?

Si l'on vous recommande de prendre l'antitoxine, mais que vous choisissez de ne pas recevoir ce traitement, vous courez un plus grand risque de devenir plus malade en raison du botulisme. Le botulisme peut causer des dommages névralgiques, ce qui peut entraîner la paralysie du visage, de la tête, de la gorge et des extrémités, et qui peut causer la mort.

Qui devrait parler à son fournisseur de soins de santé avant de recevoir l'antitoxine botulinique?

Informez votre fournisseur de soins de santé de toute réaction allergique antérieure aux protéines équine (venant du cheval).

Où puis-je trouver de plus amples renseignements?

Pour de plus amples renseignements au sujet de ce produit, veuillez consulter votre fournisseur de soins de santé.

Antitoxine botulinique — post-traitement

- Une réaction appelée « maladie sérique » peut survenir 5 à 24 jours suivant la réception de l'antitoxine. La maladie sérique peut se manifester sous forme d'urticaire, de démangeaisons, de fièvre ou de douleur articulaire ou névralgique. Si vous ressentez l'un de ces symptômes, veuillez consulter votre fournisseur de soins de santé.
- Si vous éprouvez des effets secondaires graves, comme de l'enflure à la bouche ou aux lèvres, de l'urticaire ou des crises, veuillez immédiatement en informer votre fournisseur de soins de santé.
- Si vous avez des questions ou des inquiétudes relatives à une réaction à l'antitoxine, veuillez en parler à votre fournisseur de soins de santé.



Naunaitkutikhat Titiraq

Aaniaguut Timimi Itkuumayut Titiraqmungakhimiyut

Huunauyuq tamna Aaniaguut?

Tuqunnaq imalu qanuqgituq qihimi hivuqganaktuq aaniakguut taimaililaqivaktun talvuna tuqunnaqguunikpaktun ihuikuutillakivaktuq tapfumunga mihiginnikmun attayunik imalu taimaililaqinaktuq mihingnaikguutivaktuqlu.

Nunavummiut qayangnaqtunit tapfumuna nau'nauhuqungnaqtunik tuqunnaamik nerrigumik munakgiiyauttiakhimaitkanggamik iggititikhimayumik *igunaqmik* (iggititikhimayuuq aiviq) nalliak allaanit iggititikhimayunik niqinik.

Qinaah pidjutiggyakhaa Havautikhamik?

Quyyakginnaq avvatquuhimayunik ukiunginnik atauhikmik qanuqgillihimayunnik nalliak aaniaguunikhimayuk tuqunnaamik.

Huuna tamna Havautikhak unalu qanuqtun havautituqtitaavakpat?

Havautikhak atuqtauvaktuq pittailinnaitumik aaniagunmik qanuqgitkumi qitulikaq pinnaugiiyauyut inungmik aaniakguutilikmik. Nauv'vaktuq talvanga attayuq aukmiituq immaqqigtuq (nuuqititiggut) havakhimayuuq kinmikpaknit nuukiikgiktunnit (pittailidjutiggiplugu) tapfumunga aaniakguutimit. Tuniyauvaktuq quuhiktaktumik mitquutiggut (IV) mitquutaa nallautitparaat taaqaanut auk.

Tamna Havautikhak pittailinnaitumik ilingni aaniaguutimit?

Havautikhak pittailinnaitumik aaniaguutimik inggattaqyuaqnaittumiklu illangauttivaktuq unalu tuquudjutinnauhuqungnaqtuqlu.

Imalu Havautikhak qayangnaitpa?

Hii.

Qaqqunguqgangatlu, inuin tuutkiingalikgalutiklu kidjaqtirralutiklu, qaalikgunggulikgalutiklu, nalliak quulvakpiakgalutiklu tikiktait ikangniingni attauhikmik talvuna malrukniiklunin havautituqtitaugangamiklu.

Pikkatayuituq, inuin ilituqgivaktun tuutkiingalikgalutiklunin hivugganaktumik ihuillakkivaktun ima quuquulakivaktun nalliak ammiglikpaktunlu. Uvuna tiamaililakivaktun tadjakguinnak nalliak uuvattiagungguquyarangatlu tapfumuna havautituqtitauyummut.

lilanggini aaniakguutini, inuin pidjutikalikpaktun tuutkiingalikgalutiklu ima attayuq aukmi imaqgiktumik aaniaguutimik 5 – 24nik ubluunik ahiaguutauk havautituqtitaugangamik. Attayuq Aukmilmagigtuq aukmi aaniaguut naunaikpaktuq ammiglikpaktun, quuquulakivaktun, kidjakhutik, avvataitlu ulukgiannakhivaktunlu taaqailu mihingnakhivaktun ulukgiannakhivaktunlu.

Huuna imalu hivugannangnaitpaa pidjutiginggittangani tapfumuna Aaniaguunmik?

Havautituqyauyuguvit qihimi havautituqgumangitquvit, inggataqyuumikhungguuyutin aaniakikpiaklutitlu. Aaniaguutimit immaililaqinnaqtuqlu mihingnaikguutiyuktuq, talvuna mihingnaikguttigalunilu akkuliangni, niaquqmi, iggiakmi, qattigangnilu unalu qaayangnaqpiaktuqlu unalu tuquudjuutavaktuqlu.

Qina uqaqatiggyakhaa munakhilikiyitkut hivuagut havautituqaaqtinnagit?

Uqaqlugu munakhiggyangnik pidjutikakhimmavakuvit ammiglikpakhimmavakhimaguuvit tapfumuna aung'ganit kiinmikpang'nin (kiinmikpak) nuuqititiguut.

Huumit tukihigiarutikhannik pinniakgaluakingaa?

Talvuna tukihigiarutikhannik uvuna pidjutihautikhannik, uqaqvigilugu munakhiggyangnik ikayuqtiggyaknik.

Aaniaguut Timimi Naquuhivaliyum

- Aah ihuillaqidjutivaktuq "attayuq aukmiituq imaggigtuq aaniakguut" haagyaiffayuktun 5 – 24 ubluunik ahiaguut havautituqtitauhimayunik. Attayuq Aukmiituq imaggigtuq aaniaguut imalivaktun ammiglikpaktun, quuquulakigalutiklu, kidjakhutik, avvataitlu ulukgiannakhivaktunlu. Tuutkiingalikguvit ilihimalikguvitlunin ilingnik, takuyaktuqlugit munakhiit ikayuqtiinik.
- Ilihimalikguvit hivuqgiliguvit puuvittilikguvit tapfumuna qanniit/uumilguukitlu, ammiglikguvit nalliak kiikilikguvitlunin takuyaktuklugit munakhiit qilammiuklutit.
- Ilvit apikuutikaruvit, nalliak nallukhalikguvitlunin ammiglikguvitlunin havautinnit, uqaqvigilugu munakhiit ikayuqtiinik.



Fact Sheet

Botulism Antitoxin

What is Botulism?

Botulism is a rare but serious illness caused by a toxin that affects the nervous system and can cause paralysis.

Nunavummiut are at risk for developing botulism if they are eating improperly prepared *igunaq* (fermented walrus) or through other contaminated food products.

Who should receive Botulism Antitoxin?

Anybody older than 1 year with suspected or confirmed botulism.

What is Botulism Antitoxin and how is it given?

Botulism Antitoxin is a medication used to treat botulism in a case where somebody may have been exposed to the bacteria. It is made from the immune serum (protein) made from horses who have immunity (protection) against botulism. It is given with an intravenous (IV) catheter directly into the bloodstream.

Does Botulism Antitoxin protect you against botulism?

Botulism Antitoxin can prevent the illness from getting worse and it reduces the chances of complications and death.

Is Botulism Antitoxin safe?

Yes.

Occasionally, people will experience fever, chills, or high blood pressure 1 – 2 hours into receiving

the antitoxin.

Rarely, people will experience severe reactions such as anaphylaxis or other allergic reactions. This reaction could happen minutes to hours after receiving the medication.

In some cases, people develop a reaction called serum sickness 5 – 24 days after receiving the antitoxin. Serum sickness can appear to be hives, itchiness, fever, joint or nerve pain.

What is the risk of not getting Botulism Antitoxin?

If you are recommended to take the antitoxin but choose not to, you are increasing your risk of becoming sicker with botulism. Botulism can cause nerve damage, which may result in paralysis of the face, head, throat, chest and extremities and may result in death.

Who should talk with their healthcare provider before receiving Botulism Antitoxin?

Tell your health care provider if you have had a previous allergic reaction to equine (horse) protein.

Where can I get more information?

For more information about this product, talk to your healthcare provider.

Botulism Antitoxin After Care

- A reaction called “serum sickness” may occur 5 – 24 days after receiving the antitoxin. Serum sickness may be hives, itchiness, fever, joint or nerve pain. If you experience any of these symptoms, please visit your health care provider.
- If you experience any serious side effects such as swelling of the mouth/lips, hives or seizures please tell your health care provider immediately.
- If you have any questions, or are concerned about a reaction from the antitoxin, talk with your health care provider.



Immunization Protocol for HyperHEP B[®] S/D

Hepatitis B Immune Globulin (HBIG)

Purpose	To provide information and guidance for the use of hepatitis B immune globulin (HBIG) in providing passive immunization for unimmunized or unprotected individuals exposed to the hepatitis B virus (HBV) in Nunavut. Refer to the Canadian Immunization Guide (CIG), product monograph, or insert for specific information.	
Objective	To reduce the risk of infection in those who may have been exposed to HBV.	
Indication	HBIG is offered as prophylaxis to HBV exposed individuals who have not previously been immunized for HBV or who have anti-HBs titers of less than 10 IU/L. See eligibility below for further details.	
Eligibility	<p>HBIG is offered along with the HBV vaccine (at a different injection site) as prophylaxis to the following individuals who have not previously been immunized for HBV or who have anti-HBs titers of less than 10 IU/L:</p> <ul style="list-style-type: none"> • Perinatally exposed infants born to HBsAg positive mothers • Individuals with an acute exposure to blood or body fluids containing HBsAg • Individuals with sexual exposure to an HBsAg positive person <p>Note: Unimmunized infants < 12 months of age whose primary caregiver has an acute HBV infection require further consultation with regional CDC.</p>	
Product	HyperHEP B [®] S/D	
Vaccine Type	Passive immunization	
Vaccine components	<p>Human plasma with high titers of antibody to the hepatitis B surface antigen (anti-HBs)</p> <p>0.3% tri-n-butyl phosphate (TNBP), 0.2% Sodium cholate</p> <p>HyperHEP B S/D is preservative-free and latex-free.</p>	
Formats available	<p>0.5 mL neonatal single dose syringe with attached needle</p> <p>1 mL single dose syringe with attached needle</p> <p>1 mL and 5 mL single dose vials.</p>	
Manufacturer	Talecris Biotherapeutics, Inc.	
Administration	<p>Intramuscular (IM) injection to the antero-lateral thigh muscle (infants), the deltoid muscle or the ventrogluteal site (children with adequate muscle mass and adults). HBIG should <u>not routinely</u> be given in the dorsogluteal site, due to risk of sciatic nerve damage. Aspirate to ensure that the needle is not in a blood vessel. Large volumes should be given as split doses. The HB vaccine must be administered at a different injection site.</p>	
Dose Series	Dose	Timing
Infant born to a mother with acute or chronic hepatitis infection	0.5 mL	<p>As soon as possible after birth, preferably within the first 12 hours (may be given up to 7 days after exposure). Initiate HB vaccine series at the same time (premature babies weighing < than 2,000 grams at birth require four doses of HB vaccine).</p> <p>Efficacy of HBIG decreases significantly after 48 hours, but HBIG may be given up to 7 days after birth.</p>
Percutaneous or mucosal exposure	0.06mL/Kg	HBIG should be given to susceptible individuals (based on their immunization and antibody status, and the infectious status, if known of

to blood or body fluids potentially containing hepatitis b virus		<p>the source) within 48 hours after exposure¹. The efficacy of HBIg decreases significantly after 48 hours, but HBIg may be given up to 7 days after exposure.</p> <p>Dose of HBIg for older infants, children and adults is based on body weight given IM.</p> <p>1 If known HB vaccine non-responder, or if HB vaccine contraindicated, give second dose of HBIg 4 weeks after the first dose.</p>
Sexual contacts of an acute case or chronic carrier of hepatitis B	0.06 mL/kg	<p>A single IM dose of HBIg based on body weight should be given within 48 hours after exposure.</p> <p>The efficacy of HBIg decreases significantly after 48 hours, but HBIg may be given up to 14 days after exposure.</p>
Booster Dose	Not Applicable	
Vaccine interchangeability	Not Applicable	
Contraindications	<p>None known.</p> <p>HyperHep B S/D should be used with caution in pregnancy and in individuals with any coagulation disorder that would contraindicate intramuscular injections. The benefits must outweigh the risk in these cases.</p>	
Precautions and Additional Notes	<p>Live vaccines should be deferred for at least 3 months after HBIg, as HBIg may interfere with the immune response. For specific guidelines, discuss with the regional CDC.</p> <p>Individuals who have documented vaccination for HBV who have had an acute exposure to blood or body fluids or have been sexually exposed to an HBsAg positive person should immediately be tested for anti-HBs titers. For those who have an anti-HBs titer of less than 10 IU/L HBIg may be given, along with 1 dose of HBV vaccine. Titers should be redrawn in 1 month.</p> <p>Products made from human plasma may contain infectious agents that can cause disease. This risk has been reduced by a thorough screening of donors, however there is still a potential for disease transmission. The risks and benefits of HBIg should be discussed with the patient or their parent/guardian before administration.</p>	
Vaccine Supply and Distribution	Regional pharmacy is responsible for territorial vaccine supply and distribution. Vaccine should be ordered and distributed in accordance with recommended practice.	
Storage	<p>Store in monitored vaccine refrigerator between 2°C and 8°C.</p> <p>Protect from light.</p> <p>DO NOT FREEZE. Freezing destroys the active components of the vaccine. Segregate damaged product keeping the cold chain protocol and inform RCDC and regional pharmacy.</p>	
Consent	Consent forms must be reviewed and signed by the client or parent/guardian prior to vaccination.	
Anaphylaxis	Review the principles of the emergency management of anaphylaxis, as found in: Anaphylaxis: Initial Management in Non-Hospital Settings , found in the Canadian Immunization Guide.	
Side Effects	<p>Local pain and tenderness at the injection site, urticaria and angioedema may occur.</p> <p>Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.</p>	
Reportable Adverse	Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC.	

Events/Side Effects	<p>The Nunavut policy is:</p> <p>Adverse Events Following Immunization (AEFI) should be used only for the reporting of serious adverse events following immunization. The form is available online at: Adverse Event Following Immunization (AEFI) Form</p> <ul style="list-style-type: none"> The Unusual Occurrence Report should be used for reporting medication errors and other events. The report can be found in the Nunavut Community Health Nursing Administration Manual, Policy 05-004. A copy of the incident report must be faxed to RCDC. <p>If there is an AEFI and a vaccination error, both AEFI and Unusual Occurrence Report forms should be completed.</p> <p>All completed forms should be faxed to RCDC at the numbers listed below: Qikiqtaaluk: 867-975-4833; Kitikmeot: 867-983-4088; Kivalliq: 867-645-8272</p>
Vaccine Coverage and Reporting	Under development.
Documentation	All immunizations given should be documented on the Immunization Card, chart, personal immunization record, and electronic record (where applicable).
Materials and Resources	All protocols and materials are available on the DH website (www.gov.nu.ca/health) Nunavut Communicable Disease and Surveillance Manual HBIG Fact Sheet
References	<ol style="list-style-type: none"> HyperHEP B[®] S/D Product Monograph. Talecris Biotherapeutics, Inc. June 2, 2005. Public Health Agency of Canada. Canadian Immunization Guide – Evergreen Edition (2012). Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Fact Sheet

Hepatitis B Immune Globulin (HBIG)

What Hepatitis B?

Hepatitis B is a viral disease that spreads from one infected person to another through blood and body fluids.

It can be passed through unprotected sexual activity, sharing injection drug equipment, household contact, and from an infected mother to her baby. It can cause infection and damage to the liver, and is the main cause of liver cancer.

Who should get Hepatitis B Immune Globulin (HBIG)?

The following unimmunized groups may be recommended to receive HBIG:

- Babies born to Hepatitis B positive mothers
- People who have been exposed to blood or body fluids containing Hepatitis B
- People who have had sexual contact with a Hepatitis B positive person

What is HBIG and how is it given?

HBIG is a medication used to prevent infection from Hepatitis B in a case where somebody may have been exposed to the virus. It is made from the plasma (blood) of people who have immunity (protection) against Hepatitis B. HBIG is given with a needle into a muscle in the leg and/or arm.

Does HBIG protect you against Hepatitis B?

Yes, Hepatitis B Immune Globulin, when given with the full series of Hepatitis B vaccines, will help protect you.

Is HBIG safe?

Yes. Some people have mild pain, swelling, or redness for a few days where the needle was given. A few people may have an itchy rash. Rarely, people will experience severe reactions such as anaphylaxis or other allergic reactions.

HBIG is made from human plasma (blood) and may contain infectious agents that can cause disease. This risk has been reduced by a thorough screening of donors, however there is still a rare possibility for disease transmission.

Who should talk with their healthcare provider before receiving HBIG?

Tell your health care provider if you have any of the following:

- Severe allergic reaction to a previous dose of Immune Globulin. Severe reactions include wheezing, chest tightness, throat constriction and difficulty breathing or swallowing.
- An allergy to any ingredient in HBIG.
- You have bleeding problems or take blood thinners.

What is the risk of not getting HBIG?

If you are recommended to take the Hepatitis B Immune Globulin but choose not to, you are increasing your risk of becoming sick with Hepatitis B which can cause irreversible liver damage and increases your risk of liver cancer.

Where can I get more information?

For more information about this product, talk to your healthcare provider.

Feuille de renseignements

Immunoglobuline anti-hépatitique B (HBIG)

Qu'est-ce que l'hépatite B?

L'hépatite B est une maladie virale qui se transmet d'une personne infectée à une autre par le sang et les liquides organiques.

Elle peut être transmise par des rapports sexuels non protégés, le partage du matériel d'injection de drogues, les contacts avec les proches et par une mère infectée à son bébé. L'hépatite B peut causer une infection et des dommages au foie et constitue la principale cause du cancer du foie.

Qui devrait recevoir l'immunoglobuline anti-hépatitique B (HBIG)?

On recommande aux groupes non vaccinés suivants de recevoir l'HBIG :

- Les bébés nés de mères porteuses de l'hépatite B;
- Les personnes qui ont été exposées à du sang ou à des liquides organiques contenant l'hépatite B;
- Les personnes qui ont eu des relations sexuelles avec une personne porteuse de l'hépatite B.

Qu'est-ce que l'HBIG et comment est-elle administrée?

L'HBIG est un médicament utilisé pour prévenir l'hépatite B dans les cas où des personnes auraient été exposées au virus. Ce médicament est produit à partir du plasma (sang) des personnes qui sont immunisées (protégées) contre l'hépatite B. L'HBIG est administrée avec une aiguille dans un muscle de la jambe ou du bras.

L'HBIG vous protège-t-elle contre l'hépatite B?

Oui, l'immunoglobuline anti-hépatitique B, lorsqu'elle est administrée avec la série complète du vaccin contre l'hépatite B, vous protégera contre cette maladie.

L'HBIG est-elle sécuritaire?

Oui. Certaines personnes ressentiront des effets mineurs (légère douleur, enflure et rougeur) pendant quelques jours au point d'injection. Quelques personnes auront des démangeaisons. Rarement, les gens présenteront des symptômes graves tels qu'une réaction de type anaphylactique ou d'autres réactions allergiques.

L'HBIG est fabriquée à partir du plasma humain (sang) et peut contenir des agents infectieux pouvant provoquer des maladies. Ce risque a été réduit par un contrôle rigoureux des donneurs, toutefois une faible possibilité de transmission des maladies existe tout de même.

Qui devrait discuter avec un professionnel de la santé avant de recevoir l'HBIG?

Mentionnez-le au professionnel de la santé si l'une des situations suivantes vous concerne :

- Vous avez déjà eu une réaction allergique grave suite à une dose précédente d'immunoglobuline. Les réactions graves incluent une respiration sifflante, des serremments de poitrine, une sensation d'étranglement dans la gorge et une difficulté à respirer ou à avaler.
- Une allergie à tout ingrédient contenu dans l'HBIG.
- Vous avez des troubles de coagulation ou vous prenez des anticoagulants.

Quel est le risque lié au fait de ne pas recevoir l'HBIG?

Si l'on vous a recommandé de vous faire administrer l'immunoglobuline anti-hépatitique B, mais que vous refusez, vous augmentez votre risque de contracter l'hépatite B, une maladie qui peut causer des dommages irréversibles au foie et augmente vos risques de développer le cancer du foie.

Où puis-je obtenir plus d'information?

Pour plus d'informations sur ce produit, adressez-vous à un professionnel de la santé.



Naunaiyariikhimayunik Titiraq Hepatitis B Immune Globulin (HBIG)

Hunauyuq Hepatitis B?

Hepatitis B hiamittaaktuq aanniarut atauhiqmit aanniarutikaktumit aallamun inungmut talvuuna aungmit timiup imaitigutlu.

Aatlamun pidjutihunnguyuuq nuliaguptik uhungmut puuqangittumik, atuqaqtigiiguffi kapuqtuinnikut, iglumi kahaqnirmun, amaama aanniagutiqaqumi biibinnuaq aannialaqtitaaktuq. Aannialaqtitaahunnguyuuq ihuigtigilunilu tinguqmun, taimaitkumilu kaansautiqarniaqtuq.

Kitkut kapurhiktuqhauyut Hepatitis B Immune Globulin (HBIG)?

Taapkuat ihumagiyaayut ataani titirarhimayut kapurhiktuqhaugaluut HBIG kappuutaannik:

- Biibinnuat amaamait Hepatitis B-mik aanniarutiqaqhimayut
- Inuit qayaringgiplutik aukmut timimitluunniit imaitiguutainnit Hepatitis B-qaqtunik
- Inuit nuliaqhimayuuq inungmik Hepatitis B-qaqhimayumit

Hunauyuq HBIG qanuqlu tuniyauva?

HBIG havautauyuq aanniaqtailitkhanik Hepatitis B-mik aanniarutiqaqtumit kahaqtauhimaguvit. Havaktauhimayuuq (aungmit) inungnit aannialaqtitaahunnguyuuq Hepatitis B-mik. HBIG havaut kapiyauluni kananganut niqiqarnikkut uvaluunniit talianut.

HBIG aannialaitkutaavaa Hepatitis B-mik?

Hii, Hepatitis B Immune Globulin, tuniyaukpat tamainnit Hepatitis B kappuutainnik, ikayuutauniaqtut ilingnut aannialaitkutauniaqtuq .

HBIG qayangnaitpa?

Hii. Ilanngit Inuit uluriahukaffukpaktut, puvittutik, aupayavyakhuni ikittuni ubluni kapiyauningani. Ikittut, inuit kukulaqivaktut amirlighutikluunniit. Ivyanngulaqiyuittut uviliglaqiyuittutlu.

HBIG havautiliuqtauhimayuuq inuup aunganit (auk) piqangniarunaghiyuq inuup aunganit havautiliuktauhimayuuq ilani aannialaqtitaahunnguyuuq ilainut. Qayangnaighinahaqpakut auktaqtauhimayuuq ihivriuttiaghugit auktaqtauhimayut, Kihimi ilani nalunaqtuq aannirutit hiamitauyangita inungmut.

Kitkut uqaqatiqaqtughauvat munaghimingnut taaktimutluunniit kapiyaunatik HBIG?

Taaktit munaghitluunniit uqautilugu hapkuninga piqaruvit:

- Hivuanu angiyumik timimut nakuunngirutauyaaqtunut kapuutinut umaga Immune Globulin. Allujiutit hapkuat an'ngayuhuliqtuq, puvsangminik mikiguhuliqtuq, igginga nirruhiyuq annikhagiaminik ayukhaktuq, ihigiagiaminiklu uluriahuktuq.
- Allujikpakhimayuuq havaunmit ilanganik uminga HBIG.
- Auklaqinnakpakuvit aunnaruilimaikpakuvitluunniit aungnut havautituruvit.

Hunauva hamna aannirut kappiyaungitunut uminga HBIG?

Hunauva hamna aanniaut kappiyaungitunut uminga Hepatitis B-mik Immune Globulin kappiyauyumangitkuvit, aannialaqtitaaktutit uminga Hepatitis B nakuuhilimaittumik tingunglirnaqtuq hunngiutittaaktuq tinungnut Tingungni kaansaniktuqlu.

Nakit naunaihittiangniaraluaqqiq?

Naunaighittiarumaguvit avuuna, munagitkut uqaqatigillugit.



Immunization Protocol for GamaSTAN[®] S/D

Immune Globulin (Ig)

Purpose	To provide information and guidance for the use of immune globulin (Ig) in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph or insert for specific information.		
Objective	To prevent measles and hepatitis A infection in exposed and susceptible Nunavummiut.		
Indication	Immune Globulin (Ig) is indicated for individuals requiring post-exposure prophylaxis under the guidance of the Chief Medical Officer of Health (CMOH) for Nunavut.		
Eligibility	Publicly funded post-exposure Ig is given only in consultation with and as directed by the office of the CMOH in some unimmunized or under immunized individuals requiring post-exposure prophylaxis for either Hepatitis A or Measles.		
Product	GamaSTAN [®] S/D		
Vaccine Type	Passive Immunizing Agent		
Vaccine components	15-18% immune globulin (human) as active ingredient. 0.21-0.32 M glycine, USP.		
Formats available	2 mL, 5 mL and 10 mL single use vials.		
Manufacturer	Grifols Therapeutics Inc.		
Administration	Intramuscular (IM) injection to the anterolateral thigh muscle (infants), the deltoid muscle or the ventrogluteal site (children with adequate muscle mass and adults). Ig should <u>not routinely</u> be given in the dorsogluteal site, due to risk of sciatic nerve damage. Large volumes should be given as split doses.		
Dose Series	Post-exposure prophylaxis for:	Dose	Timing
	Hepatitis A	0.02 mL/kg	As soon as possible, up to 2 weeks after exposure.
	Measles (in an immune-competent individual)	0.25 mL/kg (maximum 15 ml)	As soon as possible, up to 6 days after exposure.
	Measles (in a severely immune-compromised individual)	0.5 mL/kg (maximum 15 ml)	As soon as possible, up to 6 days after exposure.
Booster Dose	Not applicable		
Vaccine interchangeability	Not applicable		
Contraindications	<p>Ig should not be given to patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.</p> <p>Ig should not be given to persons with isolated immunoglobulin A (IgA) deficiency. Such persons have the potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.</p> <p>Ig should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.</p>		
Precautions and Additional Notes	<p>Live vaccines should be deferred for at least 5 months after as Ig may interfere with the immune response. For specific guidelines, discuss with the regional CDC.</p> <p>Ig is made from human plasma and may contain infectious agents that can cause disease. This risk has been reduced by a thorough screening of donors, however there is still a</p>		

	<p>potential for disease transmission. The risks and benefits of Ig should be discussed with the patient or their parent/guardian before administration.</p> <p>The effects of Ig on pregnancy are unknown. Ig should be given to a pregnant woman only if clearly needed.</p> <p>The effects of Ig on breastfeeding are unknown. It is recommended that a decision should be made to either discontinue breastfeeding or discontinue the administration of Ig, taking into account the importance of Ig therapy to the mother and the possible risk to the infant.</p> <p>Vials are single use only and unused and unused contents should be discarded after use.</p>
Vaccine Supply and Distribution	Regional pharmacy is responsible for publicly funded territorial vaccine supply and distribution. Vaccine should be ordered and distributed in accordance with usual practices.
Storage	<p>Store in monitored vaccine refrigerator between 2°C and 8°C.</p> <p>DO NOT FREEZE. Freezing destroys the active components of the vaccine. Segregate damaged product keeping the cold chain protocol and inform RCDC and regional pharmacy.</p>
Consent	Consent forms must be reviewed and signed by the client or parent/guardian prior to vaccination.
Anaphylaxis	Review the principles of the emergency management of anaphylaxis, as found in: Anaphylaxis: Initial Management in Non-Hospital Settings , found in the Canadian Immunization Guide.
Side Effects	<p>Local pain and tenderness at the injection site. Urticaria and angioedema may rarely occur.</p> <p>Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.</p>
Reportable Adverse Events/Side Effects	<p>Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC.</p> <p>The Nunavut policy is:</p> <ul style="list-style-type: none"> Adverse Events Following Immunization (AEFI) should be used only for the reporting of serious adverse events following immunization. The form is available online at: Adverse Event Following Immunization (AEFI) Form The Unusual Occurrence Report should be used for reporting medication errors and other events. The report can be found in the Nunavut Community Health Nursing Administration Manual, Policy 05-004. A copy of the incident report must be faxed to RCDC. <p>If there is an AEFI and a vaccination error, both AEFI and Unusual Occurrence Report forms should be completed.</p> <p>All completed forms should be faxed to RCDC at the numbers listed below: Qikiqtaaluk: 867-975-4833; Kitikmeot: 867-983-4088; Kivalliq: 867-645-8272</p>
Vaccine Coverage and Reporting	Under development.
Documentation	All immunizations given should be documented on the Immunization Card, chart, personal immunization record, and electronic record (where applicable).
Materials and Resources	Ig Fact Sheet
References	<ol style="list-style-type: none"> GamaSTAN® S/D Product Monograph. Grifols Canada Ltd. July 30, 2012. Public Health Agency of Canada. Canadian Immunization Guide – Evergreen Edition (2012). Source: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Fact Sheet

Immune Globulin

What is Immune Globulin and how is it given?

Immune Globulin is a medication used to prevent Hepatitis A or Measles in a case where somebody may have been exposed. It is made from the plasma (blood) of people who have immunity (protection) against Hepatitis A and Measles. Immune Globulin is given into a muscle in the leg and/or arm.

What is Hepatitis A?

Hepatitis A is a viral disease that spreads from one infected person to another through the fecal-oral route. Hepatitis A can cause infection and damage to the liver. Sickness from Hepatitis A can be a mild illness lasting 1 to 2 weeks or a severely disabling disease lasting several months.

What is Measles?

Measles is a virus that can spread easily between people. People with measles often have a high fever and rash. Measles can cause serious infections in the brain, ears, eyes and lungs. In the past, before vaccines, it was the leading cause of death for many children.

Who should get Immune Globulin?

If a person has not been completely immunized against Hepatitis A or Measles, and they have been exposed to one of these diseases, they may require Immune Globulin for protection.

Is Immune Globulin safe?

Yes. Some people have mild pain, swelling, and redness for a few days where the needle was given. A few people may develop a rash, hives or swelling under the skin (angioedema). Rarely, people will experience severe reactions such as anaphylaxis or other allergic reactions.

Immune Globulin is made from human plasma (blood) and may contain infectious agents that can cause disease. This risk has been reduced by a thorough screening of donors, however

there is still a rare possibility for disease transmission.

Who should talk with their healthcare provider before receiving Immune Globulin?

Tell your health care provider if you have had any of the following:

- Severe allergic reaction to a previous dose of Immune Globulin. Severe reactions include wheezing, chest tightness, throat constriction and difficulty breathing or swallowing.
- An allergy to any ingredient in Immune Globulin.
- You have bleeding problems or take blood thinners.
- You have isolated immunoglobulin A (IgA) deficiency.
- You are pregnant or breastfeeding.

What is the risk of not getting Immune Globulin?

If you are recommended to take Immune Globulin but choose not to, you are increasing your risk of becoming sick with either Hepatitis A or Measles. There is no medical treatment for Hepatitis A or Measles once a person is infected.

Where can I get more information?

For more information about this product, talk to your healthcare provider.



Feuille de renseignements

L'immunoglobuline

Qu'est-ce que l'immunoglobuline et comment l'administre-t-on?

L'immunoglobuline est un médicament utilisé pour prévenir l'hépatite A ou la rougeole chez les personnes ayant été exposées à ces maladies. Elle est fabriquée à partir du plasma sanguin de personnes immunisées (protégées) contre l'hépatite A et la rougeole. L'immunoglobuline est administrée dans un muscle de la jambe ou du bras.

Qu'est-ce que l'hépatite A?

L'hépatite A est une maladie virale qui se transmet d'une personne infectée à une autre par voie oro-fécale. L'hépatite A peut infecter et endommager le foie. La maladie de l'hépatite A peut être peu grave, et durer une à deux semaines, ou être gravement invalidante, et durer plusieurs mois.

Qu'est-ce que la rougeole?

La rougeole est une maladie causée par un virus qui se transmet facilement d'une personne à une autre. Les personnes atteintes de rougeole ont souvent une fièvre élevée et une éruption cutanée. La rougeole peut causer des infections graves dans le cerveau, les oreilles, les yeux et les poumons. Dans le passé, avant l'arrivée des vaccins, la rougeole était l'une des principales causes de décès chez les enfants.

Qui devrait recevoir l'immunoglobuline?

Si une personne qui n'a pas été complètement immunisée contre l'hépatite A ou la rougeole est exposée à l'une de ces maladies, elle pourrait avoir besoin de recevoir l'immunoglobuline pour se protéger.

L'immunoglobuline est-elle sécuritaire?

Oui. Certaines personnes ressentent une douleur légère, de l'inflammation et de la rougeur au lieu d'insertion de l'aiguille pendant quelques jours. Quelques personnes pourraient éprouver une éruption cutanée, de l'urticaire ou de l'inflammation sous-cutanée (œdème de Quincke). Dans de rares cas, les personnes recevant l'immunoglobuline auront de graves réactions telles qu'un choc anaphylactique ou d'autres réactions allergiques.

L'immunoglobuline est fabriquée à partir de plasma (sang) humain, et peut contenir des agents infectieux pouvant entraîner des maladies. Ce risque a été réduit par un dépistage rigoureux des donneurs, mais

il existe toujours un très faible risque de transmission d'une maladie.

Qui devrait parler à son fournisseur de soins de santé avant de recevoir l'immunoglobuline?

Informez votre fournisseur de soins de santé si vous avez déjà subi l'un des événements suivants :

- Réaction allergique grave à une dose antérieure d'immunoglobuline, par exemple : respiration sifflante, serrement de poitrine, constriction de la gorge et difficulté à respirer ou à avaler;
- Une allergie à l'un des ingrédients de l'immunoglobuline;
- Vous souffrez d'un trouble de saignement ou vous prenez un anticoagulant;
- Vous avez un déficit isolé en immunoglobulines A (IgA);
- Vous êtes enceinte ou allaitez.

Quels sont les risques auxquels on s'expose en ne prenant pas l'immunoglobuline?

Si l'on vous recommande de prendre l'immunoglobuline, mais que vous choisissez de ne pas recevoir ce traitement, vous courez un plus grand risque de contracter l'hépatite A ou la rougeole. Il n'existe aucun traitement médical pour l'hépatite A ou la rougeole pour soigner une personne infectée.

Où puis-je trouver de plus amples renseignements?

Pour de plus amples renseignements au sujet de ce produit, veuillez consulter votre fournisseur de soins de santé.



Kangikhitjutikhaq

(Immune Globulin) Havautikhak Aamigyukhauyut Titiraamungakhimayut

Huunauyuq tamna (Immune Globulin) havautikhak imalu qanutun tuniyauvakpa?

Immune Globulin imalu havautikhak atuqauvaktuq talvuna pittailinnaitumik (Hepatitis A) Aaniakgut nalliak (Measles) Aaniakgut qanuqgittkumi inuk aaniakinnahuqungnarrami aaniaktumin. Havakhikhimayuuq aukmit (auk) tapqunanga inuknin auggiktunit (pittailidjutiggiplugu) tapfumanga (Hepatitis A) Aaniakgut unalu (Measles) Aaniakgut. (Immune) (Globulin) havautikhak imalu tuuniyauvaktuq Niung'gattigut/nalliak talliatigut.

Huna tamna (Hepatitis A) Aaniakgut?

(Hepatitis A) Aaniakgut imalu hivugannaktuq aaniakgut hiammitikpaktuq inuknit aaniakguttillingnik talvuna inakkatigigangamiuk aaniaktuuyuumit. (Hepatitis A) Aaniakgut aaniakinnaktuq imalu tingguklingnaktuklu. Aaniakguutimit tapfumuanga (Hepatitis A) Aaniakgut immailakinnaktuq tuutkiing'guyyalikgalutiklu atauhikmik nalliak malrukniikunin unaguiqhikniiknik nalliak aaniakpialliktum aaniakgaakpakjuutiggiplugulu.

Huna tamna (Measles) Aaniakgut?

(Measles) Aaniakgut imalu aaniagutauyuq imalu hiammitaqpiaktuq inuungni. Inuin aaniakgutilingni (measles) aaniagut pidjutikalipaktun kijjakpiakgalutiklu ammiglikpakhutiklu. (Measles) Aaniakgut hivukgannakpiaktuq aaniaguutin naudjuutivaktuq talvani qarritakmi, hiutikni, iyyikni unalu puuvangnilu. Qang'gakgaluk, havautikalikaktinnagit, taimmaitugaluaktuq hivuliupluni tuqquyukakganggat nutaqaanik.

Qina pidjutiggiyahaa tamna havautikhak (Immune Globulin)?

Imalu inuk qapuhikkatanggitpan talvuna (Hepatitis A) Aaniakgut nalliak (Measles) Aaniakgut, unalu tapquat qanuqgittkumi aaniakinnahuqungnagami aaniaktumin, pidjutikakgiaktun (Immune Globulin) havautikhak tapfumuna pittailinnaitumik aaniakgunmik.

Ima (Immune Globulin) Havautikhak qayangnaitpa?

Hii. Ilangit inuit uulukgiahuutjuutiggiyagaat, puvitikaalutik, unalu auppajilakigalutiklu qaffinik ublunik qapukhingniangani. Ilangit inuit ammiglikpaktun, puvitikuhtik nalliak puvitpiakpaktun ataani uviniup (angioedema). Pikkaqluayuituq inuin

ilitukgitjuutigiblugu hivvuganaktumik ammiglitigiblugu tamna aaniagut nalliak alaanut aaniakgutinnit.

(Immune Globulin) Havautikhak havakhimayuuq inuit aunginnit (auk) unalu pidjutikangnahuqqungnaktuklu aaniakgutimik aaniakinnaktun. Uvuna qayangnaiyaktauhimayuuq ihiviuktiakguutiggiplugit aittuqtuqaktunit, qihimi pinnahuqqungnaktuk pikkatayuitun pinnahuqungnaktuq talvuna aaniakguutimik aulikhikganggamik.

Qina uqaqatigiiyahaa munakhilikiyitkut hivvuagut havautituqaagtinnagit (Immune Globulin) Havautikhak?

Uqaqlugu munakhigiiyangnik ikayuqtiggiyankik pidjutikakhimavakuvit uk'kungninga:

- Hivugannakpiaktuq ammiglikgangat talvuna havautittuqtitaugangami (Immune Globulin) Havautikhak. Hivugannakpiaktuq aaniakhaakluaggungnaikgalutik, huukkatikhuni qattikqangni, iggiangaa uumiktikhunilu aiyuqhalikhuni aaniakhaaktaakgiamilu nalliak iihiyamilu.
- Unalu ammiglikhuni talvuna quuyakginnamik havautiitumit (Immune Globulin) Havautikhak.
- Ilvit aiyuqhautikakin auknikmun nalliak havautittuqtitaavit aukgikhautimik .
- Pidjutikakhimavakpin qayanggiyauvakhimavakpin (immunoglobulin A (IgA) havautittuqtitaayuq aiyukhautiggiyankik.
- Hingaiyauviin nalliak ammamaqtuqtiviin.

Huna imalu hivugannakniakpa qapuhinggitkuma havautikhak (Immune Globulin) havautikhak?

Imalu havautittukuyauguvit (Immune Globulin) havautikhak qihimi havautittuqumanggitkuvit, ing'gatakyuumihungguuyutit aaniakilutitlu tapfumanga (Hepatitis A) Aaniakgut nalliak (Measles) Aaniagut. Talvuna havautikhaituq (Hepatitis A) nalliak (Measles) Aaniakgut aaniakikpan inuk.

Huumit tukihigiarutikhamnik pinnialgaluakingaa?

Talvuna tukihigiarutikhamnik uvuna pidjutihautikhamik uqaqvigilugu munakhigiiyangnik ikayuqtiggiyankik.



Immunization Protocol for HYPERTET[®] S/D

Tetanus Immune Globulin (Tlg)

Purpose	To provide information and guidance for the use of tetanus immune globulin (Tlg) in providing passive immunization in post-exposure prophylaxis of individuals exposed to tetanus in Nunavut. Refer to the Canadian Immunization Guide (CIG), product monograph, or insert for specific information.
Objective	To reduce the risk of infection of <i>Clostridium tetani</i> in Nunavummiut.
Indication	Tlg is offered along with a tetanus containing vaccine (at a different injection site) as prophylaxis for incompletely immunized or unimmunized Nunavummiut requiring prophylactic wound management. See eligibility below for further details.
Eligibility	<ul style="list-style-type: none"> • Tlg is indicated in those individuals who have not completed primary immunization against tetanus (at least 3 documented doses), who have sustained one of the following tetanus prone wounds: <ul style="list-style-type: none"> ○ wounds contaminated with dirt, feces, soil and saliva ○ puncture wounds ○ bites, avulsions and wounds resulting from missiles, crushing, burns or frostbite <p>Individuals with unknown or uncertain previous vaccination histories should be considered to have had no previous tetanus toxoid doses.</p> <ul style="list-style-type: none"> • Individuals with humoral immune deficiency (e.g., HIV, agammaglobulinemia or hypogammaglobulinemia) may not respond adequately to tetanus toxoid-containing vaccine. Individuals with humoral immune deficiency who have wounds that are not minor and clean should receive both Tlg and tetanus toxoid-containing vaccine, regardless of the time elapsed since the last booster. <p>Individuals for whom tetanus containing vaccines are contraindicated should receive Tlg, as required for wound management.</p>
Product	HYPERTET [®] S/D
Vaccine Type	Passive immunization
Vaccine components	Human plasma with greater than 250 tetanus antitoxin units per container. 0.3% tri-n-butyl phosphate (TNBP), 0.2% Sodium cholate
Formats available	250 unit single dose prefilled disposable syringes with attached needles or 250 unit single dose vials.
Manufacturer	Talecris Biotherapeutics, Inc.
Administration	Intramuscular (IM) injection to the antereolateral thigh muscle (infants) and the deltoid muscle or ventrogluteal muscle (in children with adequate muscle mass and adults). The plunger of the syringe should be drawn back before injection to ensure that the needle is not in a blood vessel.
Dose Series	The recommended dose of Tlg for adults and children is 250 units by IM injection. It is advisable to administer the entire contents of the vial of Tlg regardless of the child's size; theoretically the same amount of toxin will be produced in a child or adult's body by the infecting tetanus organism.
Booster Dose	Not Applicable
Vaccine interchangeability	Not Applicable

Contraindications	None known.
Precautions and Additional Notes	<p>HYPERTET S/D should be used with caution in pregnancy and in individuals with any coagulation disorder that would contraindicate intramuscular injections. The benefits must outweigh the risk in these cases.</p> <p>Live vaccines should be deferred for at least 3 months after Tlg, as Tlg may interfere with the immune response. For specific guidelines, discuss with the Regional CDC.</p> <p>Products made from human plasma may contain infectious agents that can cause disease. This risk has been reduced by a thorough screening of donors, however there is still a potential for disease transmission. The risks and benefits of Tlg should be discussed with the patient or their parent/guardian before administration.</p> <p>Ensure the completion of the primary series of vaccinations (at least 3 doses) with age appropriate Tetanus containing vaccine.</p>
Vaccine Supply and Distribution	<p>Regional pharmacy is responsible for territorial vaccine supply and distribution. Vaccine should be ordered and distributed in accordance with recommended practice.</p> <p>NOTE: Each health center must maintain a supply of 1dose of Tlg <u>at all times</u>. Please ensure on a routine basis that the Tlg stocked has not expired.</p>
Storage	<p>Store in monitored vaccine refrigerator between 2°C and 8°C.</p> <p>Protect from light.</p> <p>DO NOT FREEZE. Freezing destroys the active components of the vaccine. Segregate damaged product keeping the cold chain protocol and inform RCDC and regional pharmacy.</p>
Consent	<p>Consent forms must be reviewed and signed by the client or parent/guardian prior to vaccination.</p>
Anaphylaxis	<p>Review the principles of the emergency management of anaphylaxis, as found in: Anaphylaxis: Initial Management in Non-Hospital Settings, found in the Canadian Immunization Guide.</p>
Side Effects	<p>Slight soreness at the site of injection and slight temperature elevation may occur.</p> <p>Anaphylactic reactions, angioneurotic edema, and nephrotic syndrome, have occurred rarely after injection.</p>
Reportable Adverse Events/Side Effects	<p>Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC.</p> <p>The Nunavut policy is:</p> <ul style="list-style-type: none"> • Adverse Events Following Immunization (AEFI) should be used only for the reporting of serious adverse events following immunization. The form is available online at: Adverse Event Following Immunization (AEFI) Form • The Unusual Occurrence Report should be used for reporting medication errors and other events. The report can be found in the Nunavut Community Health Nursing Administration Manual, Policy 05-004. A copy of the incident report must be faxed to RCDC. <p>If there is an AEFI and a vaccination error, both AEFI and Unusual Occurrence Report forms should be completed.</p> <p>All completed forms should be faxed to RCDC at the numbers listed below:</p> <p>Qikiqtaaluk: 867-975-4833; Kitikmeot: 867-983-4088; Kivalliq: 867-645-8272</p>
Vaccine Coverage and Reporting	Under development.

Documentation	All immunizations given should be documented on the Immunization Card, chart, personal immunization record, and electronic record (where applicable).
Materials and Resources	All protocols and materials are available on the DH website (www.gov.nu.ca/health) Nunavut Communicable Disease and Surveillance Manual Tetanus Immune Globulin (Tlg) Fact Sheet
References	<ol style="list-style-type: none"> 1. HYPERTET[®] S/D Product Monograph. Talecris Biotherapeutics, Inc. June 1, 2005. 2. Public Health Agency of Canada. Canadian Immunization Guide – Evergreen Edition (2012). Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

Fact Sheet

Tetanus Immune Globulin (Tlg)

What is tetanus?

Tetanus (lockjaw) is a bacteria that can enter through scrapes and cuts, and causes painful tightening of muscles of the body, breathing problems, and occasionally death.

Who should get Tetanus Immune Globulin (Tlg)?

The following injuries can cause tetanus infection:

- Open cuts or wounds contaminated with dirt, feces, or soil.
- Bites (both human and animal)
- Puncture wounds
- Burns or frostbite

Any person with an injury listed above who meets the following criteria may require Tlg:

- Has not had 3 doses of a vaccine containing tetanus.
- Is not medically able to receive the tetanus vaccine.
- Has a condition that makes them less able to fight off infections (immune compromise).

What is Tlg and how is it given?

Tlg is a medication used to prevent tetanus in a case where somebody may have been exposed to the bacteria. It is made from the plasma (blood) of people who have immunity (protection) against tetanus. Tlg is given with a needle into a muscle in the leg and/or arm.

Does Tetanus Immune Globulin protect you against tetanus?

Yes, Tetanus Immune Globulin, when given with the full series of a tetanus vaccine, will protect you.

Is Tetanus Immune Globulin safe?

Yes. Some people have mild pain, swelling, and redness for a few days where the needle was given.

A few people may have headaches, muscle ache, and fatigue. Rarely, people will experience severe reactions such as anaphylaxis or other allergic reactions.

Tlg is made from human plasma (blood) and may contain infectious agents that can cause disease. This risk has been reduced by a thorough screening of donors, however there is still a rare possibility for disease transmission.

Who should talk with their healthcare provider before receiving Tetanus Immune Globulin?

Tell your health care provider if you have had any of the following:

- Severe allergic reaction to a previous dose of Immune Globulin. Severe reactions include wheezing, chest tightness, throat constriction and difficulty breathing or swallowing.
- An allergy to any ingredient in Tlg.
- You have bleeding problems or take blood thinners.

What is the risk of not getting Tetanus Immune Globulin?

If you are recommended to take the Tetanus Immune Globulin but choose not to, you are increasing your risk of becoming sick with tetanus which can cause painful tightening of muscles in the body, breathing problems, and may lead to death. There is no medical treatment for tetanus once a person is infected.

Where can I get more information?

For more information about this product, talk to your healthcare provider.



Feuille de renseignements

L'immunoglobuline anti-tétanique (Tlg)

Qu'est-ce que le tétanos ?

Le tétanos (lockjaw ou « mâchoire bloquée ») est une bactérie qui peut pénétrer par des égratignures et des coupures et causer des spasmes musculaires douloureux, des problèmes respiratoires et occasionnellement la mort.

Qui devrait recevoir l'immunoglobuline anti-tétanique (Tlg) ?

Les blessures suivantes peuvent causer une infection tétanique :

- Une coupure ou plaie ouverte contaminée par de la saleté, des excréments ou de la terre.
- Une morsure (humaine ou animale)
- Une coupure profonde
- Une brûlure ou une engelure

Toute personne avec subi l'une des blessures énumérées ci-dessus et qui rencontre les critères suivants peut avoir besoin de recevoir la Tlg :

- Elle n'a pas reçu 3 doses d'un vaccin contre le tétanos.
- Elle n'est pas médicalement en mesure de recevoir le vaccin contre le tétanos.
- Elle présente une condition médicale qui la rend moins apte à se défendre contre des infections (immuno-déficiente).

Qu'est-ce que l'immunoglobuline anti-tétanique (Tlg) et comment est-elle administrée ?

La Tlg est un médicament utilisé pour prévenir le tétanos dans les cas où des personnes auraient été exposées à la bactérie. Ce médicament est produit à partir du plasma (sang) des personnes qui sont immunisées (protégées) contre le tétanos. La Tlg est administrée avec une aiguille dans un muscle de la jambe et/ou du bras.

L'immunoglobuline anti-tétanique vous protège-t-elle contre le tétanos ?

Oui, l'immunoglobuline anti-tétanique, lorsqu'elle est administrée avec la série complète du vaccin contre le tétanos, vous protégera contre cette maladie.

L'immunoglobuline anti-tétanique est-elle sécuritaire ?

Oui. Certaines personnes ressentiront des effets mineurs (légère douleur, enflure et rougeur) pendant quelques jours au point d'injection.

Quelques personnes subiront des maux de tête, des douleurs musculaires et de la fatigue. Rarement, les gens présenteront des symptômes graves tels qu'une réaction de type anaphylactique ou d'autres réactions allergiques.

La Tlg est fabriquée à partir du plasma humain (sang) et peut contenir des agents infectieux pouvant provoquer des maladies. Ce risque a été réduit par un contrôle rigoureux des donneurs, toutefois une faible possibilité de transmission des maladies existe tout de même.

Qui devrait discuter avec un professionnel de la santé avant de recevoir l'immunoglobuline anti-tétanique ?

Mentionnez-le au professionnel de la santé si l'une des situations suivantes vous concerne :

- Vous avez déjà eu une réaction allergique grave suite à une dose d'immunoglobuline. Les réactions graves incluent une respiration sifflante, des serremments de poitrine, une sensation d'étranglement dans la gorge et une difficulté à respirer ou à avaler.
- Une allergie à tout ingrédient compris dans la Tlg.
- Vous avez des troubles de coagulation ou vous prenez des anticoagulants.

Quel est le risque lié au fait de ne pas recevoir l'immunoglobuline anti-tétanique ?

Si l'on vous a recommandé de vous faire administrer l'immunoglobuline anti-tétanique, mais que vous choisissez de refuser cette alternative, vous augmentez votre risque de contracter le tétanos, lequel peut occasionner des spasmes musculaires douloureux, des problèmes respiratoires et éventuellement la mort. Il n'existe aucun traitement médical contre le tétanos une fois qu'une personne est infectée.

Où puis-je obtenir davantage d'information ?

Pour plus d'informations sur ce produit, adressez-vous à un professionnel de la santé.



Naunaitkut Titiraq

Tetanus Immune Globulin (Tlg) Kapuut

Hunauva hamna aannirut tetanus?

Tetanus ((lockjaw) agliruup niqinginnik aannirut) aannialaqinnaqtuq timimut kilirnikkut itiqtaaktuq, nukingnut hukatirnaqtumik ulurianaqpiaktuq, arnirlirnaqtuqlu, tuqungnaqtuqlu.

Kinatkut kapiyauyukhauvat Tetanus Immune Globulin (Tlg) kappunmik?

Hapkuat aanniutit aanniruhirnaqtut uminga tetanus-mik aannirunmik:

- Killit mattutaittumik halumaikhimayut hallumailrumit, arnarmit, uvaluuniit nunamit.
- Kiittirniit (inungmit niryutinlitlu)
- Kappiniit killit
- Uttirniit uvalu qiqittirniit

Inuk kinaliqaak aannikhimayuuq qulanittunik uminga kappiyaunginariaqtaqtuq Tlg:

- Kappiyauhimitut pingahunik kapputinik havautiqatqumik tetanus-mik.
- Aanniarunminit kappiyaulimaittunut kapputinik havautiqatqumik .
- Aanniarutiqatqunut aanniaqtaaktunutlu (aannialaqinnaitkutit timimut).

Hunauva hamna Tlg havaut qanuqtut tuniyauvakpa?

Havautauyuuq aanniaqtaailitjut tetanus-mik inuuk aanniarutiqatqumut qanniklihimakpata. Havautiliuqtauhimayuuq plasmamit (aukmit) aannialaqilimaitunut uminga tetanus-mik . Tlg kappunmut havauhiktauvaktut kannangagut niqiqarnikkut tallianutluuniit.

Una Tetanus Immune Globulin ikayuutauva umunga tetanus-mit?

Hii, una Tetanus Immune Globulin-mik, tamainik kappuutikhanik kapiyauyunut tetanus-mik kappuut, aanniarnaittuq.

Una Tetanus Immune Globulin Kappuutit qayangnaitpat?

Hii, ilangit Inuit uluriahukapfukpaktut, puvittutikluuniit, aupayalikhutiklu ikittuni upluni kappiniagut.

Ilangit Inuit niaquqliukpaktut, aannimallaqiplutiklu, imatutlu uunaguhulaqiplutik. Ikitut allujikpaktut uminga anaphylaxis uviniklukhutikluuniit.

Tlg inuup aunganit havautiliuktauhimayuuq ilani aannialaqinnaktuq ilainut. Ihivriuktautjarikhivaktut Inuit aukmingnik aittutait aanniarnaittumik, imaaluniit ilani hiamitiqtaaktuq aanniarut.

Kitkut uqaqqatiqariaqtaqtat munakhinut kapiyaunatik uminga havaunmik Tetanus Immune Globulin?

Uqaqlutit munakhinut hapkuninga nallianik piqaruvit:

- Allujikpiakhimaguviit hivuagut kappunmit imaitumit Immune Globulin. Allujiutit hapkuat an'ngayuhuliqtuq, puvsangminik mikiguhuliqtuq, igginga nirruhiyuuq annikhagiainik ayukhaktuuq, ihigiagiainiklu uluriahuktuq.
- Allujikpakhimayuuq havaunmit ilanginik uminga Tlg.
- Auklaqinnakpakuvit aunnaruilimaikpakuvitluuniit aungnut havautituruvit.

Hunauva hamna aannirut kappiyaungitunut uminga Tetanus Immune Globulin?

Kappitquyauyuuq uminga Tetanus Immune Globulin kihimik piyungitkuvit, aannialaqittaaktutit tetanus-mik uuluriannaqpiaktuq qilluhiniq nukiini timingni, aannikhaaktagiaini ayukhaktuuq, tukunnaqtuqlu. Havautikhaittuq inungmut aanniaruhitqumut uminga tetanus-mik.

Nakit ilitturitjarikhiniaqqik naunairutikhanik?

Naunairutikhanik uvuuna havautikkut, apikhuqlugit munakhit.



