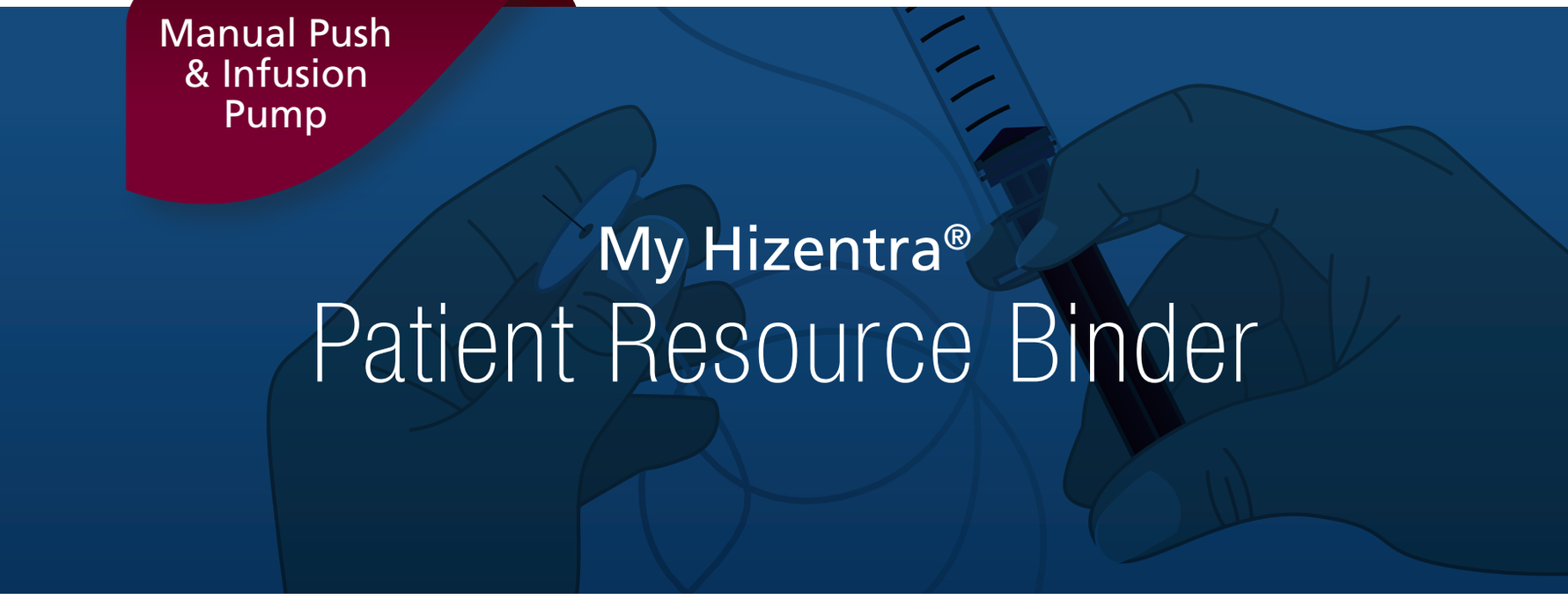
Hizentra®

Subcutaneous Immune Globulin (Human), **20%**

Manual Push & Infusion Pump



My Hizentra®
Patient Resource Binder

Information about Hizentra®

Log Sheets

Step-by-Step Guide

CAN-HIZ-0173

Biotherapies for Life® CSL Behring

Hizentra®
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Welcome to your Hizentra®
Patient Resource Binder

Support for you and your family

We created the Hizentra® Patient Resource Binder to help you every step of the way in your Hizentra® treatment. Inside, you will find information and tools to help make the most out of your therapy, including:

- **My Hizentra® Therapy Log Sheets and Infusion Schedule Worksheets** so you can track your treatment.
- **How to administer Hizentra® – Step-by-Step Guide** to help you learn how to self-administer your therapy. This is intended as a reference document after receiving training from your healthcare professional (HCP). You also have access to a video version, if you prefer.
- **Information about Hizentra®** so you can learn more about the treatment you've been prescribed.
- **Contact information** for your healthcare team.
- **Resources**, including patient support groups and helpful websites.

We at CSL Behring value our relationships with the people who benefit from our products, and look forward to providing you with additional support to help make your Hizentra® therapy successful.

If you have any questions about your Hizentra® therapy, please speak to your HCP.

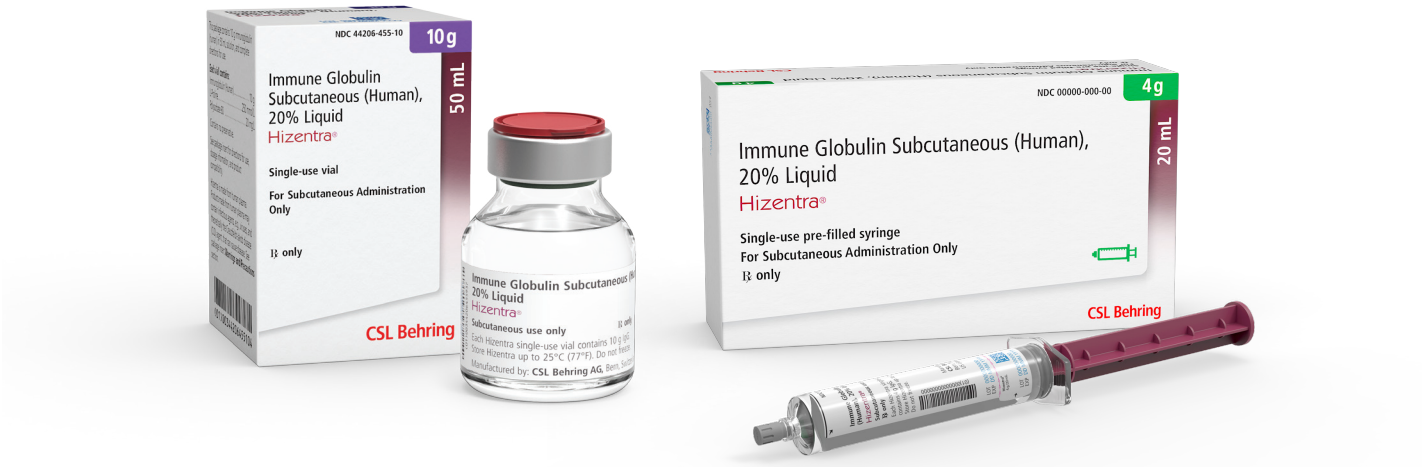
Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

About Hizentra®

- Hizentra® is a highly purified product, called an immunoglobulin, made from human plasma.
- Hizentra® contains the antibody **immunoglobulin G (IgG)**, which is found in the blood of healthy individuals to help combat germs, such as bacteria and viruses. Because it helps the body rid itself of these bacteria and viruses, IgG is important in helping the body fight disease and illness.

What is Hizentra® used for?

- Hizentra® is a medicine used to treat **primary immunodeficiency (PID), secondary immunodeficiency (SID)** and **chronic inflammatory demyelinating polyneuropathy (CIDP)**.
- People with PID and SID can get many infections. Hizentra® is known as **antibody replacement therapy** because it replaces the missing and much-needed IgG antibodies in people who have low levels of these infection-fighting proteins. By replacing these important antibodies, Hizentra® helps make people with immune deficiencies better able to avoid infections and fight them when they do occur.
- People with CIDP have a form of autoimmune disease where it is believed the body's defenses attack the nerves and cause muscle weakness and numbness mainly in the legs and arms. IgG is believed to help protect the nerve from being attacked. For people with CIDP, Hizentra® is believed to help protect the nerve from being attacked.



Biotherapies for Life® CSL Behring

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

About Hizentra®

When Hizentra® should not be used

Hizentra® should not be used in patients:

- who have had an anaphylactic or severe systemic reaction to the administration of human normal immunoglobulin or to components of Hizentra®.
- with hyperprolinemia type I and II (high levels of proline in the blood) because it contains the stabilizer L-proline.

For serious warnings and precautions please refer to the Product Monograph.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

About Hizentra®

Dose forms of Hizentra®

- Hizentra® is supplied in single-use **5 mL, 10 mL and 20 mL pre-filled syringes** and single-use **20 mL, 50 mL vials**.
- Hizentra® is a solution for subcutaneous (under the skin) injection. DO NOT inject Hizentra® into a blood vessel (vein or artery).
- Hizentra® is supplied in a single-use, tamper-evident vial or pre-filled syringe containing 0.2 g of protein per mL of preservative-free liquid.

Pre-filled Syringes	
Fill Size (mL)	**IgG Protein (g)**
5	1
10	2
20 (coming soon)	4
Vials	
Fill Size (mL)	**IgG Protein (g)**
20	4
50	10

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

About Hizentra®

Usual dose of Hizentra®

Your HCP will individualize your dose based on your response to Hizentra® and the level of immunoglobulin G (IgG) in your blood. Your dose may be adjusted over time.

Inform your HCP if you miss a dose. A missed dose should be administered as soon as possible to ensure adequate IgG serum levels.

If you think you've taken too much Hizentra®, contact an HCP, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

About Hizentra®

How to store Hizentra®

- Hizentra® can be stored either in the refrigerator or at room temperature (at 2°C to 25°C).
- Hizentra® is stable for the period indicated by the expiration date printed on the outer carton and vial/pre-filled syringe label.
- Do NOT use after the expiration date. The Hizentra® solution contains no preservatives and should be administered as soon as possible after opening the vial/pre-filled syringe.
- Do NOT freeze Hizentra®.
- Do NOT use product that has been frozen.
- Do NOT shake the vial/pre-filled syringe.
- Keep Hizentra® in its original carton to protect it from light.
- Keep Hizentra® and all other medications out of the reach of children.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

Important Safety Information

Serious warnings and precautions

- Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. Suspicion of allergic or anaphylactic-type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment should be administered.
- There is clinical evidence of an association between the administration of immunoglobulins and thromboembolic events, such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis. Therefore, caution should be exercised when prescribing and administering immunoglobulins.
- Risk factors for thromboembolic events include: advanced age, use of estrogens, in-dwelling central vascular catheters, history of vascular disease or thrombotic episodes, acquired or inherited hypercoagulable states, prolonged periods of immobilization, severe hypovolemia, diseases that increase blood viscosity and cardiovascular risk factors (including obesity, hypertension, diabetes mellitus, history of atherosclerosis and/or impaired cardiac output).
- Thrombosis may occur even in the absence of known risk factors.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

Important Safety Information

Side effects

No related serious adverse drug reactions were observed in subjects treated with Hizentra® during the clinical studies evaluating its safety. However, there have been reports of serious thrombotic events (blood clots) following the use of other subcutaneous immunoglobulin (human).

Reactions at the injection site are a common occurrence with subcutaneous immunoglobulin (human) infusions and this side effect is expected. Overall, the adverse events were mild or moderate in intensity.

The following symptoms are common: local reactions at the injection sites (e.g., swelling, redness, heat, pain and itching), headaches, diarrhea, back pain, nausea, pain in extremity, cough, rash, vomiting, abdominal pain (upper), migraine, pain, pruritus, urticaria, fatigue and nasopharyngitis.

In isolated cases: severe hypersensitivity (anaphylactic) reactions of the immune system, aseptic meningitis syndrome (AMS: a temporary and reversible noninfectious meningitis resulting in an inflammation of the protective membranes surrounding the brain and spinal cord), and thromboembolism (formation of blood clots, which may be carried off in the blood circulation and which may result in blockage of a blood vessel) have been observed in treatment with Hizentra®.

If any of the above-listed symptoms occur, are severe or worry you, talk to your HCP.

Tell your HCP right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness or fainting. These could be signs of a bad allergic reaction.

Tell your HCP right away if you have any of the following symptoms. **They could be signs of a serious problem.**

- Bad headache with nausea, vomiting, stiff neck, fever and sensitivity to light. These could be signs of a brain swelling called meningitis.
- Pain, swelling, warmth, redness or a lump in your legs or arms, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body, sudden confusion, or trouble speaking. These could be signs of a blood clot.
- Fever over 100ºF (37.8°C). This could be a sign of an infection.

This is not a complete list of side effects. Tell your HCP about any other side effects that concern you. You can also ask your HCP to give you more information.

Please refer to the enclosed consumer information for the full safety profile.

Hizentra®
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Important Safety Information

Warnings and precautions

Before you use Hizentra®, talk to your HCP if you:

- are pregnant or think that you may be pregnant
- are nursing
- have a history of allergic or other adverse reactions to immunoglobulins
- have been recently vaccinated
- have been previously advised that you have IgA deficiency
- have a kidney disease
- have hyperprolinemia (high levels of proline in the blood)
- have a history of thromboembolic events (e.g., deep vein thrombosis, blockage of blood vessel, blood clots, stroke)

Interactions with Hizentra®

- Hizentra® may interfere with the response to certain viral vaccines, such as measles, mumps, rubella and varicella. Inform the immunizing physician of recent therapy with Hizentra® so appropriate measures may be taken.
- Other products must not be mixed with the Hizentra® solution.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

Important Safety Information

How do I use Hizentra®?

- Your HCP will teach you the proper techniques for administering Hizentra®. **Only after training should you follow the instructions below.**
- Hizentra® is to be infused subcutaneously (under your skin) only.
- DO NOT inject Hizentra® into a blood vessel (vein or artery).
- You will use needles and tubing to infuse Hizentra®.
- You may have more than one needle inserted subcutaneously into different places of your body at one time.
- You can have infusions as often as every day up to every 2 weeks. Discuss your infusion options with your HCP.
- Never infuse into areas where the skin is tender, bruised, red or hard.
- Avoid infusing into scars or stretch marks.
- For weekly infusions, it takes about 1 to 2 hours to complete an infusion; however, this time may be shorter or longer depending on the dose and frequency of Hizentra® your HCP has prescribed for you.
- Your HCP will instruct you how to dispose of unused product or waste material.

If you have any further questions on the use of Hizentra®, please ask your HCP.

How do I administer Hizentra®?

- Discuss your infusion options with your HCP. The instructions in the step-by-step section are intended only as a guide. Before administering Hizentra®, you should be under the care of an HCP and should have received proper training on preparation and administration.
- Please ensure that you have received proper guidance from your HCP in case you experience a severe adverse reaction.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

My Hizentra®
Therapy Log Sheets

The simple way to keep track of your Hizentra® therapy

Now that your HCP has prescribed Hizentra®, you or your caregiver will be administering your treatment at home following the regimen that your HCP has recommended.

To help ensure that you get the desired effect from your Hizentra® treatment, we've developed **My Hizentra® Therapy Log Sheets** specifically for you. These allow you to easily keep a written record of your treatment. You will be able to log:

- dates and times of your infusions
- your administered dosage
- lot numbers of the Hizentra® vials/pre-filled syringes
- any side effects you may experience

You can also note how you are feeling overall and any questions for your HCP. **Be sure to take your My Hizentra® Therapy Log Sheets with you whenever you visit your HCP to monitor your progress.**

How to use the My Hizentra® Therapy Log Sheets

Please refer to Page 15 for an example of how to complete the My Hizentra® Therapy Log Sheet.
Please complete the sections identified by your HCP.

Hizentra®
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My Hizentra® Infusion Schedule Worksheet

Dosing options that give you flexibility in treatment

If the total weekly dose is maintained, any administration frequency from every day up to every 2 weeks can be used. Hizentra® therapy should be started 1 week after the last intravenous immunoglobulin (IVIG) infusion.

CIDP

Weekly Dose Calculation: 0.2 g/kg*
Infusion Details:

	1st Infusion	Subsequent Infusions
Volume (mL/site)	≤20	≤50
Rate (mL/hr/site)	≤20	≤50

Example Patient

Karen
47 years old
155 lb (70 kg)

Weekly Dose: 14 g or 70 mL
Rate of Infusion: 45 mL/hr/site
Infusion Sites: 2
Time per Infusion: ~45 minutes

- Busy mother of 3 who needs a dosing schedule that won't get in the way of work and taking care of her kids.
- She has successfully infused Hizentra® at a lower infusion rate without issues, so her physician has decided to increase her infusion rate to 45 mL/hr/site as tolerated.

SU	M	T	W	TH	F	SA
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

● dates of infusion

* The recommended subcutaneous dose range is 0.2 to 0.4 g/kg (1 mL to 2 mL/kg) body weight per week.

Injection Sites	A Hizentra® dose may be infused into multiple injection sites. There is no limit to the number of injection sites used. More than one infusion device can be used simultaneously. Injection sites should be at least 2 inches apart (5 cm). Never infuse into areas where the skin is tender, bruised, red or hard. Avoid infusing into scars or stretch marks.
Volume	If you are not already on SCIG therapy, the maximum initial volume per injection site should not exceed 20 mL. The volume may be increased to a maximum of 50 mL per site for subsequent infusions as tolerated.
Rate	For the first infusion of Hizentra®, the maximum recommended flow rate is 20 mL per hour per site. For subsequent infusions, the flow rate may be increased to a maximum of 50 mL per hour per site as tolerated.

Hizentra®
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My Hizentra® Infusion
Schedule Worksheet

Name: Mrs. Jane Smith

Date of Birth: May 31, 1963

Treating Physician: Dr. John Greg

	SUN	MON	TUE	WED	THU	FRI	SAT	WEEKLY TOTAL
1st **week infusion plan** (g or mL/infusion)		80 mL				70 mL		150 mL
Infusion rate (mL/hour/site)		20				25		
Number of SC sites used		4				4		
2nd **week infusion plan** (g or mL/infusion)		80 mL				70 mL		150 mL
Infusion rate (mL/hour/site)		25				30		
Number of SC sites used		3				2		
3rd **week infusion plan** (g or mL/infusion)		100 mL				50 mL		150 mL
Infusion rate (mL/hour/site)		30				40		
Number of SC sites used		2				1		
4th **week infusion plan** (g or mL/infusion)		150 mL						
Infusion rate (mL/hour/site)		40						
Number of SC sites used		3						
5th **week infusion plan** (g or mL/infusion)		150 mL						150 mL
Infusion rate (mL/hour/site)		50						
Number of SC sites used		3						
6th **week infusion plan** (g or mL/infusion)		150 mL						150 mL
Infusion rate (mL/hour/site)		50						
Number of SC sites used		3						

SC=subcutaneous; g=grams; mL=millilitres

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

My Hizentra® Infusion
Schedule Worksheet

Name:

Date of Birth:

Treating Physician:

	SUN	MON	TUE	WED	THU	FRI	SAT	WEEKLY TOTAL
1st **week infusion plan** (g or mL/infusion)								
Infusion rate (mL/hour/site)								
Number of SC sites used								
2nd **week infusion plan** (g or mL/infusion)								
Infusion rate (mL/hour/site)								
Number of SC sites used								
3rd **week infusion plan** (g or mL/infusion)								
Infusion rate (mL/hour/site)								
Number of SC sites used								
4th **week infusion plan** (g or mL/infusion)								
Infusion rate (mL/hour/site)								
Number of SC sites used								
5th **week infusion plan** (g or mL/infusion)								
Infusion rate (mL/hour/site)								
Number of SC sites used								
6th **week infusion plan** (g or mL/infusion)								
Infusion rate (mL/hour/site)								
Number of SC sites used								

SC=subcutaneous; g=grams; mL=millilitres

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Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

My Hizentra® Therapy Log Sheet

Name: Mrs. Jane Smith

Date of Birth: May 31, 1963

Treating Physician: Dr. John Greg

Blood Bank/Pharmacy Name: My Hospital **Blood Bank/Pharmacy Phone:** 416-123-4567

Infusion date (yyyy/mm/dd)	Duration of infusion (h=hours, m=minutes)	Site(s) used (see legend)	Volume/ site (mL)	Total volume infused (mL)	Lot number(s) infused	List any side effects*	List any medication(s) taken during infusion
2020-05-14	50 m	R/U/A	20 mL	40 mL	4358100016	None	None

SITE LEGEND

R	Right
L	Left
U	Upper
Lo	Lower
A	Abdomen
H	Hips
Leg	Leg/thigh

Hizentra® Waste Report

Record any wasted (broken, contaminated) or expired vials/pre-filled syringes in the table below. Follow your healthcare professional or blood bank/pharmacy instructions on product wastage. If the vial/pre-filled syringe has a manufacturer's defect (broken seal, particles or cloudy solution), record below and return to blood bank.

Date (yyyy/mm/dd)	Lot number	# of vials/ pre-filled syringes	Reason for waste
2015-11-15	4358100016	1	Broken vial, dropped on the floor.

 * To report adverse events, please refer to the instructions on Reporting Suspected Side Effects included in the Consumer Information Leaflet provided with your Hizentra® vial and/or pre-filled syringe.

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My Hizentra® Therapy
Log Sheet

Name:

Date of Birth:

Treating Physician:

Blood Bank/Pharmacy Name:

Blood Bank/Pharmacy Phone:

Infusion date (yyyy/mm/dd)	Duration of infusion (h=hours, m=minutes)	Site(s) used (see legend)	Volume/ site (mL)	Total volume infused (mL)	Lot number(s) infused	List any side effects*	List any medication(s) taken during infusion

SITE LEGEND

R	Right
L	Left
U	Upper
Lo	Lower
A	Abdomen
H	Hips
Leg	Leg/thigh

Hizentra® Waste Report

Record any wasted (broken, contaminated) or expired vials/pre-filled syringes in the table below. Follow your healthcare professional or blood bank/pharmacy instructions on product wastage. If the vial/pre-filled syringe has a manufacturer's defect (broken seal, particles or cloudy solution), record below and return to blood bank.

Date (yyyy/mm/dd)	Lot number	# of vials/ pre-filled syringes	Reason for waste

* To report adverse events, please refer to the instructions on Reporting Suspected Side Effects included in the Consumer Information Leaflet provided with your Hizentra® vial and/or pre-filled syringe.

Biotherapies for Life® CSL Behring

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

Infection Log

During Home SCIG Treatment

(List all infections)

Name: Mrs. Jane Smith

Date of Birth: May 31, 1963

Treating Physician: Dr. John Greg

Infection date	Infection site*	Symptom details (use key listed below*)					GP visit yes/no	Antibiotics taken			Patient comments (e.g., chest x-ray taken, hospital admission, etc.)
		1	2	3	4	5		Dose	Name	Frequency and # days	
2015-11-15	Sinus			✓	✓		Yes	500 mg	Amoxicillin[2]	3 x per day, 14 days	

***Infection Site** (please tick (✓) for relevant symptoms in boxes above)

Chest
1. Sputum: y = yellow, g = green
2. Increasing cough
3. Shortness of breath
4. Chest pain
5. Fever

Sinus
1. Painful/tender sinus
2. Drip in back of throat
3. Headache
4. Nasal drip: y = yellow, g = green
5. Fever

Urinary
1. Increased frequency of urine
2. Burning/pain on passing urine
3. Fever
4. Accidental urine loss
5. Pain in side

Stomach/bowel
1. Diarrhea
2. Weight loss
3. Stomach pain
4. Fever

Other
1. Eyes
2. Abscess
3. Skin
4. Ears
5. Mouth ulcers/cold sores

 To report adverse events, please refer to the instructions on Reporting Suspected Side Effects included in the Consumer Information Leaflet provided with your Hizentra® vial and/or pre-filled syringe.

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

Infection Log

During Home SCIG Treatment

(List all infections)

Name:

Date of Birth:

Treating Physician:

Infection date	Infection site*	Symptom details (use key listed below*)					GP visit yes/no	Antibiotics taken			Patient comments (e.g., chest x-ray taken, hospital admission, etc.)
		1	2	3	4	5		Dose	Name	Frequency and # days	

***Infection Site** (please tick (✓) for relevant symptoms in boxes above)

Chest

1. Sputum: y = yellow, g = green
2. Increasing cough
3. Shortness of breath
4. Chest pain
5. Fever

Sinus

1. Painful/tender sinus
2. Drip in back of throat
3. Headache
4. Nasal drip: y = yellow, g = green
5. Fever

Urinary

1. Increased frequency of urine
2. Burning/pain on passing urine
3. Fever
4. Accidental urine loss
5. Pain in side

Stomach/bowel

1. Diarrhea
2. Weight loss
3. Stomach pain
4. Fever

Other

1. Eyes
2. Abscess
3. Skin
4. Ears
5. Mouth ulcers/cold sores

To report adverse events, please refer to the instructions on Reporting Suspected Side Effects included in the Consumer Information Leaflet provided with your Hizentra® vial and/or pre-filled syringe.

Biotherapies for Life® CSL Behring

Hizentra®

Subcutaneous Immune Globulin (Human), **20%**

Manual Push

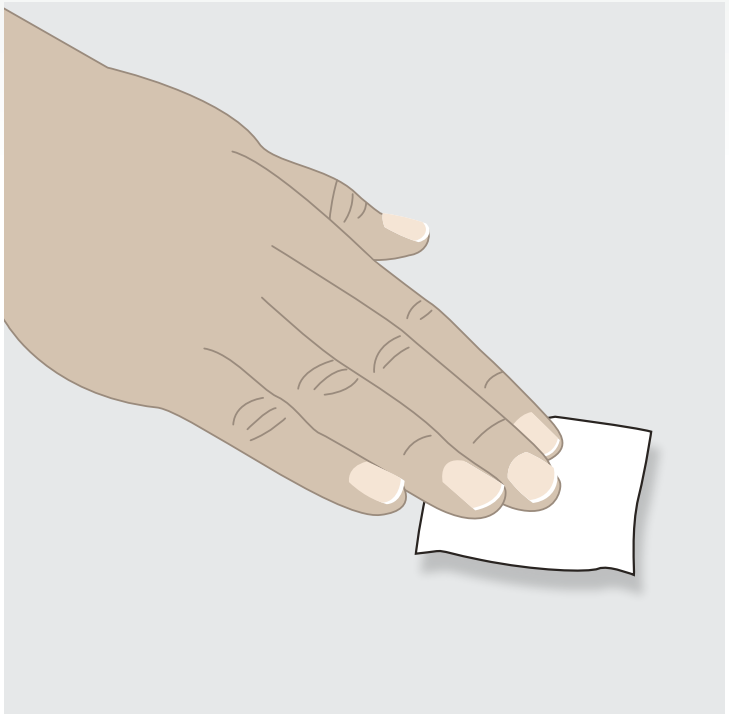
Step-by-Step Guide

The guide is intended to help train you on **how to self-administer Hizentra®**. It is not meant to take the place of your healthcare professional's (HCP) instructions and should be used only after you have received training from your HCP.

Please contact your HCP if you have any questions about your Hizentra® treatment or if you experience a severe adverse reaction.

STEP 1

Get Ready



1 Clean surface.

Clean a flat surface (or optional Hizentra® Infusion Mat) with an antiseptic wipe.

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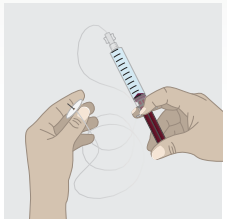
STEP 1

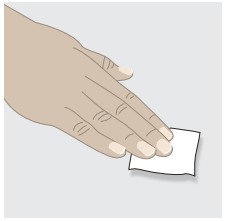
Get Ready

2 Gather supplies.

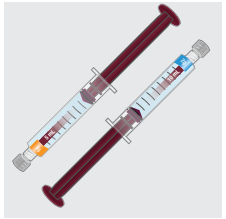
Gather Hizentra® pre-filled syringes or vials (they must be at room temperature) and the following supplies (not provided with Hizentra®), as directed by your HCP:



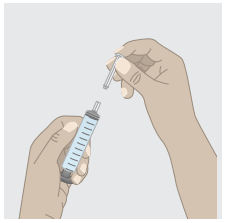
- Infusion administration set(s) (tubing & needle: butterflies or "multi-needle" sets).



- Antiseptic wipes and/or alcohol swabs.



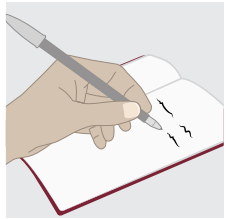
- Syringe(s).



- Transfer device,and/or transfer needle.

- Gauze and tape, or transparent dressing.

- Sharps container.



- Treatment diary or logbook.

- Gloves (if recommended by your HCP).

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

Get Ready

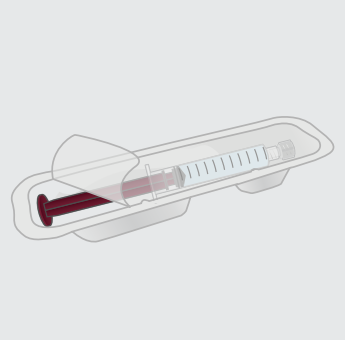
3 Wash hands.

Wear gloves if your healthcare provider told you to.

STEP 1

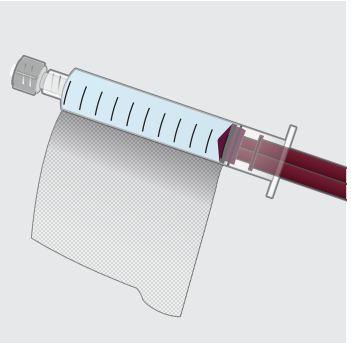
Get Ready

4 Check pre-filled syringes or vials.



If you're using pre-filled syringes:

Peel back the transparent covering from the tray. Inspect the protective cap and ensure it is secure.



Peel back the outer layer of the wraparound label label, but don't remove it. This will allow for viewing of Hizentra® through the fully transparent inner layer.

If you're using vials: Inspect the protective cap and ensure it is secure.

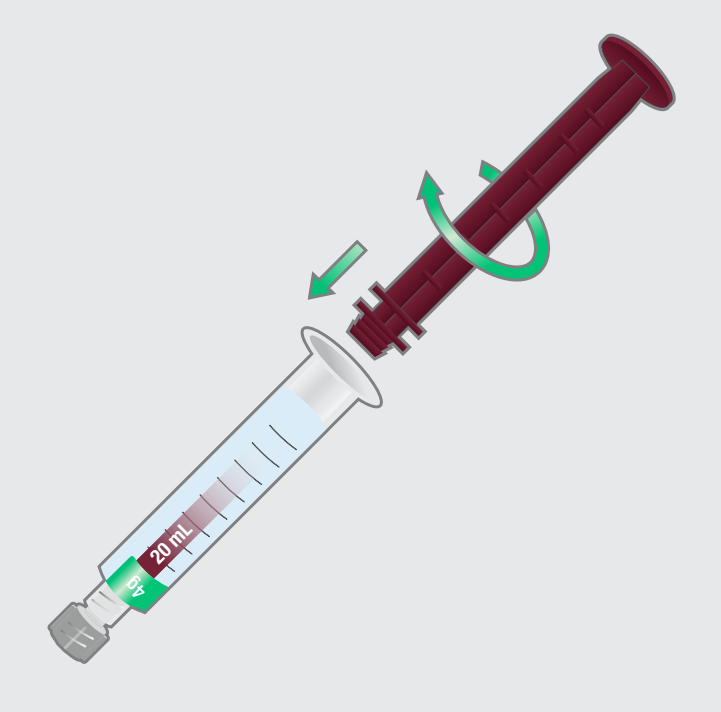
Hizentra® is a pale yellow to light brown clear solution. Check for particles or colour changes. **Do not use if:**

- ✗ Liquid looks cloudy, contains particles or has changed colour.
- ✗ Protective cap is missing or defective.
- ✗ Expiration date has passed.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
2

Prepare for Infusion



If you're using pre-filled syringes:

If you're using the 5 mL or 10 mL pre-filled syringe, go to **STEP 3** on page 26.

If you're using the 20 mL pre-filled syringe, screw the plunger rod onto the syringe stopper before using. Then, go to **STEP 3** on page 26.

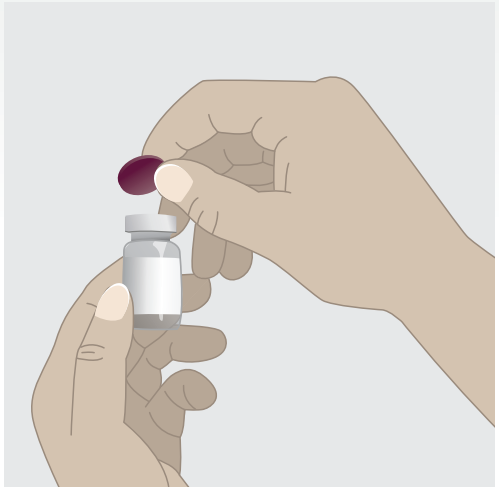
If you're using vials, please go to the next page.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

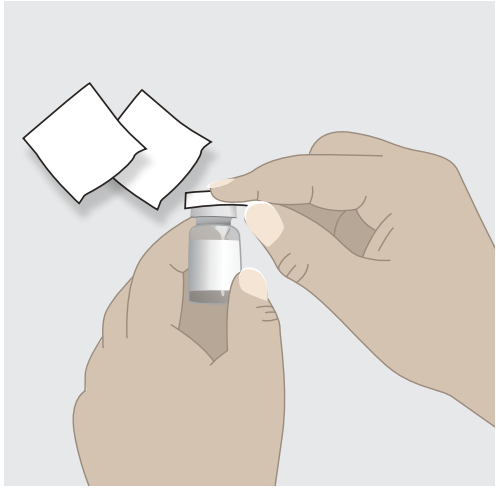
STEP
2

Prepare for Infusion

If you're using vials:



1 Take off the protective cap.



2 Clean vial stopper with an antiseptic wipe.

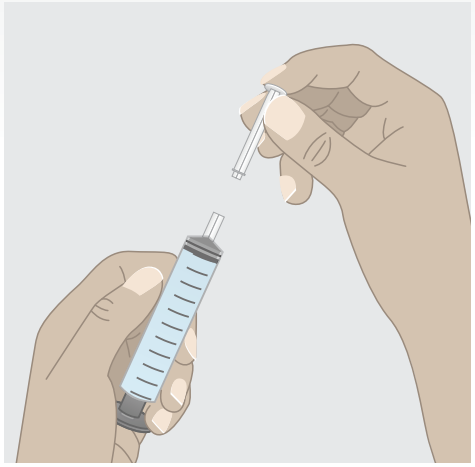
Allow to dry.

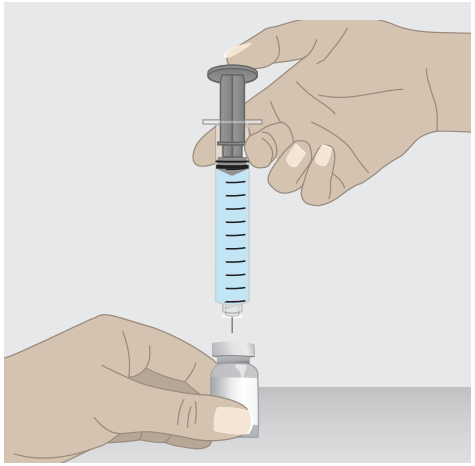
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

Prepare for Infusion

If you're using vials (con't.):

3 Transfer to syringe.





If using a **transfer device**, follow the manufacturer's instructions. Then, go to **STEP 3** on the next page.

If using a **needle and syringe**, follow these steps:

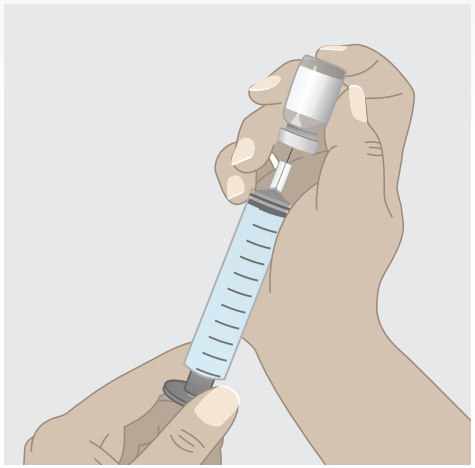
- Attach a sterile transfer needle to a sterile syringe.
- Pull out the plunger of the syringe to fill the syringe with air. Make sure the amount of air is the same as the amount of Hizentra® you will transfer from the vial.
- Put the vial on a flat surface. Keeping the vial upright, insert the needle into the centre of the rubber stopper.
- Check that the tip of the needle is not in the liquid. Then, push the plunger of the syringe down. This will inject the air from the syringe into the airspace of the vial.

STEP
2

Prepare for Infusion

If you're using vials (con't.):

3 Transfer to syringe.

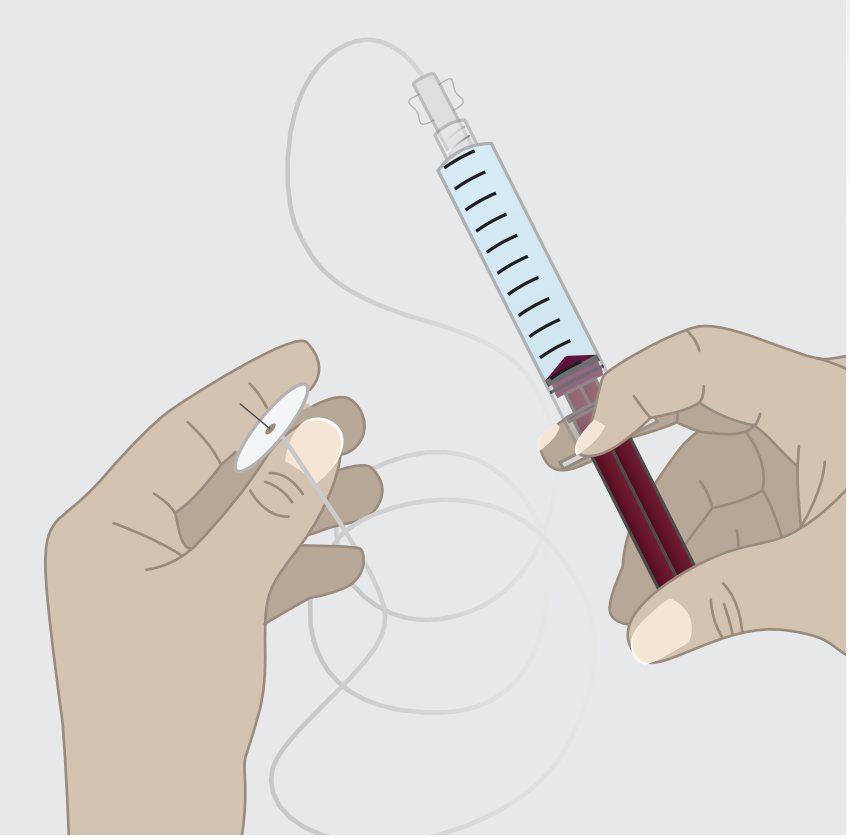


- Leaving the needle in the stopper, carefully turn the vial upside down.
- Slowly pull back on the plunger of the syringe to fill it with Hizentra®.
- Take the filled syringe and needle out of the stopper. Take off the needle and throw it away in the sharps container.

When using multiple vials to achieve the desired dose, repeat this step, then go to **STEP 3** on the next page.

STEP
3

Infuse (for vials or pre-filled syringes)



1 Prime tubing.

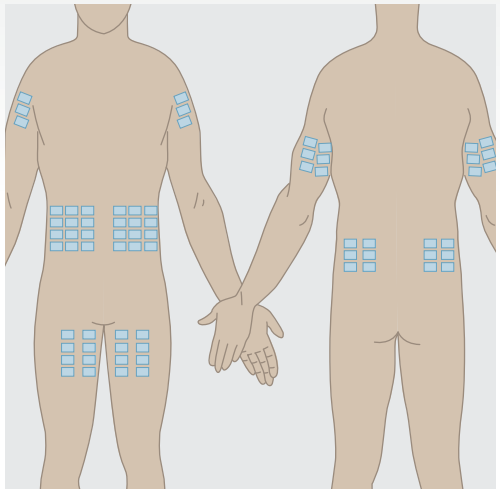
- Connect the syringe filled with Hizentra® to the infusion tubing.
- Gently push on the plunger to fill the tubing with Hizentra®.
- Stop priming before the Hizentra® fluid reaches the needle.

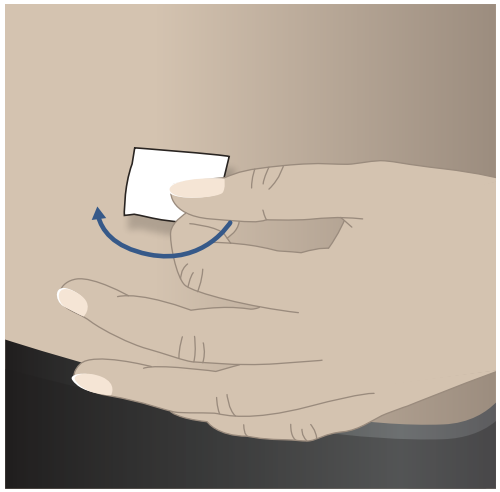
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP 3

Infuse (for vials or pre-filled syringes)

2 Prepare injection site(s).





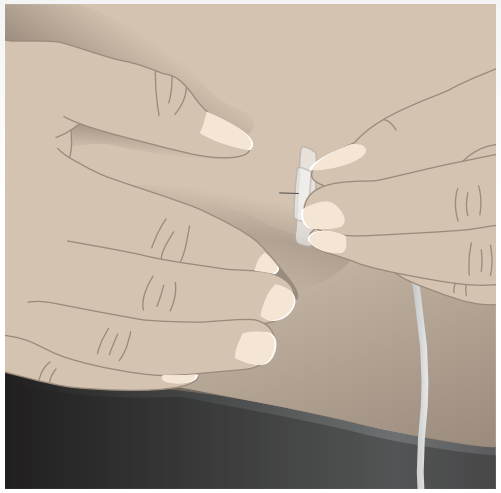
- Select an area on your abdomen, thigh, upper arm or side of upper leg/hip for the infusion. You can use more than one site at the same time.
  - Injection sites should be at least 5 cm (approximately 2 inches) apart.
- Use a different site from your last infusion that is at least 2.5 cm (approximately 1 inch) away.
- Never infuse into areas where the skin is tender, bruised, red or hard. Avoid infusing into scars or stretch marks.
- Clean the skin at each site with an antiseptic wipe and allow to dry.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

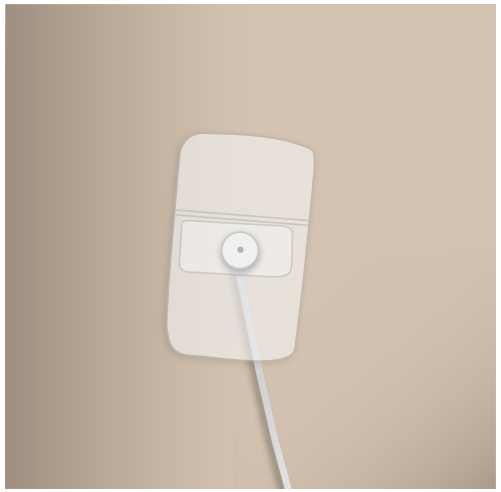
STEP 3

Infuse (for vials or pre-filled syringes)

3 Insert needles.



- Using two fingers, pinch together the skin around the injection site.
- Insert the needle under the skin.

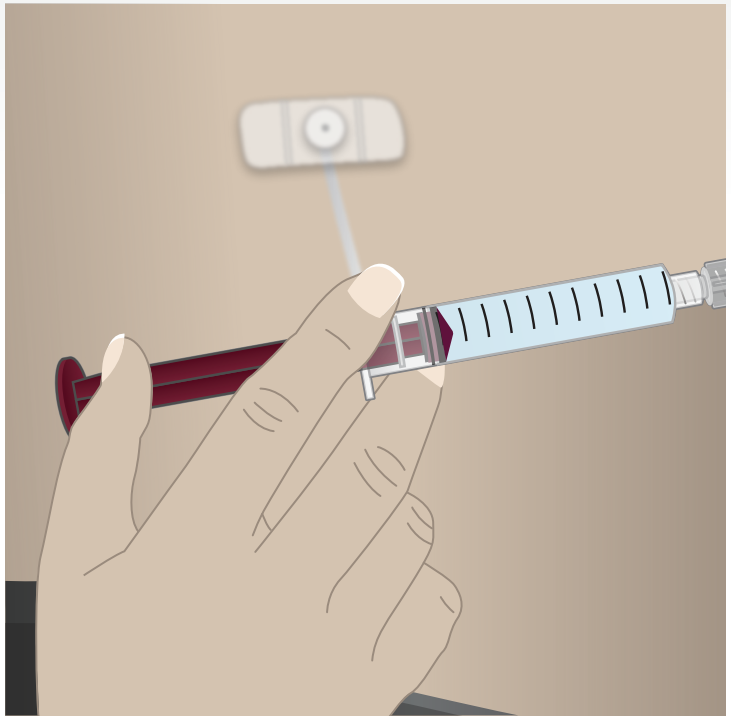


- Put sterile gauze and tape or a transparent dressing over the injection site to hold the needle in place.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP 3

Infuse (for vials or pre-filled syringes)



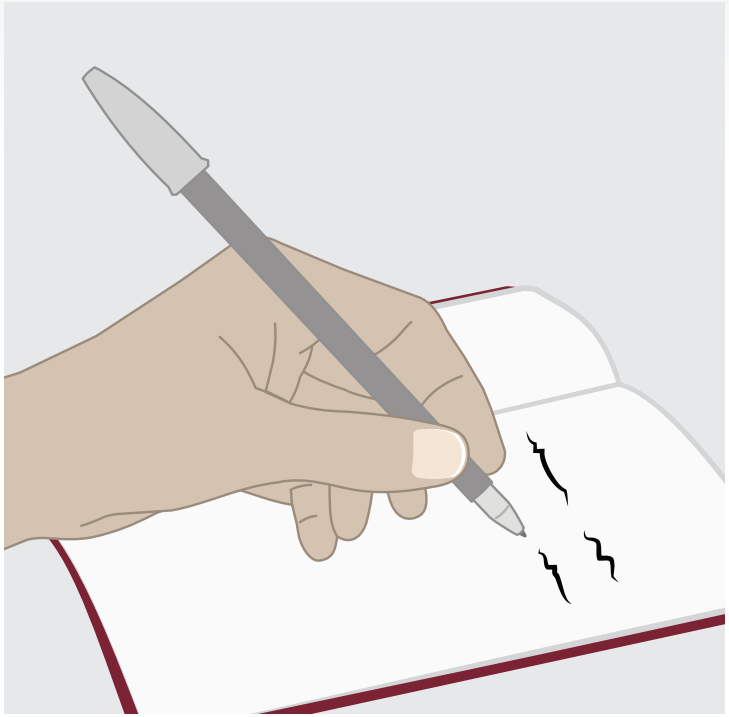
4 Start infusion.

- Hold the syringe and slowly push the plunger to deliver Hizentra® at a rate that is comfortable for you. Continue until the prescribed amount of Hizentra® has been infused.
- When you have finished, remove the dressing and needle.
- Remove the needle set and cover the injection site with a protective dressing.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
4

Record & Clean



1 Record treatment.

- Peel off the removable part of the Hizentra® vial or pre-filled syringe label.
- Stick it on your logbook with the date and time of the infusion and the exact amount of Hizentra® that you infused.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
4

Record & Clean

2 Clean up.

- Throw away the empty Hizentra® vials or pre-filled syringes, along with the used disposable supplies, in the sharps container.
- The sharps container should be disposed of according to local requirements.

Tell your healthcare provider about any problems you have during your infusions. Always follow the advice of your healthcare team.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

Hizentra®

Subcutaneous Immune Globulin (Human), **20%**

Infusion Pump

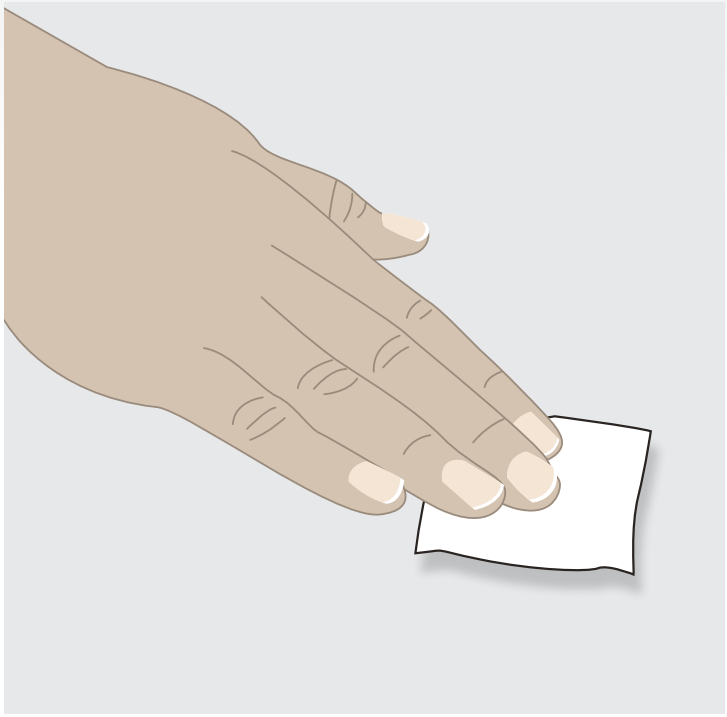
Step-by-Step Guide

The guide is intended to help train you on **how to self-administer Hizentra®**. It is not meant to take the place of your healthcare professional's (HCP) instructions and should be used only after you have received training from your HCP.

Please contact your HCP if you have any questions about your Hizentra® treatment or if you experience a severe adverse reaction.

STEP
1

Get Ready



1 Clean surface.

Clean a flat surface (or optional Hizentra® Infusion Mat) with an antiseptic wipe.

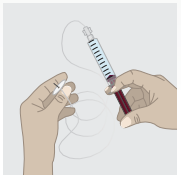
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP 1

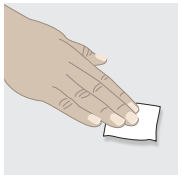
Get Ready

2 Gather supplies.

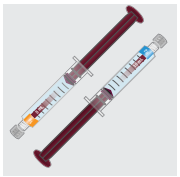
Gather Hizentra® pre-filled syringes or vials (they must be at room temperature) and the following supplies (not provided with Hizentra®), as directed by your HCP:



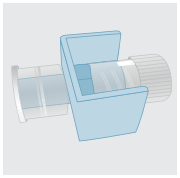
- Infusion administration set(s) (tubing & needle: butterflies or "multi-needle" sets).



- Antiseptic wipes and/or alcohol swabs.



- Syringe(s).



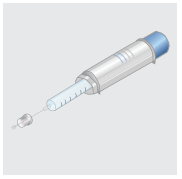
- Transfer device, syringe-to-syringe transfer device and/or transfer needle.

- Gauze and tape, or transparent dressing.

- Sharps container.

- Treatment diary or logbook.

- Gloves (if recommended by your HCP).



- Infusion pump.*

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

* Prepare the pump according to manufacturer's instructions.

STEP
1

Get Ready

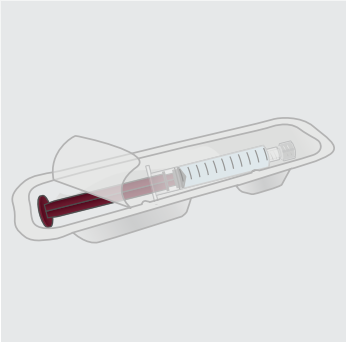
3 Wash hands.

Wear gloves if your healthcare provider told you to.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

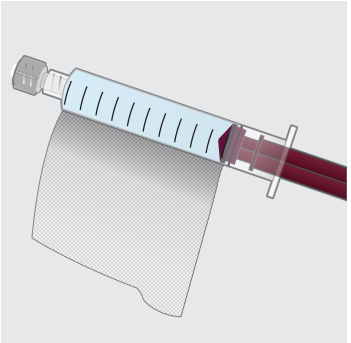
Get Ready

4 Check pre-filled syringes or vials.



If you're using pre-filled syringes:

Peel back the transparent covering from the tray. Inspect the protective cap and ensure it is secure.



Peel back the outer layer of the wraparound label, but don't remove it. This will allow for viewing of Hizentra® through the fully transparent inner layer.

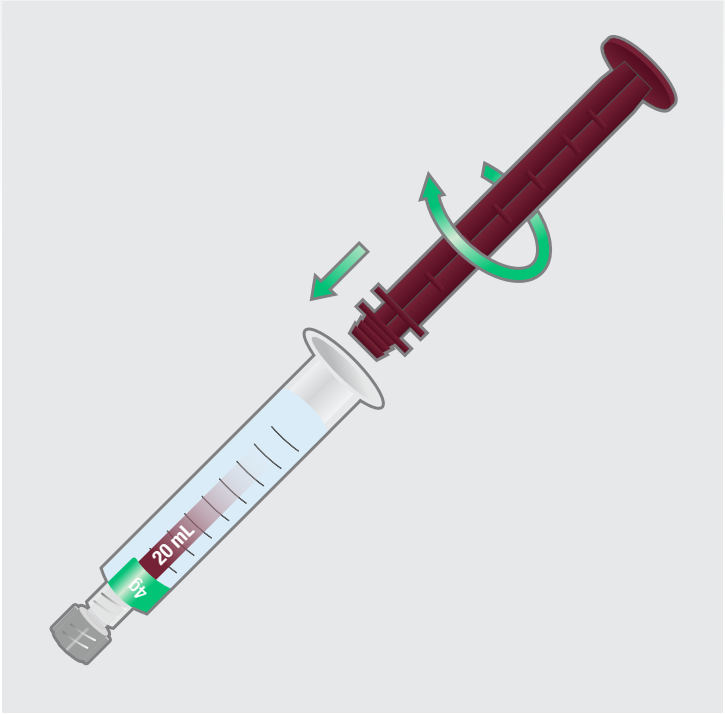
If you're using vials:
Inspect the protective cap and ensure it is secure.

Hizentra® is a pale yellow to light brown clear solution. Check for particles or colour changes. **Do not use if:**

- ✗ Liquid looks cloudy, contains particles or has changed colour.
- ✗ Protective cap is missing or defective.
- ✗ Expiration date has passed.

STEP
2

Prepare for Infusion



If you're using pre-filled syringes:

If you're using the 5 mL or 10 mL pre-filled syringe, go to **STEP 3** on page 42.

If you're using the 20 mL pre-filled syringe, screw the plunger rod onto the syringe stopper before using.

Pre-filled syringes can be placed directly in the infusion pump if the syringe size matches the pump requirements. If it does, go to **STEP 3** on page 41. Note: an additional adapter may be required. Please check with your supply provider.

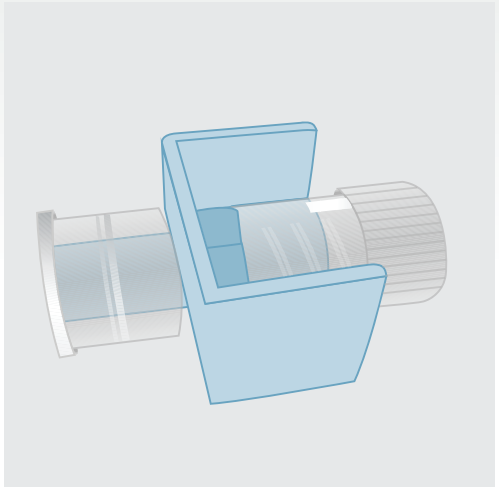
If you're using vials, please go to page 40.

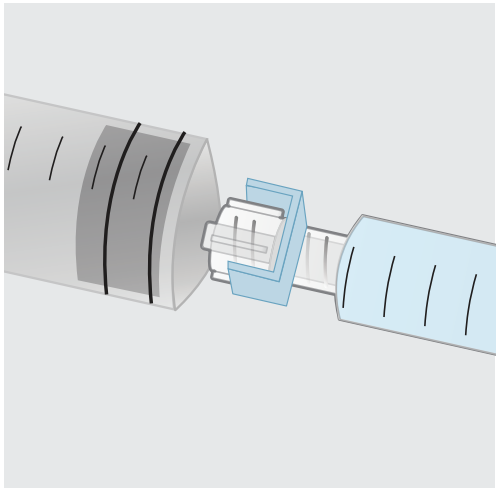
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
2

Prepare for Infusion

If you're using pre-filled syringes (con't.):





If the Hizentra® pre-filled syringe size does not match the infusion pump requirements, transfer the contents of the pre-filled syringe to another syringe specific for your pump as follows:

- Use a syringe-to-syringe transfer device (tip-to-tip connector).
- Remove the protective cap from the pre-filled syringe. Attach the transfer device by twisting it onto the pre-filled syringe. Attach the empty syringe by screwing it onto the other side of the transfer device.
- Push the plunger of the pre-filled syringe to transfer Hizentra® from the pre-filled syringe to the empty syringe.
  - If multiple pre-filled syringes are necessary to achieve the prescribed dose, repeat this step using a new pre-filled syringe.
- After the transfer is complete, remove the empty pre-filled syringe and transfer device by unscrewing them from the syringe specific for your pump.
- Go to **STEP 3** on page 41.

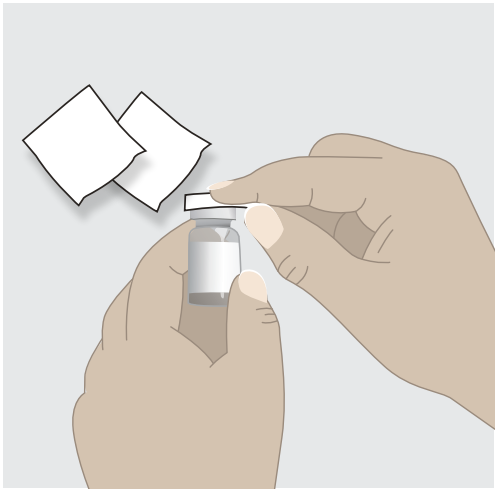
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
2

Prepare for Infusion

If you're using vials:

1 Take off the protective cap.



2 Clean vial stopper with an antiseptic wipe.

Allow to dry.

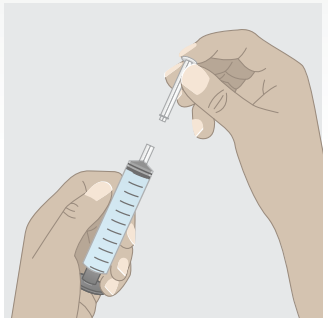
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

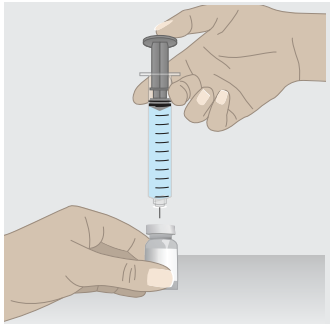
STEP 2

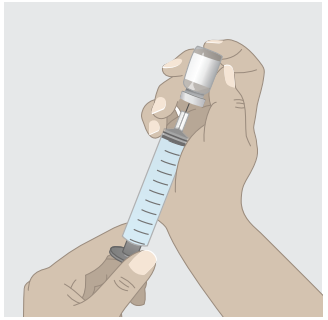
Prepare for Infusion

If you're using vials (con't.):

3 Transfer to syringe.







If using a **transfer device**, follow the manufacturer's instructions. Then, go to **STEP 3** on the next page.

If using a **needle and syringe**, follow these steps:

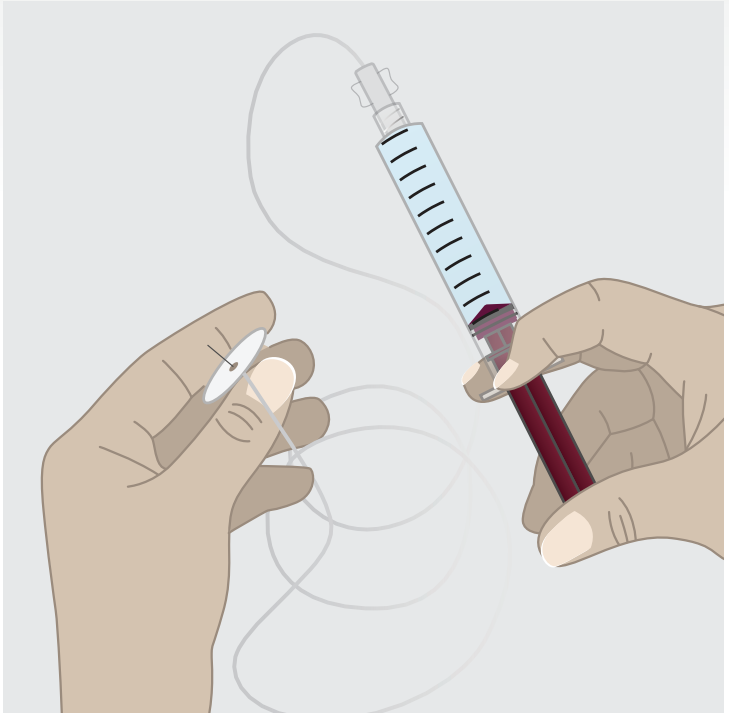
- Attach a sterile needle to a sterile syringe.
- Pull out the plunger of the syringe to fill the syringe with air. Make sure the amount of air is the same as the amount of Hizentra® you will transfer.
- Put the vial on a flat surface. Keeping the vial upright, insert the needle into the centre of the rubber stopper.
- Check that the tip of the needle is not in the liquid. Then, push the plunger of the syringe down. This will inject the air from the syringe into the airspace of the vial.
- Leaving the needle in the stopper, carefully turn the vial upside down.
- Slowly pull back on the plunger of the syringe to fill it with Hizentra®.
- Take the filled syringe and needle out of the stopper. Take off the needle and throw it away in the sharps container.

When using multiple vials to achieve the desired dose, repeat this step, then go to **STEP 3** on the next page.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
3

Infuse (for pre-filled syringes and vials)



1 Prepare pump and prime tubing.

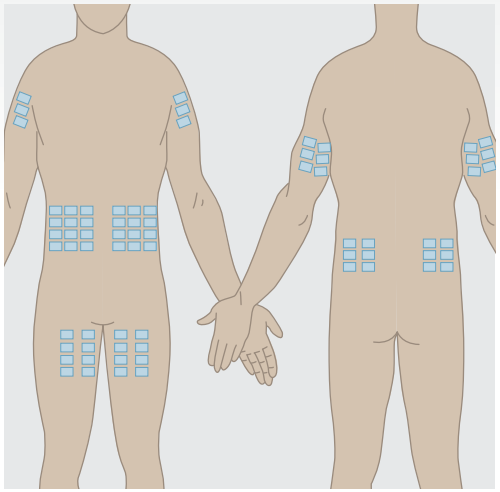
- Prepare the infusion pump according to the manufacturer's instructions.
- Connect the syringe filled with Hizentra® to the infusion tubing.
- Gently push on the plunger to fill the tubing with Hizentra®.
- Stop priming before the Hizentra® fluid reaches the needle.
- Insert syringe into pump.

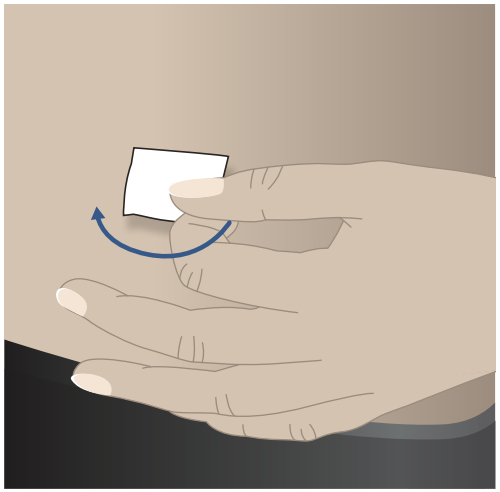
Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP 3

Infuse (for pre-filled syringes and vials)

2 Prepare injection sites.





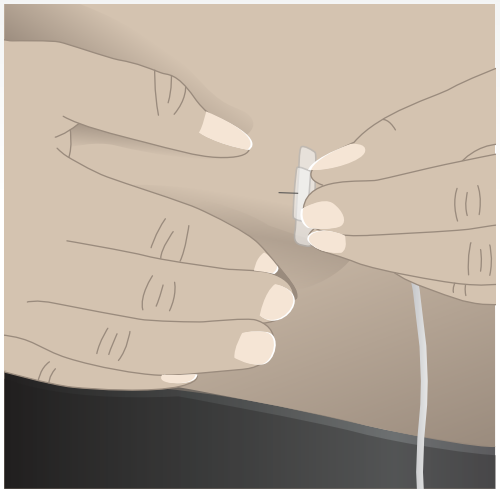
- Select an area on your abdomen, thigh, upper arm or side of upper leg/hip for the infusion. You can use more than one site.
  - Injection sites should be at least 5 cm (approximately 2 inches) apart.
- Use a different site from your last infusion that is at least 2.5 cm (approximately 1 inch) away.
- Never infuse into areas where the skin is tender, bruised, red or hard. Avoid infusing into scars or stretch marks.
- Clean the skin at each site with an antiseptic wipe and allow to dry.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

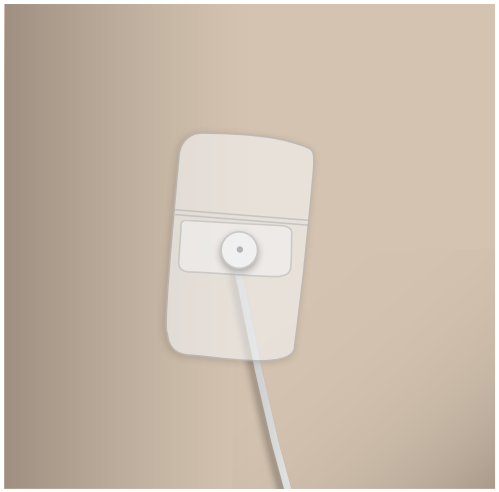
STEP 3

Infuse (for pre-filled syringes and vials)

3 Insert needle(s).



- Using two fingers, pinch together the skin around the injection site at the same time.
- Insert the needle under the skin.

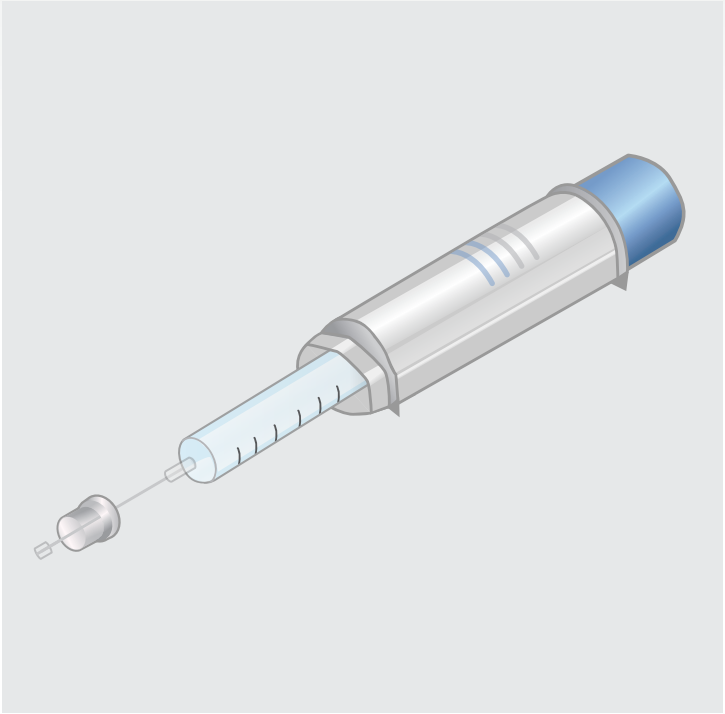


- Put sterile gauze and tape or a transparent dressing over the injection site to hold the needle in place.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
3

Infuse (for pre-filled syringes and vials)



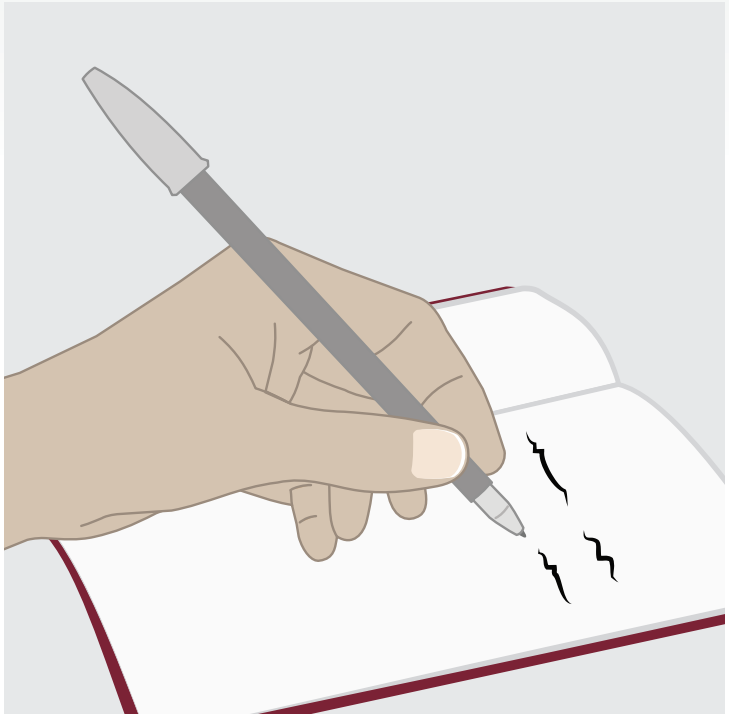
4 Start infusion.

- Follow the manufacturer's instructions to turn on the infusion pump.
- Continue until the prescribed amount of Hizentra® has been infused.
- Remove the needle set and cover the injection site with a protective dressing.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
4

Record & Clean



1 Record treatment.

- Peel off the removable part of the Hizentra® vial or pre-filled syringe label.
- Stick it on your logbook with the date and time of the infusion and the exact amount of Hizentra® that you infused.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

STEP
4

Record & Clean

2 Clean up.

- Throw away the empty Hizentra® vials or pre-filled syringes, along with the used disposable supplies, in the sharps container.
- The sharps container should be disposed of according to local requirements.

Tell your healthcare provider about any problems you have during your infusions. Always follow the advice of your healthcare team.

Hizentra®
Subcutaneous Immune Globulin (Human), 20%

Hizentra®
Subcutaneous Immunoglobulin (Human), 20%

Healthcare Team

Contact Sheet

Doctor's Name:		Telephone:	
Address:			
Email:		Fax:	

Doctor's Name:		Telephone:	
Address:			
Email:		Fax:	

Doctor's Name:		Telephone:	
Address:			
Email:		Fax:	

Notes:

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Patient Support Groups

Canadian Immunodeficiencies Patient Organization
Organisation Canadienne des personnes immunodéficientes
Toll-free: 1-877-607-2476
Email: info@cipo.ca
www.cipo.ca
@CIPONational

Canadian Immunodeficiencies Patient Organization (CIPO) became a registered charity in 1999. It has been growing ever since, working hard to assist patients in understanding their immune disorders and treatment options through education and other resources.

CIPO is an organization where you can meet and talk to other patients with primary or secondary immune disorders, both online and in person.

CIPO has six regional Chapters in Canada that hold regular meetings and offer services to patients, such as providing literature, advocacy, organizing educational events, and referrals.

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Patient Support Groups

GBS/CIDP Foundation of Canada
Fondation canadienne du SGB/PDIC
P.O. Box 80060
RPO Rossland Garden
Whitby, ON L1R 0H1
(647) 560-6842
@GBSCIDPCanada

GBS/CIDP Foundation of Canada is a registered Canadian charity founded in 2003. The foundation continues its long history of connecting patients and their families with caring and dedicated volunteers who have been affected by GBS, CIDP and variants, such as MMN, so that no patient or family will have to go through any of these disorders alone.

Along with this patient-to-patient support, the foundation has proudly established a National Medical Advisory Board of 18 Neurologists trained in the diagnosis and treatment of our disorders.

GBS/CIDP is committed to building relationships with experts in rehabilitation and support disciplines who understand the challenges facing patients during and after recovery.

The foundation supports Canadian research that will improve the diagnosis, treatment and rehabilitation of patients affected by GBS, CIDP and variants, with the ultimate goal to help pave the way to a cure.

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Patient Support Groups

Association of Immunodeficient Patients of Quebec (APIQ)
Telephone: 1-855-561-4563
Email: info@cipo-apiq.
www.cipo-apiq.ca
@CipoAPIQ

The Association of Immunodeficient Patients of Quebec (APIQ) is a non-profit organization that brings together patients with immune deficiencies (ID) as well as their families and health professionals interested in this disease.

Our association was born in 2004 thanks to the vision and dedication of patients with an immune deficiency, those who would become the founding administrators of the Quebec division of the Canadian Immunodeficiencies Patient Organization of (CIPO). All of the founding members were volunteers who wanted to make a difference for people with immune deficiencies. Thanks to their sustained efforts and their desire to offer more and more services to members, the group founded in 2012 the Association of Immunodeficient Patients of Quebec (APIQ).

APIQ works with a scientific committee and other patient groups around the world to raise awareness of immunodeficiency, promote early diagnosis and defend the interests of those affected.

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Patient Support Groups

Other Resources

For additional information and support, please visit these websites:

The Immune Deficiency Foundation (IDF): www.primaryimmune.org

The International Patient Organization for Primary Immunodeficiencies (IPOPI): www.ipopi.org

Jeffrey Model Foundation: www.info4pi.org

IG (Immunoglobulin) Living: http://www.igliving.com/

GBS/CIDP Foundation of Canada: www.gbscidp.ca

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Biotherapies for Life® CSL Behring

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Infection Log

Step-by-Step Guide

Healthcare
Team Contact

Patient
Support Groups

Other
Resources