Optimizing Hizentra Therapy

A guide to initiating therapy, troubleshooting potential issues, and managing patient expectations with Hizentra.

Indications

Hizentra is indicated for:

- Treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years and older.
- Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.
  - Limitation of Use: Maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only.

Important Safety Information

WARNING: Thrombosis may occur with immune globulin products, including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Please see full Important Safety Information on pages 24–25 and full prescribing information for Hizentra, including boxed warning, in pocket.

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Optimizing Hizentra: Overview

This guide is designed to help you set patient expectations and resolve any issues with transitioning to or maintaining Hizentra therapy. It will provide initial questions for a baseline assessment and resolutions to potential issues revealed by those questions.

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Although local site reactions are common and expected with Hizentra, it is important to remember that when patients on subcutaneous Ig therapy report tolerability issues or other infusion-related problems, administration procedures and supplies may play a contributing role.[1,2]

Adjusting infusion parameters or optimizing ancillary supplies may reduce the occurrence or severity of infusion-related problems.[1,2]

Please see full Important Safety Information on pages 24–25 and full prescribing information for Hizentra, including boxed warning, in pocket.

Baseline Assessment Questions

Here are some helpful starter questions to ask your patients about their current treatment regimen and equipment:

Infusion Regimen

- What is the total volume being infused and the infusion rate?
- How many infusion sites are you using?
- How long does your infusion usually take? Has that recently changed?
- What location(s) on your body are you using to administer your infusion?
- Do you use vials or prefilled syringes when infusing?
- Has anything recently changed in your infusion regimen?
  - Ask patients if there have been any changes in their dosage or infusion schedule
- What activities are you doing during the infusion?
  - Remind patients of typical activities that are suitable during an infusion

Equipment and Supplies

- What kind of pump are you using?
- What kind of flow-rate tubing (eg, KORU F120, F600, EMED VersaRate) are you using? Has this ever changed?
- What needle length (eg, 4, 6, 9, 12, 14 mm) are you using?
- What brand and gauge (eg, 24, 26, 27) of needle are you using?
- Have there been any substitutions in your usual infusion supplies?

Hizentra can address a range of **PI patient** challenges

While IVIg treatment helps control PI, challenges may still remain for many patients. Here are some sample patient types that can help you identify those needs, determine the proper dosing regimen, and set expectations with transitioning patients.

Marie
55 years old

Has venous access issues

Weight: 146 lb (66 kg)*
Dose: 16 g/80 mL
Infusion sites: 4
Time per infusion: ~48 minutes

Why Hizentra?
Subcutaneous self-administration means no more difficulties finding a vein, or needing a port

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Once every 2 weeks

Ian
46 years old

Experiences IVIg-related adverse reactions

Weight: 200 lb (91 kg)*
Dose: 14 g/70 mL
Infusion sites: 3
Time per infusion: ~1 hour

Why Hizentra?
Subcutaneous infusions offer the option of lower infusion volume and more frequent infusions

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Once a week

*Rate of infusion and number of infusion sites in these hypothetical case studies are based on recommended rate and volume per site of subsequent infusions. Photos do not depict actual patients.

Sara
33 years old

Wants more freedom and flexibility

Weight: 165 lb (74 kg)*
Dose: 10 g/50 mL
Infusion sites: 2
Time per infusion: ~1 hour

Why Hizentra?
- Flexible dosing and a personalized self-infusion schedule better fit the needs of her busy life
- Prefilled syringes may simplify infusions, removing the need to draw from a vial

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Every 10 days

Anthony
20 years old

Finds IVIg infusions inconvenient

Weight: 180 lb (82 kg)*
Dose: 6 g/32 mL
Infusion sites: 2
Time per infusion: ~38 minutes

Why Hizentra?
- Infusing at home means no more trips to the infusion clinic and not missing school or activities each month
- Prefilled syringes can make the infusion process more convenient

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Twice a week

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Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid

Initiating Hizentra treatment for **PI patients**

	Infusion parameters*	1st infusion	Subsequent infusions
PI Daily up to every 2 weeks	Volume (mL/site)	≤15	≤25
	Rate (mL/hr/site)	≤15	≤25

*As tolerated.

Initiate therapy with Hizentra 1 week after the last intravenous immunoglobulin (IVIg) infusion.

- Before switching to Hizentra, obtain the patient's serum IgG trough level to guide subsequent dose adjustments
- Adjust the dose based on clinical response and serum IgG trough levels

Weekly:
Start Hizentra 1 week after last infusion

$$\text{Initial weekly dose} = \frac{\text{Previous IVIg dose (in grams)}}{\text{No. of weeks between IVIg doses}} \times 1.37$$

Biweekly (every 2 weeks):
Start Hizentra 1 or 2 weeks after the last IVIg infusion or 1 week after the last weekly SCIg infusion. Administer twice the calculated weekly dose

Frequent dosing (2 to 7 times per week):
Start Hizentra 1 week after the last IVIg or SCIg infusion. Divide the calculated weekly dose by the desired number of times per week

Visit our online dosing calculator for PI

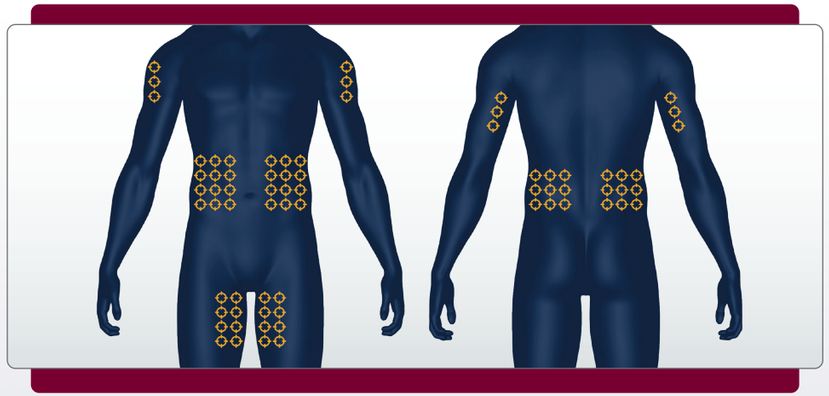
Please see full Important Safety Information on pages 24–25 and full prescribing information for Hizentra, including boxed warning, in pocket.

Monitor and adjust therapy for PI

- To determine if a dose adjustment should be considered, measure the patient's serum IgG trough level 2 to 3 months after switching to Hizentra
- Volume and rate can be adjusted after initial infusion as tolerated, which may decrease infusion time and number of sites
- Consider changing one variable at a time (eg, rate, volume, ancillary supplies, site) to continue tailoring treatment for your patient

Administering Hizentra: PI

Hizentra should be administered subcutaneously only. Do not administer intravenously. Hizentra can be dosed from daily up to every 2 weeks using an infusion pump and relatively small needle(s).



- The Hizentra dose may be infused into multiple infusion sites depending on volume
- Infusion sites should be at least 2 inches apart
- Rotate the actual site of infusion with each administration
- Use up to 8 infusion sites in parallel. More than 1 infusion device can be used simultaneously
- Recommended infusion sites include the abdomen, thighs, upper arms, or side of upper leg/hip
- SC needles are smaller than IV needles. Depending on a patient's size and weight, a needle as short as 4 mm or as long as 14 mm can be used

Hizentra can address a range of **CIDP patient** challenges

Hizentra provides flexibility for a wide range of patient needs. Here are some sample patient types that can help you identify those needs, determine the proper dosing regimen, and set expectations with transitioning patients.

James
45 years old

Experiences IV-related systemic adverse reactions

Weight: 210 lb (95 kg)*
Dose: 19 g/95 mL
Rate of infusion: 40 mL/hr/site
Infusion sites: 2
Time per infusion: 1 hour and 10 minutes

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Weekly dose:
19 g/95 mL

Why Hizentra?
Switching to subcutaneous infusions may help address systemic ARs so he can get back to everyday living.

Based on a dose of 0.2 g/kg.

Alice
80 years old

Has venous access issues

Weight: 165 lb (75 kg)*
Dose: 15 g/75 mL
Rate of infusion: 30 mL/hr/site
Infusion sites: 2
Time per infusion: ~1 hour and 15 minutes

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Weekly dose:
15 g/75 mL

Why Hizentra?
Subcutaneous infusions do not require infusions into a vein or the hassle of installing and maintaining a port.

Based on a dose of 0.2 g/kg.

*Rate of infusion and number of infusion sites in these hypothetical case studies are based on recommended rate and volume per site of subsequent infusions.
Photos do not depict actual patients.

Miguel
55 years old

Requires more frequent IV infusions

Weight: 176 lb (80 kg)
Dose: 32 g/160 mL (2 sessions over 2 days)
Rate of infusion: 40 mL/hr/site
Infusion sites: 2
Time per infusion: ~1 hour

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Weekly dose:
32 g/160 mL
(2 sessions over 2 days)

Why Hizentra?
Less volume per infusion means he can infuse in about an hour, and he prefers prefilled syringes because he has difficulty drawing up from vials

Based on a dose of 0.4 g/kg.

Allison
40 years old

Seeks flexibility, freedom, and control

Weight: 154 lb (70 kg)
Dose: 28 g/140 mL
Rate of infusion: 45 mL/hr/site
Infusion sites: 3
Time per infusion: ~1 hour

SU	M	T	W	TH	F	SA
01	02	03	04	05	06	07
08	09	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Weekly dose:
28 g/140 mL

Why Hizentra?
Self-infusion where and when she chooses, with ready-to-use prefilled syringes, lets her continue her day without infusion appointment interruptions

Based on a dose of 0.4 g/kg.

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Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid

Initiating Hizentra treatment for **CIDP patients**

	Infusion parameters*	1st infusion	Subsequent infusions
CIDP Weekly	Volume (mL/site)	≤20	≤50
	Rate (mL/hr/site)	≤20	≤50

*As tolerated.

Initiate therapy with Hizentra 1 week after the last IVIg infusion

- Recommended subcutaneous dose is 0.2 g/kg (1 mL/kg) body weight (bw) per week†
  - A dose of 0.4 g/kg body weight per week was also safe and effective
- If CIDP symptoms worsen on 0.2 g/kg consider increasing to 0.4 g/kg per week†
- Most patients remained relapse-free on either dosing option, with the 0.4 g/kg dose showing a lower rate of relapse‡§
  - If CIDP symptoms worsen on 0.4 g/kg body weight, consider reinitiating therapy with IVIg

†Administered in 1 or 2 sessions over 1 or 2 consecutive days.
‡CIDP relapse was defined as a ≥1 point increase in adjusted Inflammatory Neuropathy Cause and Treatment [INCAT] score compared with baseline.
§Statistical tests between the two doses were not conducted.

CIDP Dosing Calculation Examples (Weight to Grams)

CIDP patients self-infuse weekly, administered in 1 or 2 sessions over 1 or 2 consecutive days

		Weekly dose calculation	Weekly volume calculation
		Patient body weight (in kg) × dose (0.2 or 0.4 g/kg) = weekly dose (in g)	Weekly dose (in g) × 5 mL/1 g = Volume (in mL)
Sample weekly dosing calculations for an 80-kg patient	**0.2 g/kg**	80 kg × 0.2 g/kg = 16 g	16 g × 5 mL/1 g = 80 mL
	0.4 g/kg	80 kg × 0.4 g/kg = 32 g	32 g × 5 mL/1 g = 160 mL

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Proactively monitor and optimize therapy for CIDP

- Monitor the patient's clinical response and adjust the duration of therapy based on patient need
- Volume and rate can be adjusted after initial infusion as tolerated, which may decrease infusion time and number of sites
- Consider changing one variable at a time (eg, rate, volume, ancillary supplies, site) to continue tailoring treatment for your patient

Administering Hizentra: CIDP

- The Hizentra dose may be infused into multiple infusion sites depending on volume
- Infusion sites should be at least 2 inches apart
- Rotate the actual site of infusion with each administration
- Use up to 8 infusion sites in parallel. More than 1 infusion device can be used simultaneously
- Recommended infusion sites include the abdomen, thighs, upper arms, or side of upper leg/hip
- SC needles are smaller than IV needles. Depending on a patient's size and weight, a needle as short as 4 mm or as long as 14 mm can be used

Visit our online dosing calculator for CIDP

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

Managing expectations of common adverse reactions

Post-infusion reactions have been reported with the use of Hizentra. The most common adverse reactions (observed in ≥5% of study subjects) were local infusion-site reactions, as well as headache, diarrhea, fatigue, back pain, nausea, extremity pain, cough, upper respiratory tract infection, rash, pruritus, vomiting, upper abdominal pain, migraine, arthralgia, pain, fall, and nasopharyngitis.

In addition to managing expectations for local site reactions (see pages 14–15), patients should be advised of the following information:

Headache

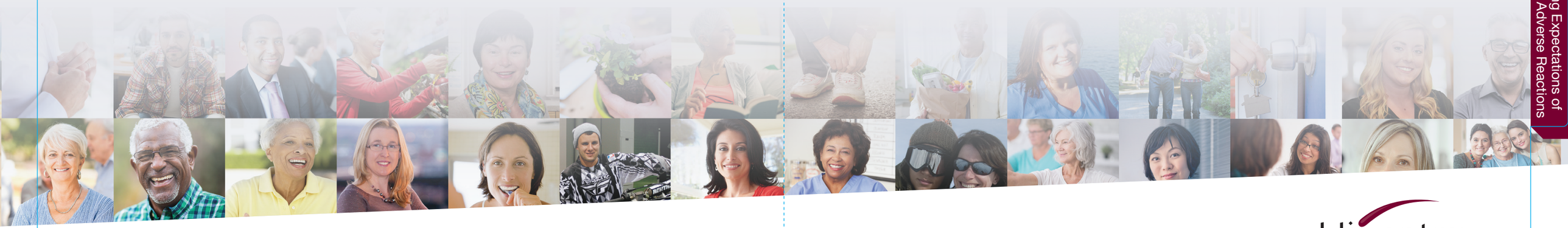
- After an infusion, patients might experience headaches of varying severity
- Adequate hydration is important during Ig therapy. Patients should drink plenty of fluids 24 hours prior to infusion and 24 hours post-infusion
- In patients with a history of migraine, prescription medication may be taken as recommended by their doctor
- Patients should report any unusual or prolonged headaches for evaluation/assessment. Adjust ancillary supplies accordingly and infusion parameters based on patient tolerability

When patients should call their healthcare provider

Inform patients to immediately report the following signs and symptoms to their healthcare provider:

- Hypersensitivity reactions to Hizentra (including hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis)
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body
- Severe headache, neck stiffness, drowsiness, fever, sensitivity to light, painful eye movements, nausea, and vomiting
- Decreased urine output, sudden weight gain, fluid retention/edema, and/or shortness of breath
- Fatigue, increased heart rate, yellowing of the skin or eyes, and dark-colored urine
- Severe breathing problems, lightheadedness, drops in blood pressure, and fever

Instruct patients to tell their doctor about any side effect that concerns them. Also instruct patients they should check with their doctor before infusing if they do not feel well, and to immediately call 911 if they have severe symptoms.



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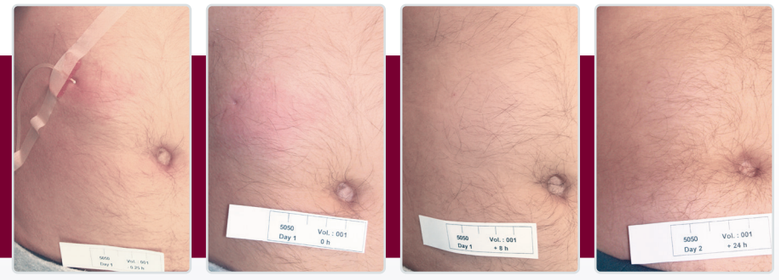
“I’m getting a reaction at the infusion site”

Patients may report reactions such as blanching, redness/rash, itching, discomfort, or swelling. It’s important to educate patients and caregivers that local reactions are common and expected. Most are mild in nature. In clinical trials, most reports of local reactions were either mild or moderate in intensity and the frequency of reports decreased over time.

The reaction should be assessed for size, duration, and intensity. In addition, assess the volume being infused per site and the infusion rate.[1]

Mild Local Reactions

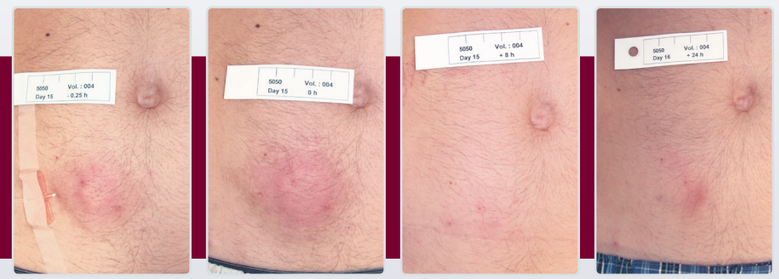
- Dime- to quarter-sized wheal and puffiness
- Mild redness, itching, discomfort, and/or pain



During infusion—15 minutes remaining | Infusion complete | 8 hours post-infusion | 24 hours post-infusion

Moderate Local Reactions

- Half dollar–sized wheal and puffiness
- Moderate redness, itching, discomfort, and/or pain



Photos are from the Hizentra Phase 1 clinical trial in PI.

Potential solutions:

Infusion Regimen Adjustment

- **Rotating sites appropriately:** Avoid infusing into scars or stretch marks, or areas where the skin is tender, bruised, red, or hard. Administer in areas that have more subcutaneous tissue and do not have other skin irritations. Rotate appropriately within those areas
- **Regimen change:** Consider decreasing volume per site, administering more frequently, increasing the number of infusion sites, and/or increasing infusion time
- **Alter priming routine:** When priming, do not allow drops of Hizentra to cover the needle. Instead leave a small amount of air before needle. Hizentra tracked through the intradermal space may cause site reactions such as redness and itching
- **Pre- or post-infusion medications:** Consider use of a topical anesthetic ointment. Advise use of gentle massage or warm/cold compress post-infusion

Equipment/Supplies Adjustment

- **Needle length:** May be too short and infusion may be intradermal (see needle discomfort [page 18] for more information)
- **Needle gauge:** Choose a needle that is consistent with volume being infused
- **Tape allergy:** Switch to paper/hypoallergenic tape

Patients with lower BMI may have more prominent local site reactions. If so, consider decreasing the amount of volume per site and/or adjusting site locations accordingly.

Stop the infusion if generalized urticaria is present. Contact the patient’s prescriber immediately.

“The infusion site is leaking”

If the infusion site is leaking medication, there is either a problem with the way the patient is infusing or what supplies they are infusing with.

Potential solutions:

Infusion Adjustment

- **Needle insertion:** Ensure it is affixed securely and fully inserted
- **Needle placement:** Site location should not be subject to movement. Assess amount of subcutaneous tissue at infusion site and, if appropriate, consider site with more tissue
- **Rate and volume:** Infusions may be too fast or administering too much volume per individual site. Adjust accordingly
- **Needle shifts:** Ensure limited/minimal activity, as movements can cause the needle to shift

Equipment/Supply Adjustment

- **Needle length:** May be too short. Change needle brand and/or length (see needle discomfort [page 18] for more information)

“There’s blood coming into one of the tubes near the end of my infusion”

It is not uncommon for traces of blood to enter the infusion set as the infusion progresses.

Potential solutions:

Apply Pressure

- If traces of blood enter the infusion set, apply pressure to the site and leave the needle in place for a minute before continuing. This may leave a small bruise

Set expectations

- Inform patients that the fill volume of the tubing is less than 1 mL, so trace amounts of blood may appear magnified
- Make sure the needle is seated correctly in subsequent infusions to lessen the chance of blood entering the infusion set again

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“These needles are uncomfortable”

If the patient is having problems with the needles they are using, it could be caused by damage or contamination, the way they insert the needles, or that the needles being used are not the appropriate size for that patient.

Potential solutions:

Infusion Adjustment

- **Infusion site:** assess and optimize the location of the infusion site
- **Premedication:** consider recommending application of topical anesthetic or cold pack prior to insertion of needle

Equipment/Supply Adjustment

- **Needle length:** needle may be too long and cause irritation, or it may be too short to reach subcutaneous tissue.[1,2] Suggest new size per assessment
- **Needle brand:** consider changing brand of needle set

4 mm
6 mm
9 mm
12 mm
14 mm

Typical needle length for pediatric use is 6 mm.* Needle length for adults is usually 9 or 12 mm. Adjust individual needle length and/or set based on patient parameters and tolerability.

*Hizentra is not indicated for pediatric use in CIDP. Hizentra is indicated for pediatric use in PI patients 2 years and older.

Potential solutions:

Check for Damage/Contamination

- **Damage:** have the patient look closely at his/her needles and discard any with obvious signs of damage, such as dullness or burrs
- **Sterility:** aseptic procedures require sterile supplies. If in doubt, discard needles in appropriate waste containers and restart procedure

Please see full Important Safety Information on pages 24–25 and full prescribing information for Hizentra, including boxed warning, in pocket.

“I’m having trouble filling the syringe from the vial”

For some patients, dexterity issues or improper transfer techniques may result in difficulty drawing Hizentra into the syringe.

Potential solutions:

Supply Adjustment

- Patients experiencing difficulty with vial transfer may find prefilled syringes a simpler and more convenient way to use Hizentra, depending on dose
- Consider training the patient to use a transfer device such as a spike needle to simplify the transfer process with vials
- Pull out the plunger of the syringe to fill the syringe with air before starting the transfer

Transfer Process Adjustment

- If using a traditional needle set, pull back the amount of air to be infused into the vial and then attach the needle aseptically to the syringe
- If using a transfer device, mark the level of mL to which the syringe should be drawn back by placing tape on the outside barrel at the necessary level

“How do I use a prefilled syringe with my infusion pump?”

Potential solutions:

Transfer Device

- Prefilled syringes are transferred to a pump syringe using a syringe-to-syringe transfer device
- You can share a video with patients that explains using a syringe-to-syringe transfer device on the Hizentra website
- Download and share the Hizentra Infusion Guide on the Hizentra website

“My infusion time is longer than I was told it would be”

If patient expectations are not being met in terms of infusion time, there could be several factors involved. The pump, tubing, or human error may slow a Hizentra infusion. An observation of patient technique may be required to ensure the patient is infusing correctly.

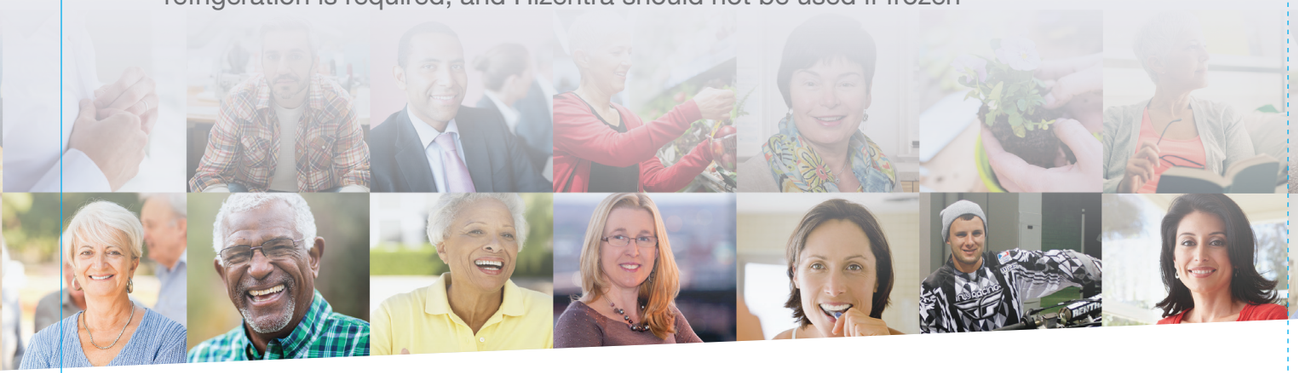
Potential solutions:

Equipment/Supply Adjustment

- **Tubing check:** check patency of tubing, number of sites, and volume per site. Adjust ancillary supplies and infusion parameters based on patient tolerability
- **Pump settings:** assess infusion rate settings, correct selection of tubing size and length to match infusion rates, check pump function, battery function, and any other pump settings unique to the pump model

Infusion Routine Adjustment

- **Prefilled syringes:** patients may find that eliminating the vial transfer from infusions may reduce steps and effort, depending on dose
- **Site location:** may need to move infusion to different site. Confirm how many infusion sites are being used, don’t infuse into skin with scar tissue, bruising, or stretch marks
- **Infusion rate:** confirm whether infusion rate has been adjusted based on patient’s tolerability since therapy was initiated
- **Product storage:** Hizentra is ready to use at room temperature for up to 30 months as indicated by the expiration date printed on the outer carton and vial label. No refrigeration is required, and Hizentra should not be used if frozen



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“The pump stopped during my infusion”

If the pump doesn't work when starting an infusion, ensure the pump has been turned on. If it stops during the infusion and has not inadvertently been turned off, verify that the patient is using the recommended supplies to help ensure accuracy and rate delivery.

Potential solutions:

Equipment/Supply Adjustment

- Check tubing for any line blockage. Do not override occlusion alarm or increase PSI delivered
- Check sets for down-line blockage. Multisite sets may cause alarm to sound because of codependence of lines
- Change catheter brands or use single independent lines that connect equally to a multiextension pigtail
- Change gauge of catheter needle
- Check with pump manufacturer for any specific issues
- Change type of infusion pump
- Change batteries if using a pump with batteries

Infusion Adjustment

- Assess the volume being infused per site and optimize as needed

Skills Checklist for Self-Administration of Hizentra

Patient Name (Please print clearly)

Record of Instructions

Foundational information	Introduced RN Initials/Date	Reinforced RN Initials/Date	Independence Mastered RN Initials/Date
Define subcutaneous administration			
Describe aseptic technique			
Describe appropriate sites for infusion			
Describe appropriate care of subcutaneous infusion site			

Preparation and process	Introduced RN Initials/Date	Reinforced RN Initials/Date	Independence Mastered RN Initials/Date
Visually inspect each vial or prefilled syringe; do not use if liquid looks cloudy, has particles, has changed color, or if the protective cap is missing. Check the expiration date on the vial or prefilled syringe; do not use beyond the expiration date			
Gather appropriate supplies for proper administration and aseptic technique			
Demonstrate proficiency in filling a pump syringe using ☐ vials or ☐ prefilled syringes			
Demonstrate proficiency in setting up (priming) tubing			
Demonstrate proficiency in setting up and operating the infusion pump			
Demonstrate proficiency in the completion of a subcutaneous infusion			

Managing complications	Introduced RN Initials/Date	Reinforced RN Initials/Date	Independence Mastered RN Initials/Date
Describe signs/symptoms of subcutaneous needle complications			
Identify appropriate interventions Scenarios to be discussed: • Pump malfunction/alarms • Site reactions: expectations and management • Other adverse reactions			
Demonstrate understanding of circumstances requiring and appropriate use of epinephrine auto-injector (eg, EpiPen®)			

Postinfusion care	Introduced RN Initials/Date	Reinforced RN Initials/Date	Independence Mastered RN Initials/Date
Demonstrate understanding of postinfusion site care			
Demonstrate understanding of care and maintenance of infusion pump			

Who is responsible for administering Hizentra? (Please select)

☐ Patient ☐ Caregiver ☐ Clinician

Comments: _____

Please see full Important Safety Information on pages 24–25 and full prescribing information for Hizentra, including boxed warning, in pocket.

Hizentra Progress Report

Date of visit/phone interaction: _____ Last visit w/prescriber: _____

Patient: _____ Prescriber: _____

Weight: _____ Height: _____ DOB: _____

Diagnosis: _____

Current Hizentra treatment:

- Dose: _____ • Rate of infusion: _____
- Site location: _____ • Number of sites: _____
- Needle length/gauge: _____ • Volume/infusion site: _____

☐ Vials ☐ Prefilled syringes • Other: _____

Pertinent history/labs: _____

Infections since last report: _____

Antibiotics since last report: _____

Treatment-related adverse events*:

☐ Description of sites after infusion: _____

☐ Patient report of adverse events (explain):

- Local: _____
- Systemic: _____
- Timing of onset and duration: _____

Intervention:

☐ No intervention

☐ Infusion regimen adjustments made:

- Rate of infusion: _____
- Site location: _____ • Number of sites: _____
- Needle length/gauge: _____ • Volume/infusion site: _____

☐ Vials ☐ Prefilled syringes • Other: _____

☐ Additional patient teaching:

- Next scheduled nursing visit: _____

Name: _____ Signature: _____

Phone: _____

Email: _____

Report faxed to prescriber at: _____ Report called to prescriber at: _____

Report emailed to prescriber at: _____

*All adverse events should be reported to MedWatch (1-800-FDA-1088) or the pharmacovigilance department of the product manufacturer:
CSL Behring US Pharmacovigilance Phone: 1-866-915-6958 Email: Adverse.Events.Global@cslbehring.com (Available 24 hrs/day)

Hizentra® Immune Globulin Subcutaneous (Human) 20% Liquid

Important Safety Information

WARNING: Thrombosis may occur with immune globulin products, including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin (Ig) or components of Hizentra (eg, polysorbate 80), as well as in patients with immunoglobulin A deficiency with antibodies against IgA and a history of hypersensitivity. Because Hizentra contains L-proline as stabilizer, use in patients with hyperprolinemia is contraindicated.

IgA-deficient patients with anti-IgA antibodies are at greater risk of severe hypersensitivity and anaphylactic reactions. Thrombosis may occur following treatment with Ig products, including Hizentra.

Monitor patients for aseptic meningitis syndrome (AMS), which may occur following treatment with Ig products, including Hizentra. In patients at risk of acute renal failure, monitor renal function, including blood urea nitrogen, serum creatinine and urine output. In addition, monitor patients for clinical signs of hemolysis or pulmonary adverse reactions (eg, transfusion-related acute lung injury [TRALI]).

Hizentra is derived from human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

The most common adverse reactions (observed in ≥5% of study subjects) were local infusion-site reactions, as well as headache, diarrhea, fatigue, back pain, nausea, extremity pain, cough, upper respiratory tract infection, rash, pruritus, vomiting, upper abdominal pain, migraine, arthralgia, pain, fall, and nasopharyngitis.

The passive transfer of antibodies can interfere with response to live virus vaccines and lead to misinterpretation of serologic test results.

Indications

Hizentra is indicated for:

- Treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years and older.
- Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.
  - Limitation of Use: Maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only.

Please see full prescribing information for Hizentra including boxed warning.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. Murphy E, Burton J, Riley P. Nursing approaches to a novel subcutaneous immunoglobulin therapy. *Infusion*. 2007;13(4):1-8. **2.** Duff C, Ochoa D, Riley P, Murphy E, Zampelli A. Importance of ancillary supplies for subcutaneous immunoglobulin infusion: management of the local infusion site. *J Infus Nurs*. 2013;36(6):384-390.

Hizentra®
Immune Globulin Subcutaneous (Human)
20% Liquid

Proven Results. Greater Freedom.

If you have a medical question:
Call CSL Medical Information
at 1-800-504-5434
Mon–Fri, 9 AM–5 PM ET

If your patient has a nonmedical question:
Have them call
1-877-355-4447
Mon–Fri, 8 AM–8 PM ET

**For all other questions,
feel free to contact your local rep:**

Name: _____
Phone #: _____
Email: _____
ISS: _____

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Biotherapies for Life® CSL Behring

Please see full Important Safety Information on pages 24–25 and full prescribing information for Hizentra, including boxed warning, in pocket.