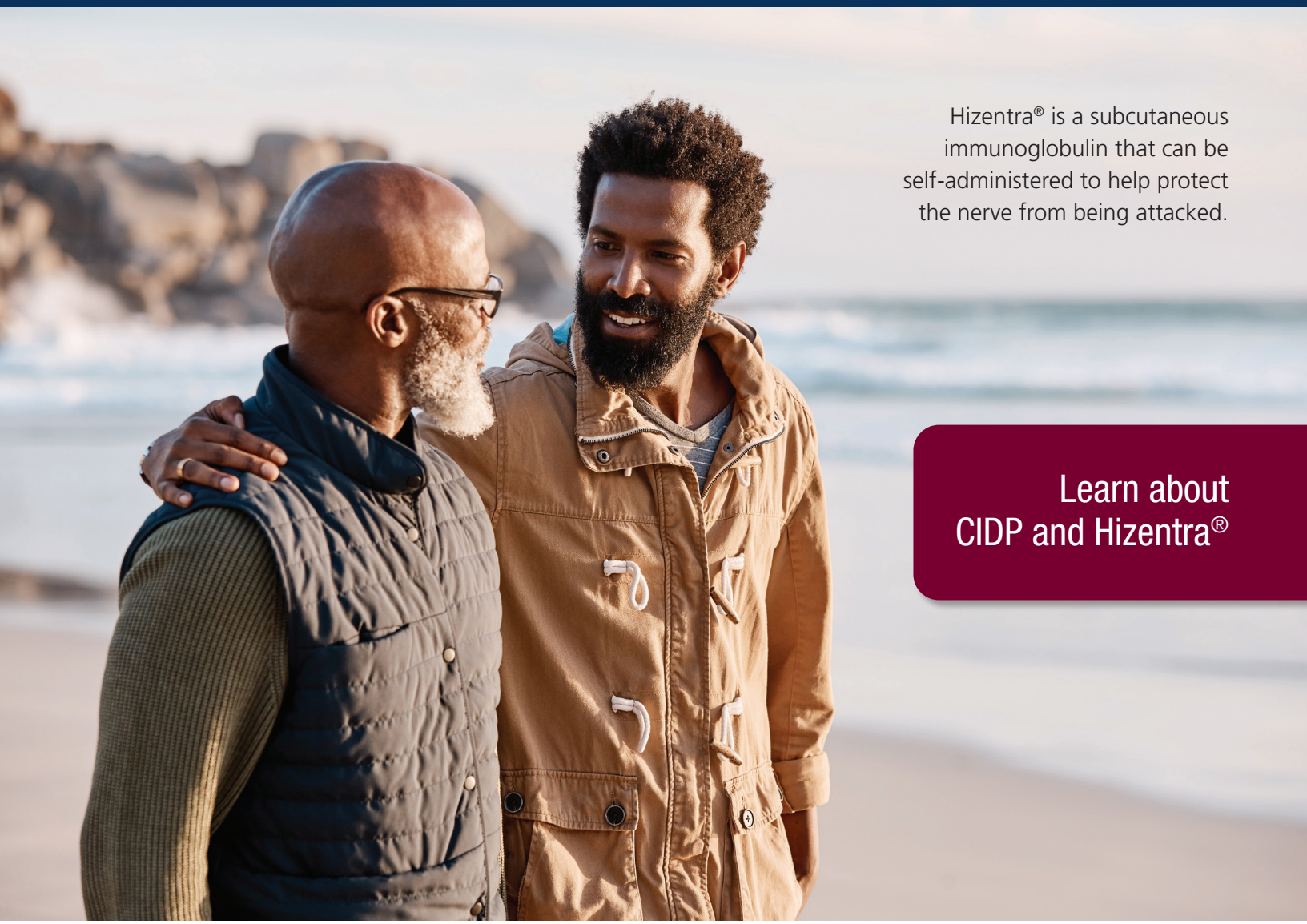
Hizentra®

Subcutaneous Immunoglobulin (Human), **20%**

Hizentra® and You

Information for people living with CIDP



Hizentra® is a subcutaneous immunoglobulin that can be self-administered to help protect the nerve from being attacked.

Learn about CIDP and Hizentra®

CIDP = chronic inflammatory demyelinating polyneuropathy.

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What is CIDP?

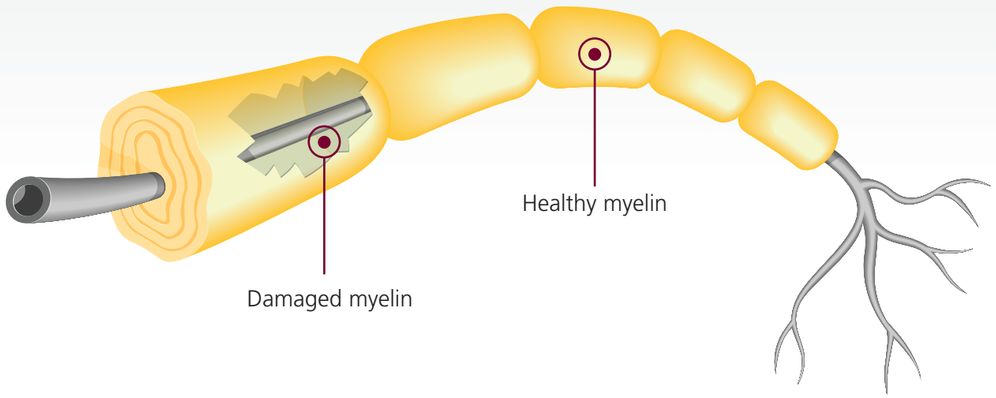
Chronic inflammatory demyelinating polyneuropathy (CIDP) is a neurological disorder that causes progressive weakness and impaired sensory function in the legs and arms.

Symptoms often include tingling or numbness (first in the toes and fingers), weakness of the arms and legs, loss of deep tendon reflexes, fatigue, and abnormal sensations.

The immune system uses many types of cells, including B cells and T cells, to help the body fight infections caused by viruses or bacteria.

The immune system behaves abnormally in CIDP. Instead of fighting infections, some B cells and T cells attack myelin (the fatty sheath that protects nerves and helps maintain the signals carried by the nerves).

Early treatment may help limit damage to the nerves.



About Hizentra®

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Hizentra® contains the antibody **immunoglobulin G (IgG)**, which helps the body combat germs, such as bacteria and viruses. Antibodies are major components of immunity and IgG is the main type of antibody found in blood allowing it to control infection of body tissues.

What is Hizentra® used for?

Hizentra® is a medicine used to treat primary immunodeficiency (PID), secondary immunodeficiency (SID) and chronic inflammatory demyelinating polyneuropathy (CIDP), conditions in which a person's natural defense system (or immune system) does not function properly.

How does Hizentra® work?

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. For people with CIDP, Hizentra® is believed to help **protect the nerves from being attacked**.

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About Hizentra®

If your doctor is transitioning you from IVIg (intravenous immunoglobulins) to Hizentra®, you should expect to start Hizentra® within a week of your last IVIg treatment. Be sure to get instructions from your healthcare provider about this transition.

How do I administer Hizentra®?

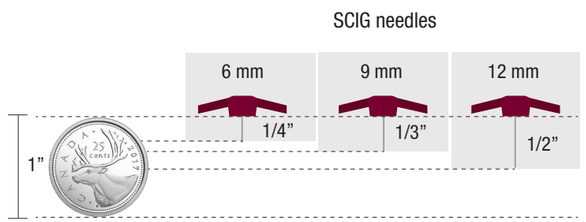
Hizentra® is infused subcutaneously (under the skin, not into a vein) by following the instructions for administration provided. Your healthcare provider will teach you the proper techniques for administering Hizentra®.

For step-by-step guidance on infusing Hizentra® at home, please refer to your Hizentra® Patient Resource Binder. If you don't have one, please ask your healthcare provider.

Visit patients.cslbehring.ca today!
An online patient portal with helpful resources, including Hizentra® infusion guides and videos.

Infuse Hizentra® only after you have been trained by your healthcare provider.

Actual needle sizes that can be used for infusing Hizentra®



Examples only. Follow the instructions provided by your healthcare provider.

Hizentra® dosage forms

Hizentra® is supplied in single-use, tamper-evident vials or single-use, pre-filled syringes.Your healthcare provider will teach you the proper techniques for administering Hizentra®.

Access it by entering the 8-digit DIN number located in the upper left-hand corner of your Hizentra® package.

SCIG = subcutaneous immunoglobulin.

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The following may interact 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.

How do I store Hizentra®?

✔ Store Hizentra® in either the refrigerator or at room temperature (+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.

X Do NOT use after the expiration date.
X The Hizentra® solution contains no preservatives and should be administered as soon as possible after opening the vial/pre-filled syringe.
X Do NOT freeze Hizentra®.
X Do NOT use product that has been frozen.
X Do NOT shake the vial/pre-filled syringe.

✔ DO keep Hizentra® in its original carton to protect it from light.
✔ DO keep Hizentra® and all other medications out of the reach of children.

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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 SCIG 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 non-infectious 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 if they worry you, talk to your healthcare provider.

Tell your healthcare provider 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 healthcare provider 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, 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 37.8°C (100°F). This could be a sign of an infection.

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

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

SCIG = subcutaneous immunoglobulin.

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Before using Hizentra®

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Hizentra®. Tell them about any health conditions or problems you may have, including 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).

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 which 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.

IgA = immunoglobulin A.

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Important
Safety Information

Serious side effects and what to do about them

	Talk to your healthcare professional		Stop taking Hizentra® and get immediate medical help
Symptom/effect	**Only if severe**	**In all cases**	
Rare[1]			
Severe hypersensitivity and anaphylactic reactions: a fall in blood pressure, swollen face or tongue, swelling of the throat, shortness of breath, fever, chills, dizziness, fast heartbeat, flushing.		✓	✓
Signs of a blood clot: 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		✓	✓
Very Rare[2]			
Non-infectious meningitis: bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light.		✓	✓

[1] May affect patients in less than 10 of 10,000 infusions.
[2] May affect patients in less than 10 of 100,000 infusions.

Notes

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**If you have any questions along your Hizentra®
treatment journey, please talk to your healthcare provider.**

Visit patients.cslbehring.ca today!

An online portal with information for patients taking Hizentra®. You will need to enter the 8-digit number located in the upper left-hand corner of your Hizentra® package to access the portal.

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