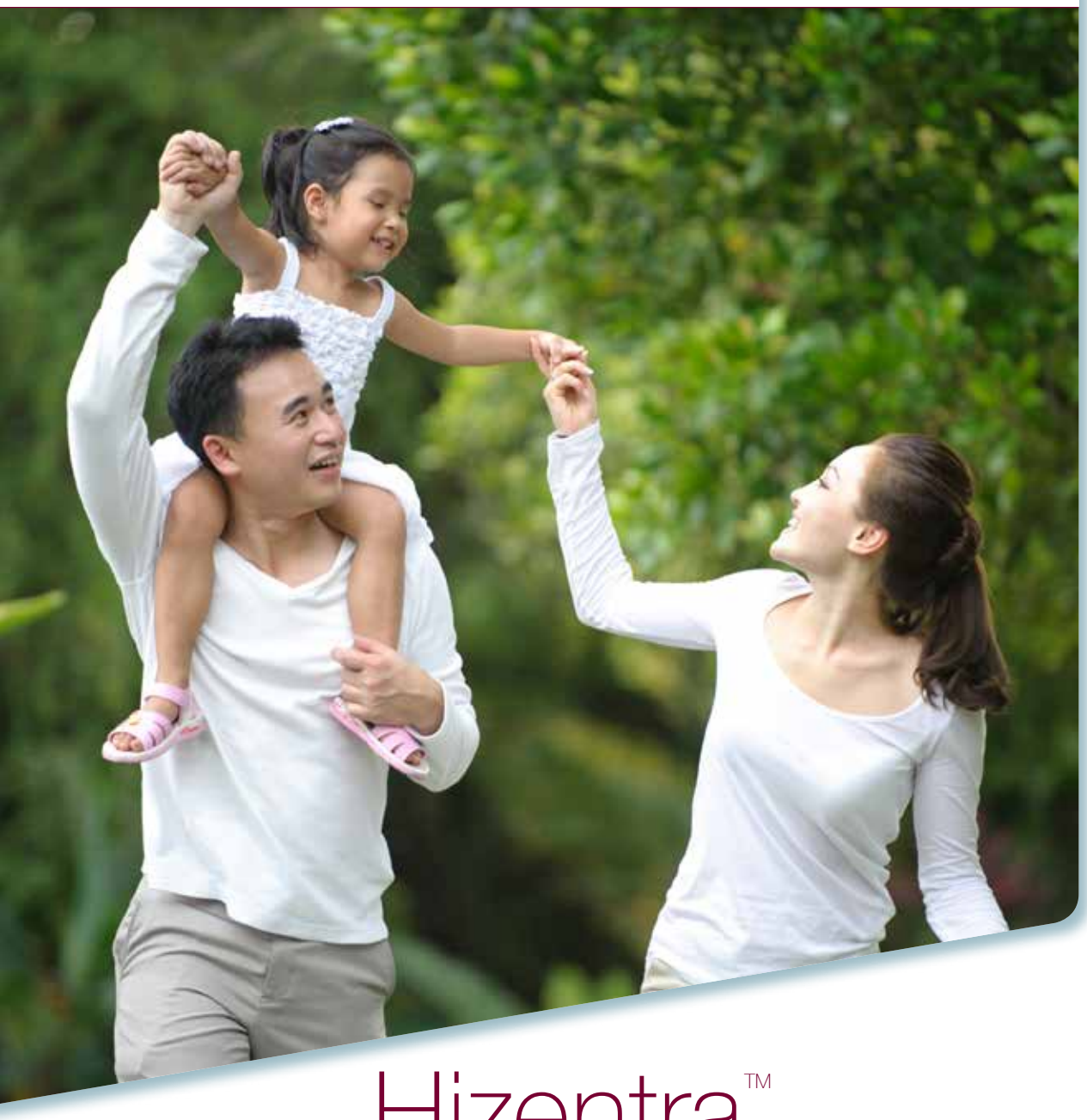
CSL Behring



Hizentra™ Self Infusion Manual

This material is strictly for patients prescribed with Hizentra™ by healthcare professionals only.
Do not display at public area.

Welcome to Treatment with Hizentra™

You have been prescribed Hizentra™ by your Healthcare Professional.

You and your healthcare professional have made an important decision to start treatment with Hizentra™. Hizentra™ is a subcutaneous 20% immunoglobulin therapy approved for use in the treatment of primary immunodeficiency disease. Your healthcare professional will ensure you receive detailed instructions and training on how to use Hizentra™. This will include the dosage and how often you need Hizentra™, as well as how to administer it. Once you and your healthcare professional feel comfortable with self-administration, you can have the freedom and flexibility to infuse therapy on your own.

We want you to be comfortable with your infusions so you can stay as healthy as possible. We recommend that you read through all the information in this booklet, and always have it and your Hizentra™ Treatment Journal handy when you infuse therapy on your own. We hope that with this manual, together with the support and training provided by your healthcare provider – and a little practice – you will find that Hizentra™ fits easily into your life.

Note: This booklet provides information that supports your self-infusion. It does not replace the advice or training from your healthcare professional. If you have question about infusion at any time during your treatment, please contact your healthcare professional.

Important Safety Information

WARNING:

Thrombosis (blood clotting) can occur with immune globulin products, including Hizentra™. Risk factors can include: advanced age, oestrogen use, in-dwelling vascular catheters, history of blood vessel disease or blood clot episodes, cardiovascular risk factors (including history of atherosclerosis and/or impaired cardiac output), acquired or inherited blood clot tendencies, prolonged periods of immobilization, severe low blood volume, and diseases which increase blood viscosity.

If you are at high risk of thrombosis, your doctor will monitor you for signs of thrombosis and hyperviscosity. The first symptoms of thromboembolic events include shortness of breath, chest pain, pain and swelling of limbs, and focal neurological deficits. Contact your healthcare professional immediately if any of the symptoms occur. Always make sure you are sufficiently hydrated before administration.

Aseptic Meningitis Syndrome (AMS) cases have occurred with use of intravenous or subcutaneous immunoglobulin. The syndrome usually begins within several hours to 2 days following immune globulin treatment. AMS is characterised by the following signs and symptoms: severe headache, neck stiffness, drowsiness, fever, photophobia, nausea, and vomiting. Contact your healthcare professional immediately if any of the symptoms occur.

Important Safety Information

Do not use Hizentra™ if you:

- are allergic to human immunoglobulin products.
- have too much proline in your blood (hyperprolinaemia).
- have previously reacted to any ingredient in Hizentra™.

If you are not sure whether you should be using Hizentra™ talk to your doctor.

SIDE EFFECTS:

Side effects of Hizentra™ include chills, headache, fever, vomiting, allergic reactions, nausea, joint ache, low blood pressure and moderate low back pain. Tell your healthcare professional if you experience any side effect that concerns you. If the side effect is severe, seek medical attention immediately.

For further information about your medical condition or treatment, please contact your healthcare professional.

IMPORTANT Read Before Infusing

When infusing

- Ensure you have enough time to complete the infusion before starting.
- Do not infuse if you feel unwell or have an untreated infection.
- Do not open the Hizentra™ vial(s) or needles until you are ready to use them.
- The needles must remain sterile. If you touch one by mistake, discard in a sharps box and use a new one.
- Choose a suitable area for your infusion e.g. kitchen work surface.
- Use an infusion tray or a sterile towel to lay out your infusion kit.

Remember to remove the vial record label

Always have your Hizentra™ Treatment Journal handy to record details of the infusion. Remember to stick the self-adhesive label from your vial(s) into your diary each time you infuse.

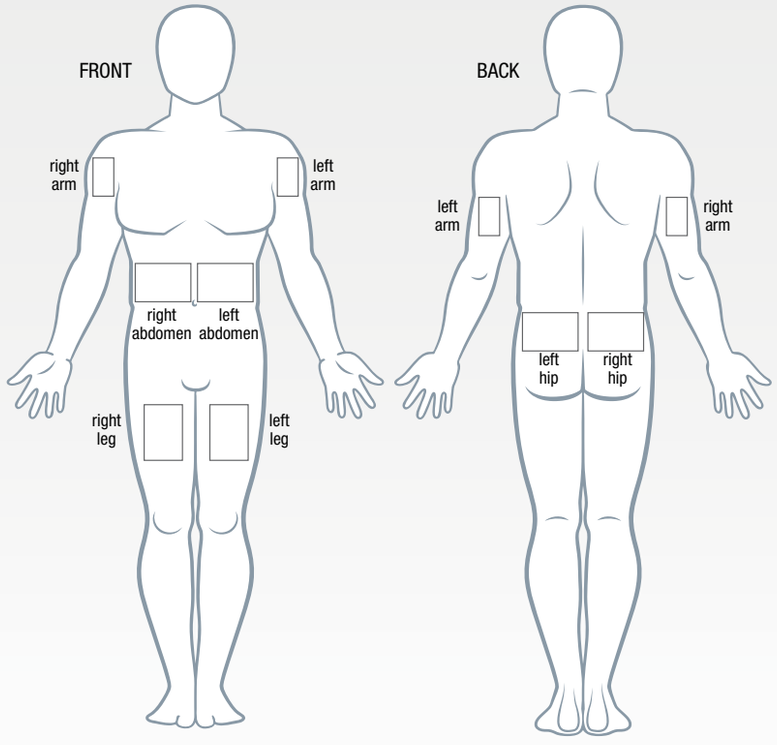
Storing your Hizentra™

- Hizentra™ is supplied in single, ready-to-use vials.
- Store the vial below or up to 25°C. Do not freeze. Keep the vial in the outer carton in order to protect from light.
- Take out Hizentra™ from the fridge in advance of your infusion and make sure it is at room or body temperature before use.
- Hizentra™ has no preservatives. Once a vial has been opened it is important to use your Hizentra™ straightaway. In the unlikely event you stop your infusion before it is complete it is important to throw away any unused open vials.
- Keep out of the reach and sight of children.

Decide on an infusion site

Vary site each time you infuse

It is important to vary the site of your infusion each time you infuse. To help you do this, simply record the body area in your diary and rotate the site each time you infuse.



- The recommended initial infusion rate depends on individual needs of the patient and should not exceed 15 ml/hour/site. If well-tolerated, the infusion rate can then gradually be increased as per your healthcare professional's instruction.
- If large doses are given (> 25 ml), it may be advisable to administer the dose at multiple sites. Up to 4 injection sites can be used simultaneously. More than one infusion device can be used simultaneously. The volume of product infused into a particular site may vary.
- Infusion sites should be at least 5 cm apart.

Your Hizentra™ Infusion Regimen at a Glance

About this guide

- This infusion guide is meant to help you every step of the way in the infusion process. It is helpful as a teaching tool when you are first learning the infusion process, but can also serve as a refresher when you become more comfortable. You are encouraged to take notes on this guide as you learn and practice.
- Each of the 11 steps is divided into 3 buckets to help you understand where each step fits in the overall process:

Get Ready	Get Set	Go
1. Gather your supplies	5. Prepare syringe	9. Start infusion
2. Clean surface	6. Prepare infusion equipment	10. Record your infusion
3. Sanitize your hands	7. Prepare infusion site(s)	11. Complete infusion and clean up
4. Inspect each vial of Hizentra™	8. Insert subcutaneous needle(s)	

- Some steps are simple, while others may take a bit more time – however, they are all important parts of your infusion and should be followed with care.

Step 1.
Wash your hands & gather your infusion kit

Thoroughly wash your hands with soap and use a clean towel to dry them

Generally, you will need:

- Hizentra™ vial(s)
- Hizentra™ Infusion Diary and pen
- Infusion pump(s)
- Infusion tubing
- Infusion tray or sterile towel
- Infusion needles (as directed by your Specialist Nurse)
- Alcohol wipes
- Antiseptic skin wipes
- Syringes
- Transfer needles
- Gauze and tape, or transparent dressing
- Sharps container
- Waste paper container
- Gloves and alcohol hand gel (if recommended by your Specialist Nurse)
- Spare battery for pump (if required)

Notes:

The vial should be at room or body temperature before use

Disclaimer: Some of the items shown in the picture are for illustration purpose only and may not be included in the product package.

Step 2.
Clean the surface

Thoroughly clean your infusion area

- Thoroughly clean your working area using a disposable disinfectant wipe or household disinfectant. If using an infusion tray thoroughly clean with soap and water and wipe with an antiseptic wipe. Allow to dry.

Step 3.
Wash your hands

Wash your hands again

- Thoroughly wash your hands and use a clean towel to dry them. Alternatively you can use an alcohol hand gel.
- If you have been told to wear gloves when preparing your infusion, put the gloves on now.

Step 4.
Inspect each vial of Hizentra™

Check each bottle of Hizentra™ carefully

- Check the dose is correct on each bottle.
- Do you have enough bottles for your infusion?
- Is the bottle damaged?

Carefully look at the liquid in each vial of Hizentra™

- Hizentra™ vials are clear and can vary from almost colourless to pale yellow/light brown.
- Check for particles or colour changes.

Do not use the vial if:

- The liquid looks cloudy, contains particles, or has changed colour.
- The bottle is cracked or broken.
- The protective cap is missing.
- The expiry date on the label has passed.

Step 5.
Prepare the syringe

Ensure supplies are ready

- Attach a transfer needle(s) to the syringe tip(s) and place on infusion tray or on a sterile towel.
  - If you touch the needle by mistake use a new needle.
  - If you touch the tip of the syringe by mistake use a new syringe.
- Open up everything else required for your infusion and place onto your infusion tray or towel (gauze, infusion needle(s), antiseptic wipes).

Take the protective cap off the vial

- Clean the vial stopper with an alcohol wipe; let the stopper dry.

Transfer air into the Hizentra™ vial

- Pull out syringe plunger to fill it with air.
  - The amount of air should be the same as the volume of Hizentra™ you will transfer from the vial.
  - Be careful not to touch the inner portion of the plunger to keep it sterile.
- Put the Hizentra™ vial on a flat surface.
- Keeping the vial upright, insert the transfer needle into the centre of the rubber stopper.
- Check that the tip of the needle is not in the liquid.
- Push the plunger on the syringe down.
  - This will inject the air from the syringe into the airspace of the vial.

Step 5.
Prepare the syringe (con't)

Transfer Hizentra™ from the vial to the syringe

- Leaving the needle in the stopper, carefully turn the vial upside down.
- Slowly pull back on the plunger to fill the syringe while keeping the needle submerged the entire time.
- Take the filled syringe and needle out of the stopper.
- Expel air by gently tapping the syringe and pushing the liquid up to the base of the needle.
- Take off the needle carefully and discard in sharps container.
- Immediately attach to the infusion tubing once you have discarded the needle.
- Repeat for multiple syringes (if appropriate).

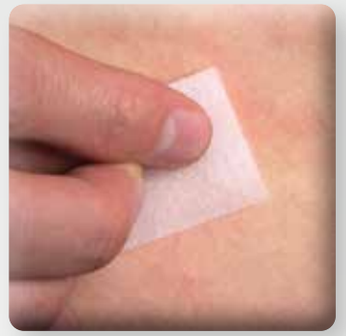
Step 6.
Prepare the infusion equipment

Prepare the infusion pump following the manufacturer's instructions and prime (fill) the infusion tubing

- To prime the tubing, connect the syringe filled with Hizentra™ to the administration tubing.
- Expel the air in the tubing by gently pushing on the syringe plunger to fill the tubing with Hizentra™ (or follow the pump manufacturer's instructions).
- Do not let the medicine reach the tip of the needle.

Step 7.
Prepare the infusion site(s)

Select an area for infusion



- Use a different site from the last time you infused Hizentra™.
  - Your healthcare professional will tell you how many infusion sites (that is, sites where the needle is inserted) you need to use and how much Hizentra™ to infuse at each site.
  - New sites should be at least 5 cm from a previous site.
  - Never infuse into areas where the skin is tender, bruised, red, or hard.
  - Avoid small veins which are visible on the skin surface.
  - Avoid infusing into scars or scratch marks.
- Clean the skin at each site with an antiseptic wipe and let the skin dry.

Step 8.
Insert the subcutaneous needle

- Infusion needles may vary depending on the type you are using. Always follow your healthcare professional's instructions when inserting your needle.

Insert the needle(s)

- With 2 fingers, pinch together the skin around the infusion site.
- Insert the needle under the skin at an angle of 45° to 90° – as instructed by your healthcare professional and depending on the type of needle used. Take care not to touch the needle prior to insertion. Discard if contaminated.
- If required, support the needle with sterile cotton wool or gauze. Secure the needle with 2 pieces of micropore tape in a cross shape for extra security.
- Repeat if using 2 or more sites until all the needles have been inserted.

Make sure you are not infusing Hizentra™ into a blood vessel

- Hizentra™ should only be administered subcutaneously (beneath the skin).
- To test for this, pull the syringe plunger back gently.
- If you see any blood in the tubing, take the needle out of the infusion site, remove the tubing from the syringe and discard in the sharps bin.
- Attach and prime (fill) a new needle and tubing to the syringe, then insert the needle into a different site. Check again that you are not infusing into a blood vessel.
- If there are multiple infuson sites, repeat for each needle inserted.

Step 9.
Start the infusion

Start your infusion

- Insert the syringe into the infusion pump.
- Set the infusion rate (if required).
  - Your healthcare professional will tell you what rate to use for your Hizentra™ infusion.
- Turn on the infusion pump.

Image is for illustration purpose. The infusion pump model may be different from what is available in your country.

Step 10.
Record infusion information

Record each infusion in your Hizentra™ Treatment Journal

- Peel off the removable part of the label(s) from the Hizentra™ vial(s).
- Put the label(s) in your Hizentra™ Treatment Journal with the date and time of the infusion.
- Also include the exact amount of Hizentra™ that you infused and complete all sections.
- Remember to take your Hizentra™ Treatment Journal with you to all clinic appointments.

Step 11.
Complete the infusion and clean up

When all of the Hizentra™ has been infused

- Turn off the infusion pump.
- Take off the dressing and take the needle out of the infusion site.
- Cover the infusion site on your skin with gauze, tape or plaster.
- Discard needles, infusion tubing and bottles in the sharps bin.
- Clean and store the infusion pump following the manufacturer's instructions.
- Clean infusion area with a disinfectant wipe.
- Thoroughly wash and dry your hands.

Notes

Notes

Please refer to approved full prescribing information before use

Abridged Prescribing Information

Hizentra 200 mg/ml solution for subcutaneous injection. **Therapeutic Indications:** Replacement therapy in adults and children in primary immunodeficiency (PID) syndromes such as congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiency and Wiskott-Aldrich syndrome. Replacement therapy in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections. Treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilization with intravenously administered immunoglobulins (IVIg). **Posology:** ***Adults and children: Replacement therapy:*** A loading dose of at least 0.2 to 0.5 g/kg (1.0 to 2.5 ml/kg) body weight to be divided over several days. After steady state IgG levels have been attained, maintenance doses are divided into smaller doses and administered at repeated intervals to reach a cumulative monthly dose in the order of 0.4 to 0.8 g/kg (2.0 to 4.0 ml/kg) body weight. For patients switching from intravenous treatment the monthly dose is divided into smaller doses and administered at repeated intervals. ***Immunomodulatory therapy in CIDP patients:*** Initiate Hizentra therapy 1 week after the last IVIg infusion. The recommended subcutaneous dose is 0.2 to 0.4 g/kg bw per week. The weekly dose can be divided into smaller doses and administered by desired number of times per week. For dosing every two weeks, double the weekly Hizentra dose. If CIDP symptoms worsen on 0.4 g/kg bw per week, re-initiating therapy with IVIg should be considered, while discontinuing HIZENTRA. **Method of administration:** Hizentra must be administered via subcutaneous route only, using an infusion device or by manual push with syringe. ***Infusion rate:*** Should not exceed 20 ml/hour/site.If well-tolerated, gradually increase to 35 ml/hour/site for the following two infusions. Thereafter, the infusion rate can be further increased as per patient`s tolerability. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients Hyperprolinaemia type I and II and it is extremely rare. **Warnings and precautions for use:** ***Route of administration-*** If Hizentra is accidentally administered into a blood vessel, patients could develop shock. ***Hypersensitivity / Anaphylaxis:*** True allergic reactions are rare. They can particularly occur in patients with anti-IgA antibodies who should be treated with particular caution. Thromboembolism: Arterial and venousthromboembolic eventssuch asmyocardial infarction,stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. Particular caution should be exercised in patients with pre-existing risk factors for thrombotic events. Patients should be informed about first symptoms of thromboembolic events and sufficiently hydrated before use of immunoglobulins. ***Aseptic Meningitis Syndrome (AMS):*** AMS cases have occurred with use ofintravenous orsubcutaneousimmunoglobulin. Patients exhibiting signs and symptoms of AMS should receive a thorough neurological examination. Discontinuation of immunoglobulin treatment may result in remission of AMS within several days without sequelae. ***Information on safety with respect to transmissible agents:*** Hizentra is made from human plasma. The possibility of transmitting infective agents cannot be totally excluded. **Interactions:** ***Live attenuated virus vaccines:*** After administration of Hizentra, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, up to a year. Patients receiving measles vaccine should have their antibody status checked. ***Interference with serological testing:*** After infusion of IgG, the transitory rise of the various passively transferred antibodies in patient's blood may lead to misinterpretation of the results of serological testing. **Fertility, pregnancy and lactation:** ***Pregnancy:*** Hizentra should only be given with caution to pregnant women and breast-feeding mothers. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus or the neonate are to be expected. Continued treatment of the pregnant woman is important to ensure that the neonate is born with appropriate passive immunity. ***Lactation:*** Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate. ***Fertility:*** Based on clinical experience with IgG it is suggested that no harmful effects on fertility are to be expected. **Effects on ability to drive and use machines:** No adverse effect. I**ncompatibilities:** This medicinal product must not be mixed with other medicinal products. **Shelf life and special precautions for storage:** Do not store above 25 °C. Do not freeze. Keep the vial in the outer carton to protect from light. Hizentra should be administered as soon as possible after opening the vial. Hizentra comes as a ready-to-use solution in single-use vials. The medicinal product should be at room or body temperature before use. The solution should be clear and pale-yellow or light brown. Do not use if the solution is cloudy or has particulate matter. **Date of revision:** July 2022

Reference: Malaysia approved Hizentra Prescibing Information, July 2022.

MAL-HIZ-0021 Date of Preparation: June 2023

CSL Behring

CSL Behring

Manual Infusi Kendiri Hizentra™

Buku ini hanya untuk pesakit yang diberi preskripsi HIZENTRA™ oleh pegawai kesihatan sahaja.
Tolong jangan dipamerkan di kawasan awam.

Selamat Datang ke Rawatan Hizentra™

Penjaga Kesihatan Profesional telah memberikan anda preskripsi Hizentra™.

Anda dan penjaga kesihatan profesional anda telah membuat keputusan penting untuk memulakan rawatan menggunakan Hizentra™. Hizentra™ ialah terapi imunoglobulin subkutaneus 20% yang diluluskan untuk rawatan penyakit imunodefisiensi primer. Penjaga kesihatan profesional akan memastikan anda menerima arahan dan latihan terperinci tentang cara menggunakan Hizentra™. Ia termasuk dos dan kekerapan pengambilan Hizentra™, serta cara mengambilnya. Sebaik sahaja anda dan penjaga kesihatan profesional anda berasa selesa dengan pengambilan kendiri, anda mempunyai kebebasan dan fleksibiliti untuk melakukan terapi sendiri.

Kami mahu anda berasa selesa melakukan infusi agar anda kekal sihat. Kami mengesyorkan anda membaca semua maklumat dalam buku kecil ini, dan sentiasa memastikan ia dan Jurnal Rawatan Hizentra™ sentiasa ada bersama anda apabila anda melakukan terapi sendiri. Kami berharap melalui manual ini dan sokongan serta latihan yang disediakan oleh pembekal penjagaan kesihatan anda – dan sedikit latihan – akan meyakinkan anda bahawa Hizentra™ mudah diamalkan dalam kehidupan anda.

Nota: Buku kecil ini mengandungi maklumat yang menyokong infusi kendiri. Ia bukanlah pengganti nasihat atau latihan daripada penjaga kesihatan profesional. Jika anda mempunyai soalan tentang infusi pada bila-bila masa semasa rawatan anda, sila hubungi penjaga kesihatan profesional anda.

Maklumat Keselamatan Penting

AMARAN:

Trombosis (pembekuan darah) boleh berlaku daripada penggunaan produk globulin imun, termasuk Hizentra™. Faktor risiko boleh termasuk: usia lanjut, penggunaan estrogen, kateter vaskular di kediaman, sejarah penyakit saluran darah atau darah beku, faktor risiko kardiovaskular (termasuk sejarah aterosklerosis dan/atau gangguan output jantung), kecenderungan pembekuan darah yang diperoleh atau diwarisi, tempoh imobilisasi yang berpanjangan, volum darah rendah yang teruk, dan penyakit yang meningkatkan kelikatan darah.

Jika anda berisiko tinggi mengalami trombosis, doktor akan memantau anda untuk melihat tanda-tanda trombosis dan hiperviskositi. Gejala pertama tromboembolik termasuk sesak nafas, sakit dada, sakit dan bengkak anggota badan, dan defisit neurologi fokus. Hubungi penjaga kesihatan profesional dengan segera jika mana-mana gejala tersebut berlaku. Sentiasa pastikan anda cukup terhidrat sebelum pengambilan.

Kes Sindrom Meningitis Aseptik (AMS) pernah berlaku akibat penggunaan intravena atau imunoglobulin subkutaneus. Sindrom ini biasanya bermula antara beberapa jam hingga 2 hari selepas rawatan imun globulin. AMS dicirikan oleh tanda dan gejala berikut: sakit kepala yang teruk, kaku leher, mengantuk, demam, fotofobia, loya dan muntah. Hubungi penjaga kesihatan profesional dengan segera jika berlaku mana-mana gejala.

Maklumat Penting Keselamatan

Jangan gunakan Hizentra™ jika anda:

- alah kepada produk imunoglobulin manusia.
- mempunyai terlalu banyak prolin dalam darah anda (hiperprolinemia).
- sebelum ini pernah bertindak balas terhadap sebarang ramuan dalam Hizentra™.

Jika anda tidak pasti sama ada anda perlu menggunakan Hizentra™ berbincanglah dengan doktor anda.

KESAN SAMPINGAN:

Kesan sampingan Hizentra™ termasuk menggigil, sakit kepala, demam, muntah, tindak balas alahan, loya, sakit sendi, tekanan darah rendah dan sakit pinggang yang sederhana. Beritahu penjaga kesihatan profesional jika anda mengalami sebarang kesan sampingan yang membimbangkan anda. Jika kesan sampingannya teruk, dapatkan rawatan dengan segera.

Untuk maklumat lanjut tentang keadaan perubatan atau rawatan anda, sila hubungi penjaga kesihatan profesional anda.

PENTING Baca Sebelum Melakukan Infusi

Ketika melakukan infusi

- Pastikan anda mempunyai masa yang cukup untuk melengkapkan infusi sebelum bermula.
- Jangan lakukan infusi jika anda berasa tidak sihat atau mempunyai jangkitan yang tidak dirawat.
- Jangan buka botol atau jarum Hizentra™ sehingga anda bersedia untuk menggunakannya.
- Jarum mesti sentiasa steril. Jika anda tersentuh jarum, buang dalam kotak barang tajam dan gunakan yang baru.
- Pilih tempat yang sesuai untuk melakukan infusi seperti permukaan kerja di dapur.
- Gunakan dulang infusi atau tuala steril untuk meletakkan kit infusi anda.

Jangan lupa tanggalkan label rekod bebuli

Sentiasa pastikan Jurnal Rawatan Hizentra™ ada bersama anda untuk merekod butiran infusi. Jangan lupa lekatkan label lekat sendiri daripada bebuli ke dalam diari anda setiap kali anda melakukan infusi.

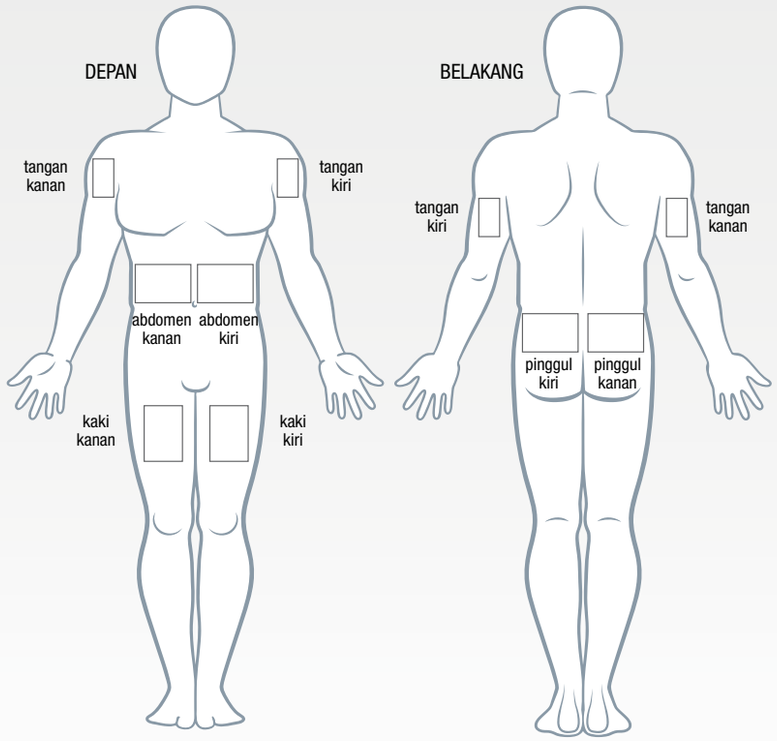
Menyimpan Hizentra™

- Hizentra™ dibekalkan dalam bebuli tunggal yang sedia untuk digunakan.
- Simpan bebuli pada suhu bawah atau sehingga 25°C. Jangan bekukan. Simpan bebuli di dalam kotak luarannya agar tidak terkena cahaya.
- Keluarkan Hizentra™ daripada peti sejuk sebelum melakukan infusi dan pastikan ia berada pada suhu bilik atau badan sebelum digunakan.
- Hizentra™ tidak mempunyai bahan pengawet. Sebaik sahaja bebuli dibuka, gunakan Hizentra™ dengan segera. Sekiranya anda menghentikan infusi sebelum ia selesai, adalah penting untuk membuang sebarang bebuli terbuka yang tidak digunakan.
- Jauhkan daripada dicapai dan dilihat oleh kanak-kanak.

Tentukan bahagian infusi

Ubah bahagian badan setiap kali anda melakukan infusi

Penting untuk mengubah bahagian yang diinfusi setiap kali anda melakukannya. Untuk membantu anda, rekodkan bahagian badan dalam diari dan gilirkannya setiap kali anda melakukan infusi.



- Kadar infusi awal yang disyorkan bergantung pada keperluan pesakit dan tidak boleh melebihi 15 ml/jam/bahagian. Jika diterima dengan baik, kadar infusi berikutnya boleh ditingkatkan secara beransur-ansur mengikut arahan penjaga kesihatan profesional.
- Jika dos yang besar diberikan (> 25 ml), lebih baik jika dos itu diberikan di beberapa bahagian. Sehingga 4 bahagian suntikan boleh dilakukan serentak. Lebih daripada satu peranti infusi boleh digunakan secara serentak. Volum produk yang diinfusi kepada bahagian tertentu boleh berbeza-beza.
- Jarak antara bahagian diinfusi hendaklah sekurang-kurangnya 5 cm.

Sekilas Pandang Kaedah Infusi Hizentra™

Tentang panduan ini

- Panduan infusi ini bertujuan membantu anda memahami setiap langkah dalam proses infusi. Ia berguna sebagai alat pengajaran apabila anda mula-mula mempelajari proses infusi dan juga berfungsi mengingatkan semula apabila anda berasa semakin selesa. Anda digalakkan untuk mengambil nota mengenai panduan ini sambil anda belajar dan berlatih.
- 11 langkah ini dibahagikan kepada 3 kumpulan untuk membantu anda memahami di mana kedudukan setiap langkah dalam proses keseluruhan:

Bersedia	Siapkan	Mula
1. Kumpul semua barang	5. Siapkan picagari	9. Mulakan infusi
2. Bersihkan permukaan	6. Siapkan alat infusi	10. Rekod infusi anda
3. Basuh tangan anda	7. Siapkan bahagian infusi	11. Selesaikan infusi dan bersihkan
4. Periksa setiap bebuli Hizentra™	8. Masukan jarum subkutaneous	

- Beberapa langkah adalah mudah manakala yang lain mungkin mengambil masa yang lebih lama – namun, semua langkah adalah penting dalam infusi anda dan perlu diikuti dengan berhati-hati.

Langkah 1.
Basuh tangan & kumpul kit infusi anda

Basuh tangan secara teliti dengan sabun dan gunakan tuala bersih untuk mengeringkannya

Amnya, anda perlukan:

Nota:
Bebuli hendaklah berada pada suhu bilik atau badan sebelum digunakan

- Bebuli Hizentra™
- Infusi Hizentra™ Diari dan pen
- Pam infusi
- Tiub infusi
- Dulang infusi atau tuala steril
- Jarum infusi (seperti diberitahu oleh Jururawat Pakar)
- Pengelap alkohol
- Pengelap kulit antiseptik
- Picagari
- Jarum pemindahan
- Kain kasa dan pita, atau pembalut lutsinar
- Bekas benda tajam
- Bekas sisa kertas
- Sarung tangan dan gel tangan alkohol (jika disyorkan oleh Jururawat Pakar)
- Spare battery for pump (if required)

Penafian: Semua gambar yang ditunjukkan adalah untuk tujuan ilustrasi sahaja. Produk sebenar mungkin berbeza disebabkan naik tarat produk.

Langkah 2.
Bersihkan permukaan

Bersihkan tempat infusi dengan teliti

- Bersihkan kawasan kerja secara teliti menggunakan pengelap pembasmi kuman pakai buang atau pembasmi kuman kegunaan isi rumah. Jika menggunakan dulang infusi bersihkan dengan sabun dan air, dan lap dengan pengelap antiseptik. Biarkan kering.

Langkah 3.
Basuh tangan anda

Basuh tangan anda sekali lagi

- Basuh tangan anda dengan teliti dan gunakan tuala bersih untuk mengeringkannya. Sebagai alternatif, anda boleh menggunakan gel tangan alkohol.
- Jika anda diberitahu untuk memakai sarung tangan semasa menyediakan infusi, pakainya sekarang.

Langkah 4.
Periksa setiap bebuli Hizentra™

Periksa setiap bebuli Hizentra™ dengan teliti

- Periksa dosnya betul pada setiap botol.
- Adakah anda mempunyai botol yang cukup untuk infusi?
- Adakah botol itu rosak?

Lihat cecair dalam setiap bebuli Hizentra™ dengan cermat

- Bebuli Hizentra™ adalah jernih dan warnanya boleh berubah daripada hampir tidak berwarna kepada kuning pucat/coklat muda.
- Periksa jika wujud zarah atau ada perubahan warna.

Jangan gunakan bebuli jika:

- Cecair kelihatan keruh, mengandungi zarah, atau telah berubah warna.
- Botol retak atau pecah.
- Penutup pelindung hilang.
- Tarikh luput pada label telah berlalu.

Langkah 5.
Siapkan picagari

Pastikan semua peralatan tersedia

- Pasang jarum pemindahan pada hujung picagari dan letakkan pada dulang infusi atau pada tuala steril.
  - Jika tersentuh jarum, gunakan jarum baru.
  - Jika tersentuh hujung picagari, gunakan picagari baru.
- Buka semua alat yang diperlukan untuk infusi dan letakkan pada dulang infusi atau tuala (kain kasa, jarum infusi), pengelap antiseptik.

Tanggalkan penutup pelindung pada bebuli

- Bersihkan penahan bebuli dengan pengelap alkohol;

Pindahkan udara ke bebuli Hizentra™

- Tarik pelocok picagari untuk mengisi udara.
  - Jumlah udara mesti sama dengan jumlah Hizentra™ yang akan anda pindahkan daripada bebuli.
  - Berhati-hati agar tidak menyentuh bahagian dalam pelocok untuk memastikan ia steril.
- Letak bebuli Hizentra™ pada permukaan rata.
- Pastikan bebuli tegak, masukkan jarum pemindahan ke bahagian tengah penahan getah.
- Pastikan hujung jarum tidak berada di dalam cecair.
- Tekan pelocok picagari ke bawah.
  - Ini akan menyuntik udara dari picagari ke dalam ruang udara bebuli.

Langkah 5.
Siapkan picagari (samb.)

Pindahkan Hizentra™ dari bebuli ke picagari

- Cucuk jarum pada penahan dan terbalikkan bebuli dengan berhati-hati.
- Tarik semula pelocok perlahan-lahan untuk mengisi picagari sambil memastikan jarum terendam sepanjang masa.
- Keluarkan picagari dan jarum yang telah diisi daripada penahan.
- Keluarkan udara dengan mengetuk picagari perlahan-lahan dan menolak cecair sehingga ke pangkal jarum.
- Tanggalkan jarum dengan berhati-hati dan buang dalam bekas barang tajam.
- Segera pasang pada tiub infusi sebaik sahaja anda membuang jarum.
- Ulang untuk berbilang picagari (jika sesuai).

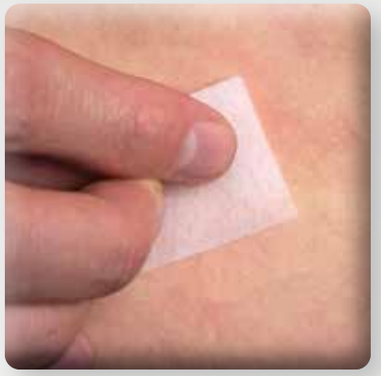
Langkah 6.
Sediakan peralatan infusi

Sediakan pam infusi mengikut arahan pengilang dan pasangkan (isi) tiub infusi

- Untuk menghidupkan tiub, sambung picagari yang diisi dengan Hizentra™ ke tiub pemberian.
- Keluarkan udara dalam tiub dengan menolak perlahan-lahan pelocok picagari untuk mengisi tiub dengan Hizentra™ (atau ikut arahan pengeluar pam).
- Jangan biarkan ubat sampai ke hujung jarum.

Langkah 7.
Siapkan bahagian infusi

Pilih bahagian untuk infusi

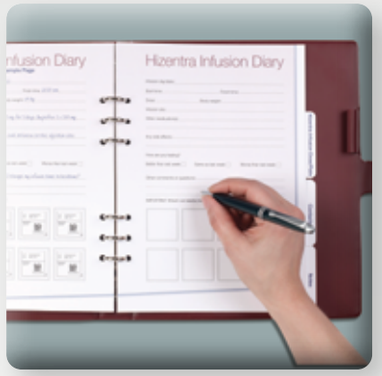


- Gunakan bahagian yang berbeza daripada kali terakhir anda menginfusi Hizentra™.
  - Penjaga kesihatan profesional anda akan memberitahu berapa banyak bahagian infusi (iaitu, bahagian jarum dimasukkan) yang perlu anda gunakan dan berapa banyak Hizentra™ untuk diinfusi di setiap bahagian.
  - Bahagian baru hendaklah sekurang-kurangnya 5 cm dari bahagian sebelumnya.
  - Jangan sekali-kali melakukan infusi pada bahagian yang kulitnya lembut, lebam, merah atau keras.
  - Elakkan urat kecil yang kelihatan pada permukaan kulit.
  - Elakkan melakukan infuse pada parut atau kesan calar.
- Bersihkan kulit pada setiap bahagian dengan pengelap antiseptik dan biarkannya kering.

Langkah 10.
Rekod maklumat infusi

Catat setiap infusi dalam Jurnal Rawatan Hizentra™ anda

- Buka bahagian label yang boleh ditanggalkan daripada bebuli Hizentra™.
- Tampal label dalam Jurnal Rawatan Hizentra™ anda dengan tarikh dan masa infusi.
- Sertakan juga jumlah tepat Hizentra™ yang anda masukkan dan lengkapkan semua bahagian.
- Jangan lupa untuk membawa Jurnal Rawatan Hizentra™ bersama anda ke semua temu janji klinik.



Langkah 11.
Complete the infusion and clean up

Apabila semua Hizentra™ telah diinfusi

- Matikan pam infusi.
- Tanggalkan balutan dan keluarkan jarum dari bahagian infusi.
- Tutup bahagian infusi pada kulit anda dengan kain kasa, pita atau plaster.
- Buang jarum, tiub infusi dan botol ke dalam bekas benda tajam.
- Bersihkan dan simpan pam infusi mengikut arahan pengilang.
- Bersihkan kawasan infusi dengan pengelap pembasmi kuman.
- Basuh dan keringkan tangan anda dengan teliti.

Nota

Nota

Please refer to approved full prescribing information before use

Abridged Prescribing Information

Hizentra 200 mg/ml solution for subcutaneous injection. **Therapeutic Indications:** Replacement therapy in adults and children in primary immunodeficiency (PID) syndromes such as congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiency and Wiskott-Aldrich syndrome. Replacement therapy in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections. Treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilization with intravenously administered immunoglobulins (IVIg). **Posology:** ***Adults and children: Replacement therapy:*** A loading dose of at least 0.2 to 0.5 g/kg (1.0 to 2.5 ml/kg) body weight to be divided over several days. After steady state IgG levels have been attained, maintenance doses are divided into smaller doses and administered at repeated intervals to reach a cumulative monthly dose in the order of 0.4 to 0.8 g/kg (2.0 to 4.0 ml/kg) body weight. For patients switching from intravenous treatment the monthly dose is divided into smaller doses and administered at repeated intervals. ***Immunomodulatory therapy in CIDP patients:*** Initiate Hizentra therapy 1 week after the last IVIg infusion. The recommended subcutaneous dose is 0.2 to 0.4 g/kg bw per week. The weekly dose can be divided into smaller doses and administered by desired number of times per week. For dosing every two weeks, double the weekly Hizentra dose. If CIDP symptoms worsen on 0.4 g/kg bw per week, re-initiating therapy with IVIg should be considered, while discontinuing HIZENTRA. **Method of administration:** Hizentra must be administered via subcutaneous route only, using an infusion device or by manual push with syringe. ***Infusion rate:*** Should not exceed 20 ml/hour/site.If well-tolerated, gradually increase to 35 ml/hour/site for the following two infusions. Thereafter, the infusion rate can be further increased as per patient`s tolerability. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients Hyperprolinaemia type I and II and it is extremely rare. **Warnings and precautions for use:** ***Route of administration-*** If Hizentra is accidentally administered into a blood vessel, patients could develop shock. ***Hypersensitivity / Anaphylaxis:*** True allergic reactions are rare. They can particularly occur in patients with anti-IgA antibodies who should be treated with particular caution. Thromboembolism: Arterial and venousthromboembolic eventssuch asmyocardial infarction,stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. Particular caution should be exercised in patients with pre-existing risk factors for thrombotic events. Patients should be informed about first symptoms of thromboembolic events and sufficiently hydrated before use of immunoglobulins. ***Aseptic Meningitis Syndrome (AMS):*** AMS cases have occurred with use ofintravenous orsubcutaneousimmunoglobulin. Patients exhibiting signs and symptoms of AMS should receive a thorough neurological examination. Discontinuation of immunoglobulin treatment may result in remission of AMS within several days without sequelae. ***Information on safety with respect to transmissible agents:*** Hizentra is made from human plasma. The possibility of transmitting infective agents cannot be totally excluded. **Interactions:** ***Live attenuated virus vaccines:*** After administration of Hizentra, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, up to a year. Patients receiving measles vaccine should have their antibody status checked. ***Interference with serological testing:*** After infusion of IgG, the transitory rise of the various passively transferred antibodies in patient's blood may lead to misinterpretation of the results of serological testing. **Fertility, pregnancy and lactation:** ***Pregnancy:*** Hizentra should only be given with caution to pregnant women and breast-feeding mothers. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus or the neonate are to be expected. Continued treatment of the pregnant woman is important to ensure that the neonate is born with appropriate passive immunity. ***Lactation:*** Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate. ***Fertility:*** Based on clinical experience with IgG it is suggested that no harmful effects on fertility are to be expected. **Effects on ability to drive and use machines:** No adverse effect. I**ncompatibilities:** This medicinal product must not be mixed with other medicinal products. **Shelf life and special precautions for storage:** Do not store above 25 °C. Do not freeze. Keep the vial in the outer carton to protect from light. Hizentra should be administered as soon as possible after opening the vial. Hizentra comes as a ready-to-use solution in single-use vials. The medicinal product should be at room or body temperature before use. The solution should be clear and pale-yellow or light brown. Do not use if the solution is cloudy or has particulate matter. **Date of revision:** July 2022

Reference: Malaysia approved Hizentra Prescibing Information, July 2022.

MAL-HIZ-0021 Date of Preparation: June 2023

CSL Behring

CSL Behring

Hizentra™

自行注射操作手册

此手册仅由专业医疗保健人员提供予注射 HIZENTRA™ 药物的患者。
请勿展示于公共区域.

欢迎使用Hizentra™进行治疗

您的医疗专家已规定您使用Hizentra™。

您和您的医疗专家已经做出了开始使用Hizentra™ 治疗的重要决定。Hizentra™是一种经批准用于治疗原发性免疫缺陷疾病的免疫球蛋白皮下注射液20%。此外，您的医疗专家将确保您收到有关如何使用Hizentra™的详细说明和培训，其中包括剂量和您所需Hizentra™的次数以及如何管理。一旦您和您的医疗专家对自行注射感到满意，您就可以自由和弹性化的进行自行注射治疗。

我们希望您对输液感到舒适，以让您可以保持健康。我们建议您熟知这本小册子中的所有信息，并在进行治疗时随身携带，同时包括您的Hizentra™治疗日志。我们希望通过此手册以及您的医疗专家所提供的支持与培训以及练习。届时，您会发现Hizentra™ 将很轻易地融入您的生活。

备注：本手册提供支持您自行输液的信息，惟不能取代您的医疗专家的建议或培训。如果您在治疗期间的任何时候对输液有任何疑问，请联系您的医疗专家。

重要的安全信息

警告:

免疫球蛋白产品(包括Hizentra™)可能会导致血栓形成(血液凝固)。风险因素可能包括高龄、使用雌激素、留置血管导管、血管疾病或血栓发作史、心血管风险因素{包括动脉粥样硬化病史和/或心输出量受损)、获得性或遗传性血栓倾向、长时间制动、严重低血容量和增加血液粘度的疾病。

如果您有血栓形成的高风险，您的医生会监测您是否有血栓形成和高粘血症的迹象。　血栓栓塞事件的最初症状包括气短、胸痛、四肢疼痛和肿胀以及局灶性神经功能缺损。如果出现任何症状，请立即联系您的医疗专家。在给药前，须时刻确保您拥有充足的水分。

使用静脉内或皮下免疫球蛋白时，会发生无菌性脑膜炎综合征(AMS)病例。该综合征通常在免疫球蛋白治疗后数小时至2天内开始，AMS的特征包括以下迹象和症状，其中有严重的头痛、颈部僵硬、嗜睡、发烧、畏光、恶心以及呕吐。若出现任何症状，请立即联系您的医疗专家。

重要的安全信息

如果您有以下情况, 请勿使用Hizentra™:

- 对人类免疫球蛋白产品过敏。
- 血液中的脯氨酸过多 (高脯氨酸血症) 。
- 曾经对Hizentra™ 中的任何成分有反应。

如果您不确定是否应该使用Hizentra™, 请咨询您的医生。

副作用:

Hizentra™副作用包括寒颤、头痛、发烧、呕吐、过敏反应、恶心、关节痛、低血压和中度腰痛。如果您遇到任何与您有关的副作用, 请告诉您的医疗专家。若副作用严重, 请立即就医。有关您的健康状况或治疗的更多信息, 请联系您的医疗专家。

输注前重点须知

输注时

- 确保您有足够的时间在开始之前完成输液。
- 如果您感觉不适或有未经治疗的感染, 请勿输注。
- 在您准备好之前勿打开Hizentra™ 药瓶或针头。
- 针头必须保持无菌状态。如果您误触, 请丢弃在利器弃置器中并使用新的。
- 为您的输液选择一个合适的区域, 例如: 厨房台面。
- 使用输液盘或无菌毛巾摆放您的输液套件。

记得取下药瓶记录标签

随时准备好Hizentra™ 治疗日志, 以记录输液的详细信息。每次输注时, 请记住将药瓶中的不干胶标签贴到日志中。

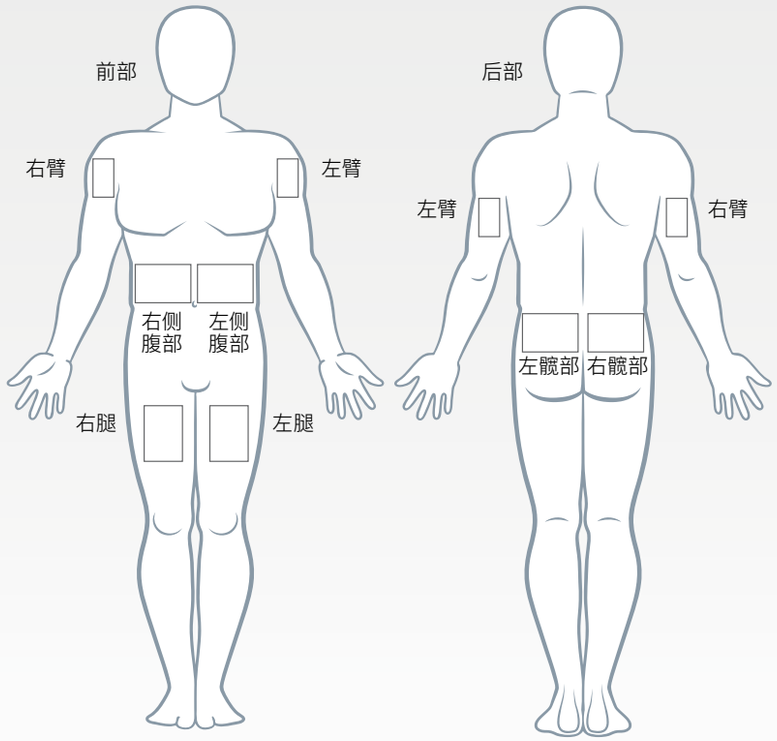
存储您的Hizentra™

- Hizentra™ 以单个即用药瓶的形式提供。
- 将药瓶存放在低于或最高 25°C 的温度下。请勿冷冻, 并将药瓶放在纸盒中以避光。
- 输液前从冰箱中取出Hizentra™, 并确保在使用前处于一般室温温度。
- Hizentra™ 不含防腐剂, 打开药瓶后须立即使用Hizentra™ 是很重要的。如果您在输液完成前停止输液, 任何已打开而未使用的药瓶必须丢掉。
- 远离孩子可以触及的地方。

决定输液部位

每次改变部位输注

每次输液时，轮换输液部位是很重要的。为了帮助您做到这一点，只需在您的日志中记录身体部位，并在每次输液时轮换部位。



- 推荐最开始输注速度取决于患者的个人需求，不应超过15毫升/小时/部位。如果耐受性良好，则可以根据您的医疗专家的指示逐渐提高输注的速度。
- 如果给予大剂量(> 25 ml)，建议在多个部位给药。最多可同时使用4个注射部位，并同时可以使用多个输液装置。惟注入特定部位的剂量则有可能会不同。
- 输液部位应至少相距5厘米。

您的Hizentra™ 输液方案概览

关于此手册

- 本输液手册旨在帮助您完成输液过程的每一步，当您第一次学习输液过程时，即可作为一种很有帮助的教学工具，当您得心应手时，也可以当作复习。因此，鼓励您在学习和练习时，可将此手册作为笔记。
- 11个步骤中的每一个都分为3个部分，以帮助您了解每个步骤在整个过程中的位置。

准备前	设置好	开始
1. 收集你的用品	5. 准备注射器	9. 开始输液
2. 清洁表面	6. 准备输液设备	10.记录您的输液
3. 消毒双手	7. 准备输液部位	11. 完成输液和清理
4. 检查每一瓶 Hizentra™	8. 插入皮下针	

- 一些步骤很简单，而其他步骤或许需要更多时间。然而都是输液的重要部分，因此应小心进行。

步骤 1.
洗手并聚集您的输液器

用肥皂彻底洗净双手，并用干净的毛巾擦干。

您通常将需要:

- Hizentra™ 药瓶
- Hizentra™ 输液日志本和笔
- 输液泵
- 输液管
- 输液盘或无菌毛巾
- 输液针(由您的专科医生指导)
- 酒精湿纸巾
- 抗菌皮肤湿纸巾
- 注射器
- 接种针
- 纱布和胶带或透明贴
- 利器弃置器
- 废纸弃置器
- 手套和酒精洗手凝胶(若您专科医生建议)
- 泵用备用电池(若需要)

备注:

药瓶使用前应处于室温或体温温度。

免责声明: 图片仅供参考产品包装内以实物为准.

步骤 2.
清洁台面

彻底清洁您的输液区域

- 使用一次性消毒湿纸巾或家用消毒剂彻底清洁您的操作区域。若使用输液盘，那请用肥皂和水彻底清洁，然后用消毒湿纸巾擦拭并晾干。

步骤 3.
清洗双手

再次清洗双手

- 您可以彻底清洗双手并用干净毛巾擦干，也可以使用酒精洗手凝胶。
- 若您在准备输液时被告知要戴手套，请立即戴上手套。

步骤 4.
检查每一瓶Hizentra™

仔细检查每一瓶Hizentra™

- 检查每瓶的剂量是否正确。
- 您是否有足够的瓶子用于输液?
- 瓶子是否损坏?

若出现以下情况, 请勿使用药瓶:

- 液体看起来混浊、含有颗粒或颜色有变化。
- 瓶子破裂或破损。
- 缺少保护盖。
- 已超过标签上的有效期限。

步骤 5.
准备注射器

准备注射器

- 确保物资准备就绪
- 将接种针连接到注射器尖端并放在输液盘或无菌毛巾上。
  - 如果您不小心接触到针, 请使用新针。
  - 如果您误触注射器尖端, 请使用新注射器。
- 打开输液所需的其他物品并放在输液盘或毛巾上 (纱布、输液针及消毒湿纸巾) 。

从药瓶上取下保护盖

- 用酒精湿纸巾清洁药瓶塞并晾干。

将空气抽进Hizentra™药瓶中

- 拉出注射器柱塞使其充满空气。
  - 空气量应与您从药瓶中转移的Hizentra™ 的体积相同。
  - 注意勿触摸柱塞的内部以确保无菌。
- 将Hizentra™ 药瓶放在平面上。
- 保持药瓶直立, 将接种针插入橡胶塞的中心。
- 检查针尖是否不在液体中。
- 将注射器上的柱塞往下推。
  - 这会将注射器中的空气注入药瓶的空气空间。

步骤 5.
准备注射器(续)

将Hizentra™从橡胶瓶塞转移到注射器

- 将针头留在塞子中, 并小心地将药瓶倒置。
- 缓慢向后拉柱塞以填入注射器, 同时针头始终保持在液体内。
- 将填充完成的注射器和针头从瓶塞中取出。
- 轻轻敲击注射器并将液体向上推至针头底部以排出空气。
- 小心取下针头并丢弃在利器弃置器中。
- 丢弃针头后立即连接到输液管上。
- 注射器可以重复使用。(若需要)

步骤 6.
准备输液设备

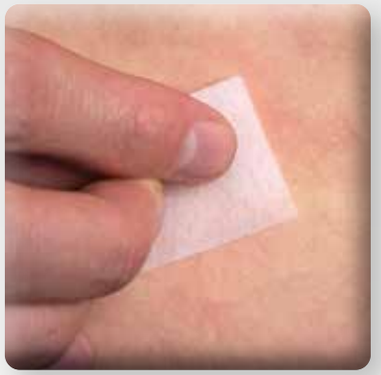
依照制造商的说明准备输液泵并灌注(注满)输液管。

- 要灌注管子, 将装有Hizentra™ 的注射器连接到给药管子。
- 轻轻推动注射器柱塞以排出管中的空气, 并用Hizentra™ 注满管子 (或按照泵制造商的说明指示) 。
- 勿让药物达到针尖。

步骤 7.
准备输液部位

选择输液部位

- 使用与上次注入Hizentra™ 时不同的位置。
  - 您的医疗专家会告诉您需要使用多少个输液部位 (即插入针头的部位) 以及在每个位置注入多少Hizentra™ 。
  - 注入新的位置时需于先前注入的位置至少5cm (厘米) 的距离。
  - 切勿注入娇嫩的皮肤、瘀伤、发红或发硬的部位。
  - 避免注入在皮肤表面可见的小静脉。
  - 避免注入在疤痕或伤痕处。
- 用消毒湿纸巾清洁每个部位的皮肤并晾干。



步骤 8.
针插入皮下注射

- 您所使用的输液针的类型或有所不同，因此插入注射时须依照医疗专家的指示。

插入针头

- 用两根手指捏住注射部位周围的皮肤。
- 以45˚至 90˚的角度将针头插入皮下组织按照医疗专家的指示以及所使用的针头类型而决定。请注意在插入之前勿接触针头，若有污染则需丢弃。
- 若有需要，请用无菌棉或纱布支撑针头，并用两条十字形微孔胶带固定针头，以增加安全性。
- 若注射两个或更多部位，请重复此步骤，直到所有针都插入。

确保您没有将Hizentra™ 注入血管

- Hizentra™ 只能皮下注射使用(皮肤表层下)。
- 在测试时，轻轻的把注射器的柱塞往下拉。
- 如果您看到管子中有血迹，请将针头从输液部位取出，并从注射器中取出管子后丢弃在利器弃置器中。
- 将新针头和管子连接并灌注(注满)到注射器上，然后将针头插入不同的部位，并再次检查您没有注入血管。
- 如果有多个注射部位，则对插入的每一针重复此动作。

步骤 9.
开始输注

您可开始输液

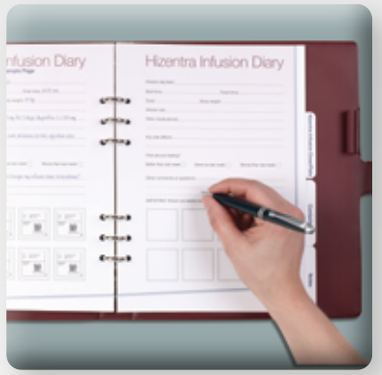
- 将注射器插入输液泵。
- 设置输注速度 (若需要) 。
  – 您的医疗专家会告诉您Hizentra™ 输液所使用的速度。
- 打开输液泵。

图片仅供参考。
输液泵型号可能与您所在国家/地区提供的都有区别。

步骤 10.
记录输注信息

在您的Hizentra™ 治疗日志中记录每次输注

- 从Hizentra™ 药瓶上撕下标签可拆除的部分。
- 在您的Hizentra™ 治疗日志贴上标签以及填上输注日期和时间。
- 同時也包括記錄您完成所有Hizentra™ 輸注的準確數量。
- 预约门诊时，请记得带上您的Hizentra™ 治疗日志。



步骤 11.
完成输注和清理

当所有Hizentra™ 都已注入。

- 关闭输液泵。
- 取下纱布并将针头从输液部位取出。
- 用纱布、胶带或胶布遮盖皮肤上的输液部位。
- 将针头、输液管和瓶子丢弃在利器弃置器中。
- 按照制造商的说明清洁和存放输液泵。
- 用消毒湿纸巾清洁输液部位。
- 彻底洗净双手并擦干。

备注

备注

Please refer to approved full prescribing information before use

Abridged Prescribing Information

Hizentra 200 mg/ml solution for subcutaneous injection. **Therapeutic Indications:** Replacement therapy in adults and children in primary immunodeficiency (PID) syndromes such as congenital agammaglobulinaemia and hypogammaglobulinaemia, common variable immunodeficiency, severe combined immunodeficiency and Wiskott-Aldrich syndrome. Replacement therapy in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections. Treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilization with intravenously administered immunoglobulins (IVIg). **Posology:** ***Adults and children: Replacement therapy:*** A loading dose of at least 0.2 to 0.5 g/kg (1.0 to 2.5 ml/kg) body weight to be divided over several days. After steady state IgG levels have been attained, maintenance doses are divided into smaller doses and administered at repeated intervals to reach a cumulative monthly dose in the order of 0.4 to 0.8 g/kg (2.0 to 4.0 ml/kg) body weight. For patients switching from intravenous treatment the monthly dose is divided into smaller doses and administered at repeated intervals. ***Immunomodulatory therapy in CIDP patients:*** Initiate Hizentra therapy 1 week after the last IVIg infusion. The recommended subcutaneous dose is 0.2 to 0.4 g/kg bw per week. The weekly dose can be divided into smaller doses and administered by desired number of times per week. For dosing every two weeks, double the weekly Hizentra dose. If CIDP symptoms worsen on 0.4 g/kg bw per week, re-initiating therapy with IVIg should be considered, while discontinuing HIZENTRA. **Method of administration:** Hizentra must be administered via subcutaneous route only, using an infusion device or by manual push with syringe. ***Infusion rate:*** Should not exceed 20 ml/hour/site.If well-tolerated, gradually increase to 35 ml/hour/site for the following two infusions. Thereafter, the infusion rate can be further increased as per patient`s tolerability. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients Hyperprolinaemia type I and II and it is extremely rare. **Warnings and precautions for use:** ***Route of administration-*** If Hizentra is accidentally administered into a blood vessel, patients could develop shock. ***Hypersensitivity / Anaphylaxis:*** True allergic reactions are rare. They can particularly occur in patients with anti-IgA antibodies who should be treated with particular caution. Thromboembolism: Arterial and venousthromboembolic eventssuch asmyocardial infarction,stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. Particular caution should be exercised in patients with pre-existing risk factors for thrombotic events. Patients should be informed about first symptoms of thromboembolic events and sufficiently hydrated before use of immunoglobulins. ***Aseptic Meningitis Syndrome (AMS):*** AMS cases have occurred with use ofintravenous orsubcutaneousimmunoglobulin. Patients exhibiting signs and symptoms of AMS should receive a thorough neurological examination. Discontinuation of immunoglobulin treatment may result in remission of AMS within several days without sequelae. ***Information on safety with respect to transmissible agents:*** Hizentra is made from human plasma. The possibility of transmitting infective agents cannot be totally excluded. **Interactions:** ***Live attenuated virus vaccines:*** After administration of Hizentra, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, up to a year. Patients receiving measles vaccine should have their antibody status checked. ***Interference with serological testing:*** After infusion of IgG, the transitory rise of the various passively transferred antibodies in patient's blood may lead to misinterpretation of the results of serological testing. **Fertility, pregnancy and lactation:** ***Pregnancy:*** Hizentra should only be given with caution to pregnant women and breast-feeding mothers. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus or the neonate are to be expected. Continued treatment of the pregnant woman is important to ensure that the neonate is born with appropriate passive immunity. ***Lactation:*** Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate. ***Fertility:*** Based on clinical experience with IgG it is suggested that no harmful effects on fertility are to be expected. **Effects on ability to drive and use machines:** No adverse effect. I**ncompatibilities:** This medicinal product must not be mixed with other medicinal products. **Shelf life and special precautions for storage:** Do not store above 25 °C. Do not freeze. Keep the vial in the outer carton to protect from light. Hizentra should be administered as soon as possible after opening the vial. Hizentra comes as a ready-to-use solution in single-use vials. The medicinal product should be at room or body temperature before use. The solution should be clear and pale-yellow or light brown. Do not use if the solution is cloudy or has particulate matter. **Date of revision:** July 2022

Reference: Malaysia approved Hizentra Prescibing Information, July 2022.

MAL-HIZ-0021 Date of Preparation: June 2023

CSL Behring