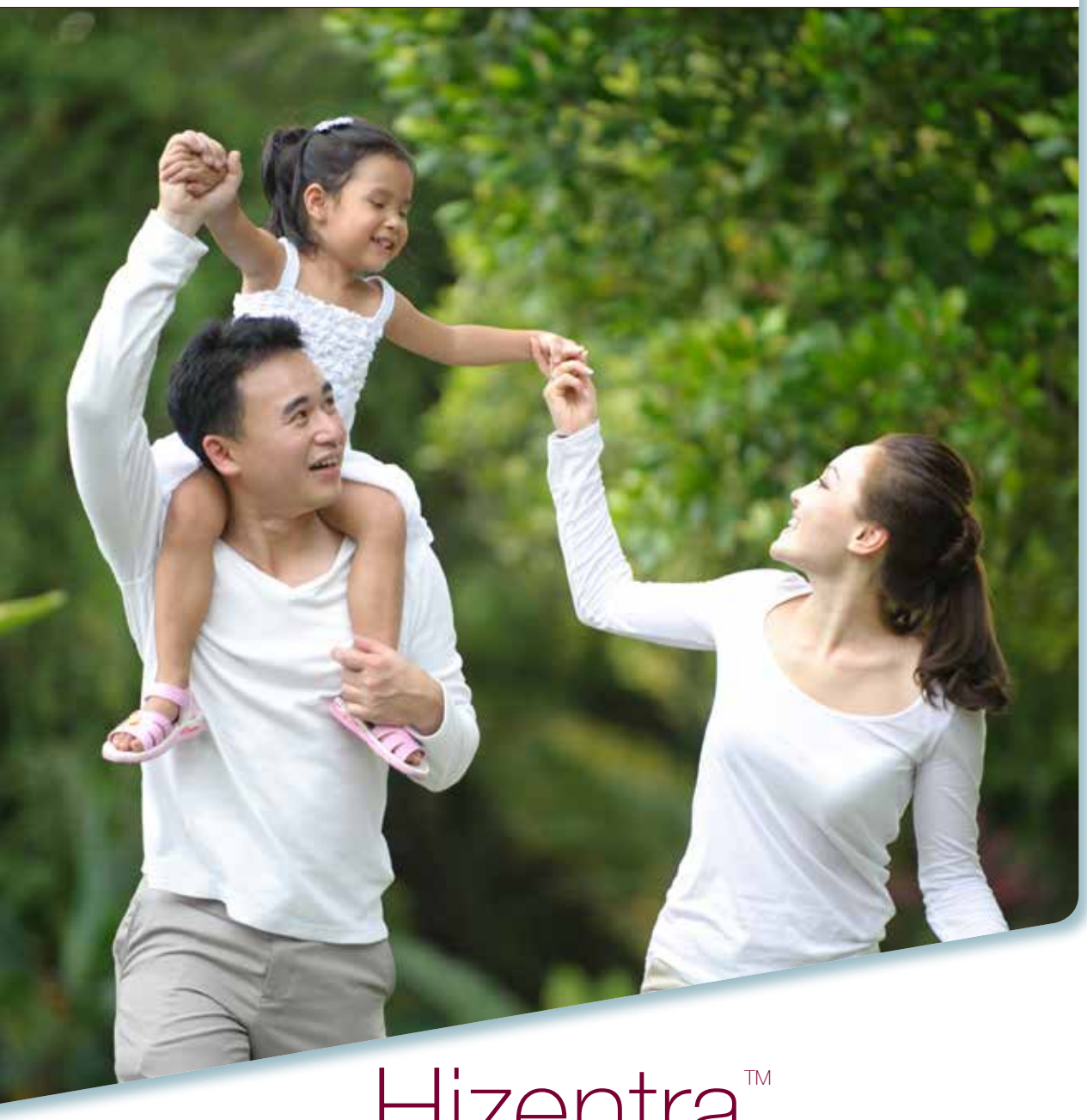
CSL Behring



Hizentra™ Troubleshooting Guide

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

Hizentra™ Troubleshooting Guide

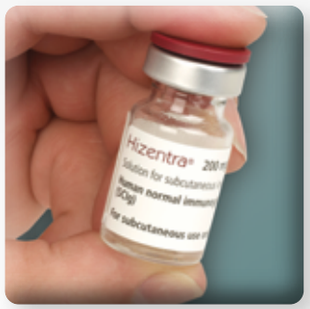
The Hizentra™ Troubleshooting Guide aims to address some issues that may arise during treatment and how they can be managed. The information in this guide does not supercede your healthcare professional's advice.

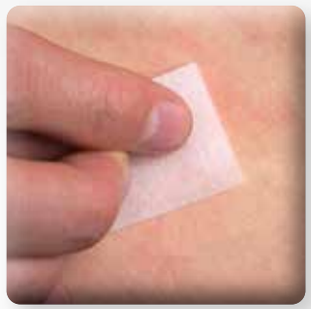
This guide is divided into 3 sections as below:

Product related issues

Infusion related issues

Adverse events related issues





Product related issues

Issue	Management
The solution in the vial is not clear. It is also not pale-yellow to light-brown.	Do not use the product. Contact CSL Behring Customer Service to return unopened vial.
The solution the vial appears cloudy, or contains particulate matters.	Do not use the product. Contact CSL Behring Customer Service to return unopened vial.
Rubber stopper of the vial was pierced in preparation for infusion, but was unable to receive the infusion that day.	Hizentra™ does not contain any preservative and must be used right after opening the vial. Use in one patient on one occasion only. Any unused solution should be discarded appropriately.
What do I do if Hizentra™ is accidentally frozen?	Do not use the product.
Hizentra™ was stored below 2°C.	Contact CSL Behring Customer Service.
Hizentra™ was stored above 25°C.	Contact CSL Behring Customer Service.
Can I refrigerate (2° to 8°C) Hizentra™?	Yes, you can refrigerate Hizentra™. Keep vial in the outer carton in order to protect from light during storage.
Can I store Hizentra™ in the refrigerator and then at room temperature (<25°C) and then put it back in the refrigerator again?	Contact CSL Behring CustomerService.

Infusion related issues

Issue	Management
Blood appears in infusion tubing.	The needle has accidentally hit a blood vessel. Hizentra™ must not be administered intravenously. Remove needle and discard needle and tubing. Start infusion at different infusion site with new needle and tubing.
Leaking at infusion site.	Needle may not be fixed securely or inserted correctly, or Infusion rate may be too high. Use appropriate needle length and fix it securely. Use appropriate infusion rate. Consider another infusion site with more subcutaneous tissue.
Discomfort from needle.	Needle length may be too long. Use appropriate needle length. Consider applying cold pack or topical anesthetic cream prior to needle insertion.
Infusion taking longer than expected.	Infusion rate may be set incorrectly, or incorrect tubing size was used, or the pump may not be working correctly. Check infusion rate, pump battery and change infusion site. Contact CSL Behring Customer Service if issue is not resolved.
Problem with infusion pump.	Check that pump is operating according to manufacturer's specifications. Use recommended supplies to ensure accuracy and rate delivery. Do not override occlusion alarm. Check for occlusions and that all clamps are in the open position.

Adverse events related issues

Issue	Management
During infusions some local injection site reactions like redness, swelling and itching may occur.	Injection site reactions are very common. Usually these are mild in severity and decreases over time. Small amounts of the medication in the upper skin layers can cause site reactions such as redness and itching. When priming the subcutaneous needle, do not allow drops of the medication to cover needle tip. The local site reaction may also be due to the skin reacting to the tape used to secure the needle and infusion tubing. Switch to hypoallergenic tape. If site reactions gets worse, report this to your healthcare professional as soon as possible.
Severe hypersensitivity/anaphylactic reaction is encountered.	Stop Hizentra™ and inform your healthcare professional immediately.
Symptoms like severe headache, neck stiffness, drowsiness, fever, photophobia, nausea and/or vomiting is encountered.	Stop Hizentra™ and inform your healthcare professional immediately.
History of thromboembolic events.	Be sufficiently hydrated before use of immunoglobulins. Hizentra™ should be administered subcutaneously at the minimum rate of infusion.
Overdose.	Consequences of an overdose are not known. Monitor closely for the occurrence of adverse drug reactions. Call your healthcare professional as soon as possible.

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-0022 Date of Preparation: June 2023

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Panduan Penyelesaian Masalah Hizentra™

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

Panduan Penyelesaian Masalah Hizentra™

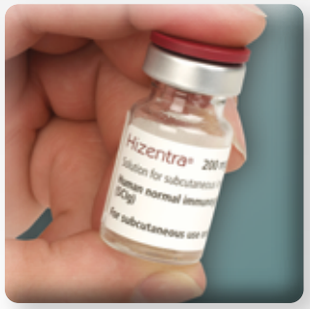
Panduan Penyelesaian Masalah Hizentra™ bertujuan menangani beberapa isu yang mungkin timbul semasa rawatan dan cara menguruskannya. Maklumat dalam panduan ini tidak mengatasi nasihat penjaga kesihatan profesional anda.

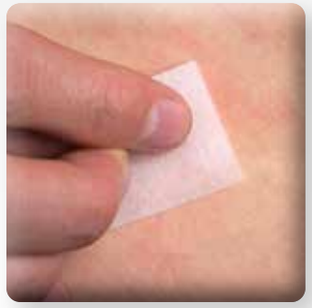
Panduan ini dibahagikan kepada 3 bahagian seperti di bawah:

Isu berkaitan produk

Isu berkaitan infusi

Isu berkaitan kejadian buruk





Isu berkaitan produk

Isu	Cara mengurus
Larutan dalam bebuli tidak jernih. Warnanya bukan antara kuning cair untuk dan coklat muda.	Jangan gunakan produk. Hubungi Khidmat Pelanggan CSL Behring untuk pulangkan bebuli yang belum dibuka.
Larutan dalam bebuli keruh, atau mengandungi zarah.	Jangan gunakan produk. Hubungi Khidmat Pelanggan CSL Behring untuk pulangkan bebuli yang belum dibuka.
Penahan getah pada bebuli tertebuk semasa persediaan infusi, tetapi infusi tidak dapat dilakukan pada hari itu.	Hizentra™ tidak mengandungi sebarang pengawet dan mesti terus digunakan selepas bebuli dibuka. Guna untuk seorang pesakit pada satu masa sahaja. Larutan yang tidak digunakan hendaklah dibuang dengan sewajarnya.
Apa perlu saya buat jika Hizentra™ beku secara tak sengaja?	Jangan guna produk.
Hizentra™ disimpan bawah 2°C.	Hubungi Khidmat Pelanggan CSL Behring.
Hizentra™ disimpan atas 25°C.	Hubungi Khidmat Pelanggan CSL Behring.
Bolehkah saya sejukkan Hizentra™ (2° to 8°C)?	Ya, anda boleh sejukkan Hizentra™. Simpan bebuli dalam kotak luaran untuk melindunginya daripada cahaya semasa penyimpanan.
Bolehkah saya simpan Hizentra™ dalam peti sejuk dan kemudian pada suhu bilik (<25°C) dan selepas itu letakkannya semula dalam peti sejuk?	Hubungi Khidmat Pelanggan CSL Behring.

Isu berkaitan infusi

Isu	Cara mengurus
Terdapat darah dalam tiub infusi.	Jarum telah terkena saluran darah secara tidak sengaja. Hizentra™ tidak boleh diambil secara intravena. Tanggalkan jarum dan buang jarum serta tiub. Mulakan infusi di bahagian lain dengan jarum dan tiub baru.
Bocor di bahagian infusi.	Jarum mungkin tidak dipasang dengan ketat atau dimasukkan dengan betul, atau kadar infuse mungkin terlalu tinggi. Guna jarum yang sesuai panjangnya dan pasang dengan ketat. Guna kadar infusi yang sesuai. Pertimbangkan bahagian infusi lain yang ada lebih banyak tisu subkutaneus.
Jarum menyebabkan ketakselesaan.	Jarum mungkin terlalu panjang. Gunakan panjang jarum yang sesuai. Pertimbangkan untuk menggunakan pek sejuk atau krim anestetik topikal sebelum memasukkan jarum.
Infusi mengambil masa lebih lama daripada jangkaan.	Tetapan kadar infusi mungkin tidak betul, atau penggunaan saiz tiub yang salah, atau pam mungkin tidak berfungsi dengan betul. Periksa kadar infusi, pam bateri dan tukar bahagian infusi. Hubungi Khidmat Pelanggan CSL Behring jika masalah tidak selesai.
Masalah pam infusi.	Pastikan pam beroperasi mengikut spesifikasi pengilang. Guna bekalan yang disyorkan untuk memastikan ketepatan dan kadar penyampaian. Jangan tolak penggera oklusi. Periksa jika ada oklusi dan pastikan semua pengapit dalam kedudukan terbuka.

Isu berkaitan kejadian buruk

Isu	Cara mengurus
Semasa infusi beberapa bahagian yang disuntik bertindak balas seperti kemerahan, bengkak dan gatal mungkin berlaku.	Reaksi bahagian yang disuntik adalah perkara biasa. Ia biasanya ringan dan akan berkurangan selepas suatu tempoh. Sejumlah kecil ubat pada bahagian atas lapisan kulit boleh menyebabkan reaksi seperti seperti kemerahan dan gatal. Semasa menyediakan jarum subkutaneus, jangan biarkan titisan ubat menutupi hujung jarum. Reaksi bahagian yang disuntik boleh juga disebabkan oleh kulit bertindak balas pada pita yang digunakan pada jarum dan tiub infusi. Tukar kepada pita hipoalergenik. Jika tindak balas semakin teruk, laporkannya kepada penjaga kesihatan profesional secepat mungkin.
Tindak balas hipersensitiviti/ anafilaktik yang teruk.	Hentikan Hizentra™ dan segera maklumkan penjaga kesihatan profesional.
Gejala seperti sakit kepala yang teruk, kaku leher, mengantuk, demam, fotofobia, loya dan/ atau muntah-muntah berlaku.	Hentikan Hizentra™ dan segera maklumkan penjaga kesihatan profesional.
Sejarah peristiwa tromboembolik.	Pastikan anda terhidrat secukupnya sebelum menggunakan imunoglobulin. Hizentra™ mesti diambil secara subkutaneus pada kadar infusi minimum.
Terlebih dos.	Kesan dos berlebihan tidak diketahui. Pantau dengan teliti untuk melihat reaksi buruk terhadap ubat. Hubungi penjaga kesihatan profesional secepat mungkin.

Nota

Nota

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MAL-HIZ-0022 Date of Preparation: June 2023

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Hizentra™

常见问题手册

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.

Hizentra™
常见问题手册

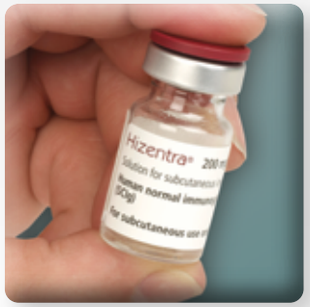
Hizentra™ 常见问题手册旨在提供治疗过程中可能出现的一些疑问，以及相关的解决方案。此手册中的信息不能取代医疗专业人士的建议。

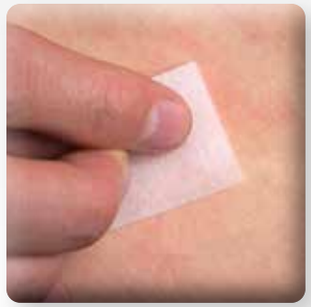
手册分为以下 3 个部分：

产品相关问题

输液相关问题

不良反应相关问题





产品相关问题

问题	处理方案
药瓶中的溶液不清晰。 也不是淡黄色至浅褐色。	请勿使用该产品。联系CSL Behring客服并退还未拆封药瓶。
药瓶溶液出现浑浊， 或含有颗粒物。	请勿使用该产品。联系CSL Behring客服并退还未拆封药瓶。
药瓶的橡胶瓶塞已刺穿准备输液，但无法获得当天输液。	Hizentra™不含任何防腐剂，必须在开瓶后立即使用。一次仅用于一名患者，任何未使用的药水应适当丢弃。
如果Hizentra™不小心冷冻了?	请勿使用该产品。
Hizentra™保存在2°C以下	请联系CSL Behring客服。
Hizentra™保存在25°C以上	请联系CSL Behring客服。
我可以冷藏Hizentra™吗 (2° 至 8°C)?	是的，您可以冷藏Hizentra™。 将药瓶保存在纸盒中以避光。
我可否将存放在冰箱中的Hizentra™，存放在温度(<25°C)的房间里，然后再放回冰箱?	请联系CSL Behring客服。

输液相关问题

问题	处理方案
输液管中出现血液	针头不小心碰到了血管。Hizentra™不能在静脉内注射。取下针头并丢弃针头和输管，用新的针头和输管在不同的输液部位再开始输液。
输液部位渗漏	针头可能没有固定或正确插入，或者输注速度太高。使用合适的针头长度并固定，以及适当的输注速度。可考虑另一个具有更多皮下组织的输注部位。
针头不适	针长度可能太长，请使用合适的针头长度，并考虑在插针前使用冷敷袋或局部麻醉霜。
输液时间比预期长	输液速度可能设置不正确，或使用了不正确的输管尺寸，也有可能是泵无法正常操作。须检查输液速度、泵电池和更换输液部位。如果问题无法解决，请联系CSL Behring客服。
输液泵有问题	检查泵是否按照制造商的说明规格操作。请使用推荐的用品，以确保准确性和速度接收。不要忽视阻塞警报。检查 是否有阻塞以及所有夹具都处于打开位置。

不良反应相关问题

问题	处理方案
在输注过程中，一些局部注射部位会出现如发红、肿胀或者瘙痒。	这些是注射部位常见的反应。这些通常是温和的，其严重性将随着时间而降低。少量药性液体触及到皮肤表皮会应发局部反应，例如发红和发痒。当启动皮下注射时，不要让药滴覆盖针尖。出现局部反应也可能是因为皮肤对用于固定针头和输液管所导致，可改用防过敏胶带。如果局部反应情况变糟，请尽快通知您的医护人员。
遇到严重的超敏感反应/过敏反应	停止使用Hizentra™并立即通知您的医护人员。
出现严重头痛、颈部僵硬、嗜睡、发烧、惧光、恶心以及或呕吐等症状	停止使用Hizentra™并立即通知您的医护人员。
曾有血栓栓塞事件病史	在使用免疫球蛋白之前须充分补充分。Hizentra™应以最低输注速度进行皮下注射。
过量用药	过量用药的后果尚不清楚，须密切监测药物不良反应的发生，并尽快致电您的医护人员。

備注

備注

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.

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