Drug News
藥 物 情 報

Issue Number 192

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in October 2025 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (http://www.drugoffice.gov.hk).

Safety Update

Australia: Risk of overdose in infants when using prilocaine/lidocaine cream (EMLA and generics)

On 2 October 2025, the Therapeutic Goods Administration (TGA) announced the risk of overdose in infants when using prilocaine/lidocaine cream (EMLA and generics).

Summary

The Therapeutic Goods Administration (TGA) has received 2 serious adverse event cases in neonates in which EMLA (topical prilocaine/lidocaine (lignocaine) cream) was applied for a circumcision procedure. Both cases were likely to have involved overdose.

Prilocaine/lidocaine cream (EMLA and various generics) is used for topical anaesthesia of the skin before various minor procedures.

Overdose of EMLA can cause serious adverse effects including methaemoglobinaemia, which in severe cases can lead to seizures or even death.

Methaemoglobinaemia is a condition in which elevated methaemoglobin in the blood disrupts the haemoglobin that transports oxygen around the body. Symptoms may include headache, dizziness, shortness of breath, nausea, poor muscle coordination and cyanosis. Complications may include seizures and heart arrhythmias.

When EMLA and other lidocaine/prilocaine topical cream preparations are provided over the counter without a prescription, consumers may not routinely receive advice on use from a health professional.

What health professionals should do

Health professionals should instruct parents and carers to use no more than the recommended amount of EMLA on the child's skin, and to leave it on the skin for only the recommended length of time.

When preparing infants for circumcision, the recommended amount is 1 g applied to the prepuce for a maximum of 1 hour.

In general, you should provide clear instructions about using any topical anaesthetic, emphasising the recommended amount and length of application.

Use of EMLA

The registered indications for EMLA are topical anaesthesia of:

- the skin prior to insertion of IV catheters, blood sampling, vaccination; superficial surgical procedures, including split skin grafting
- leg ulcers to facilitate mechanical cleansing and debridement
- the genital skin prior to superficial surgical procedures or infiltration anaesthesia
- the skin prior to minor superficial cosmetic procedures.

Adverse events reported to TGA

The TGA's publicly searchable Database of Adverse Event Notifications contains:

- 1 report of 'seizure' (1 of the reports mentioned below)
- 3 reports of 'methaemoglobinaemia', 2 of which are in patients under 1 year of age (which includes 1 of the cases mentioned below).

In October 2024, the TGA received 2 serious reports (1 case of seizure and 1 case of methaemoglobinaemia) following the topical administration of EMLA in preparation for

circumcision. The TGA conducted a signal investigation to review these cases and found both were likely to have involved an overdose of the topical anaesthetic.

The following reports triggered this signal investigation:

- A 3-week-old male neonate hospitalised with a seizure following the reported administration of 3-4 g of EMLA on the penile shaft for circumcision. The child was not exposed to any other medicines and was treated supportively.
- A 3-week-old male neonate hospitalised with cyanosis and in respiratory distress following a circumcision and 3 g of EMLA applied topically to the shaft of his penis. The child was diagnosed with methaemoglobinaemia.

Response to adverse event notifications

The risk of methaemoglobinaemia and seizure in overdose were previously described in the EMLA Product Information (PI) and Consumer Medicine Information (CMI). In response to these adverse event notifications, the product label, package insert and CMI have been updated to emphasise the need to not exceed the maximum recommended dose or application time, as well as highlight that children, particularly those under 3 months of age, are at an increased risk of serious adverse effects in overdose. The package insert also now specifies a maximum length of application (maximum of 1 hour) for neonates and infants (0-3 months) when used for circumcision. The TGA is currently working with sponsors (pharmaceutical companies) of the generic products to update their PIs, CMIs, product labels and package inserts.

In Hong Kong, there are 12 registered pharmaceutical products which are prilocaine/lignocaine cream, including EMLA Cream 5% (HK-27892) registered by Aspen Pharmacare Asia Limited O/B Aspen Pharmacare Asia Limited. All products are pharmacy-only medicines. As of the end of October 2025, the Department of Health (DH) had not received any case of adverse drug reaction with regard to prilocaine/lignocaine cream. Among the registered products in Hong Kong, nine of the registered products are indicated also for use in infants and maximum dose and application time have already been included in their package inserts, while one product is labelled to be used only as directed by physicians and another product with "Until further clinical experience is available, consult your doctor before using in infants under the age of 12 months" listed on its package insert.

The risk of methaemoglobinaemia associated with the use of prilocaine/lignocaine cream in infants, as well as the recommended maximum amount to be used with length of application, is also documented in overseas reputable drug references such as the "Martindale: The Complete Drug Reference" and "British National Formulary for Children". The DH will remain vigilant on any safety update of the drugs issued by other overseas drug regulatory authorities.

Australia: New warning on hepatotoxicity risk for Veoza (fezolinetant)

On 16 October 2025, the Therapeutic Goods Administration (TGA) announced advice to give patients and recommendations for hepatic monitoring.

Summary

New warnings on hepatotoxicity risk and monitoring recommendations have been added to the Product Information for Veoza (fezolinetant).

We undertook a review after the pharmaceutical company Astellas notified us of an analysis of their global safety database, including post-marketing cases of hepatotoxicity. We then worked with them to update the Australian Product Information (PI).

Fezolinetant is used to treat moderate to severe vasomotor symptoms associated with menopause. These symptoms include sudden feelings of warmth (hot flashes) and sweating (night sweats) that occur when the body's temperature regulation system malfunctions.

What health professionals should do

Be alert to the new advice as described in 'Updates to the PI' below.

Advise patients to discontinue Veoza immediately and seek medical attention, including hepatic laboratory tests, if they experience signs or symptoms that may suggest hepatotoxicity. Such symptoms include new-onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale faeces, dark urine or abdominal pain.

Perform follow-up evaluation of hepatic function monthly for the first 3 months after initiating Veoza, then at 6 months and 9 months, and

thereafter periodically based on clinical judgement.

Updates to the PI

The following updates have been made to the Australian Product Information:

4.2 Dose and method of administration

Perform baseline hepatic laboratory tests to evaluate for hepatic function and injury [including serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), serum alkaline phosphatase (ALP) and serum bilirubin (total and direct)] before initiating treatment with Veoza. Do not start Veoza if ALT or AST is ≥ 2 x ULN or if the total bilirubin is ≥ 2 x ULN for the evaluating laboratory.

While using Veoza, perform follow-up hepatic laboratory tests monthly for the first 3 months, at 6 months and 9 months after initiation of therapy.

Advise patients to discontinue Veoza immediately and seek medical attention including hepatic laboratory tests if they experience signs or symptoms that may suggest liver injury (see section 4.4 Special warnings and precautions for use).

4.4 Special warnings and precautions for use

In the post-marketing setting, cases of serious but reversible hepatotoxicity have been reported within 40 days of treatment. Patients have experienced transaminase elevations (greater than 10 times the ULN) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP), sometimes associated with signs or symptoms such as fatigue, pruritus, jaundice, dark urine or abdominal pain.

Evaluate hepatic function (ALT, AST, ALP and bilirubin) before initiating therapy. Do not initiate Veoza if ALT or AST is equal to or exceeds 2 times the ULN or if the total bilirubin is elevated (e.g., equal to or exceeds 2 times the ULN).

Patients should discontinue Veoza immediately and seek medical attention, including hepatic laboratory tests, if they experience signs or symptoms that may suggest hepatotoxicity such as new-onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale faeces, dark urine or abdominal pain.

Perform follow-up evaluation of hepatic function monthly for the first 3 months, at 6 months and 9 months after initiating Veoza, and thereafter periodically based on clinical judgement.

Discontinue Veoza if:

- transaminase elevations are greater than 5 times the ULN
- transaminase elevations are greater than 3 times the ULN and the total bilirubin level is greater than 2 times the ULN.

Monitoring of liver function tests should continue until they have normalised, and other causes of liver injury should be excluded.

Section 4.8 Adverse effects (undesirable effects)

Addition of the following adverse reactions:

- Aspartate aminotransferase (AST) increased with a frequency of common.
- Hepatotoxicity with a frequency of not known.

Description of selected adverse reactions:

Hepatotoxicity

Serious cases of drug-induced hepatotoxicity occurred within 40 days of starting Veoza. Patients experienced elevated transaminases (up to 50 x ULN at peak elevation), elevated alkaline phosphatase (up to 4 x ULN at peak elevation) and bilirubin (up to 5 x ULN at peak elevation), coupled with symptoms of fatigue, nausea, pruritus, jaundice, pale faeces and dark urine. After discontinuation of Veoza, these abnormalities gradually resolved.

Adverse events reported to TGA

A search of TGA's database of adverse event notifications on 17 September 2025 found a total of 14 reports for fezolinetant with any adverse event. Of these, there was 1 case of alanine aminotransferase increased, 1 case of liver function test increased and 1 case of liver function test abnormal.

In Hong Kong, Veoza Tablets 45mg (HK-68654) is currently a pharmaceutical product registered by Astellas Pharma Hong Kong Company Limited. It is a prescription-only medicine. As of the end of October 2025, the Department of Health (DH) had not received any case of adverse drug reaction with regard to fezolinetant.

Related news was previously issued by the United States Food and Drug Administration, European Medicines Agency and United Kingdom Medicines and Healthcare products Regulatory Agency, and was posted on the Drug Office website on 13 September 2024, 30 November 2024 and 11 April 2025. The current product insert of the locally registered Veoza already includes safety warnings on the risk of drug-induced liver injury and the recommended monitoring of liver function. The DH will remain vigilant on the safety update of the concerned drug issued by other overseas drug regulatory authorities.

The United States: FDA provides update to healthcare professionals about risk of inadvertent intrathecal (spinal) administration of tranexamic acid injection

On 21 October 2025, the United States Food and Drug Administration (FDA) announced the requirement of labeling change to strengthen the warnings that tranexamic acid injection should be administered only intravenously (into the vein). Tranexamic acid injection products are not to be administered intrathecally (into the spine) or as an epidural injection. FDA was taking this action after having identified and evaluated medication error cases of inadvertent neuraxial (intrathecal or epidural) administration of tranexamic acid. In these cases, tranexamic acid was erroneously administered neuraxially instead of the intended local anesthetic (e.g., bupivacaine, lidocaine, mepivacaine, and ropivacaine), which resulted in serious patient outcomes, including prolonged hospitalization and death.

Medical practice-level and facility-level human

factors (e.g., storing tranexamic acid injection close to local anesthetics and failing to verify the product before administration) contributed to the medication errors.

Tranexamic acid injection is indicated for short-term use (2 to 8 days) in patients with hemophilia to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction. Healthcare professionals should only administer tranexamic acid injection by the intravenous route. Tranexamic acid injection is supplied in single-dose ampules and single-dose vials containing 1,000 mg tranexamic acid in 10 mL and is marketed both under the proprietary name, Cyklokapron, and as a generic drug. Tranexamic acid is also supplied in sodium chloride injection in single-dose bags containing 1,000 mg of tranexamic acid in 100 mL solution for intravenous use.

FDA is requiring the following changes to the prescribing information for tranexamic acid injection:

- Add a Boxed Warning to communicate the risk of medication errors involving inadvertent neuraxial administration of tranexamic acid injection
- Add a statement to indicate that tranexamic acid injection is contraindicated as a neuraxial injection
- Update the Dosage and Administration section to clarify that tranexamic acid injection is only to be administered intravenously and to provide instructions for preparing and administering the diluted solution

Additionally, FDA is recommending that the container labels for tranexamic acid injection prominently display the product name and intravenous route of administration.

Healthcare professionals should consider the following steps to minimize the risk of inadvertent neuraxial administration of tranexamic acid injection:

Storage

- Do not store tranexamic acid injection vials or ampules near local anesthetics or in kits containing local anesthetics intended for spinal or epidural anesthesia.
- Store medication vials in a way that makes the labels visible to avoid reliance on identifying drugs by the vial cap color.
- Use barcode scanning when stocking medication cabinets to ensure the correct medication is placed in the appropriate storage bin.
- Store tranexamic acid injection vials and ampules in separate carts outside the operating room or in locked bins that require barcode scanning to remove from the bin.

Administration

- Use commercially available or pharmacy-prepared intravenous infusion bags of tranexamic acid, when possible, to minimize confusion with local anesthetics supplied in vials or ampules.
- Use barcode scanning and always check the container label to ensure the correct product is selected and administered.
- If withdrawing tranexamic acid injection from a vial or ampule, promptly label each syringe when it is prepared unless it is immediately administered.
- If using pre-packaged spinal or epidural kits, carefully inspect the container labels of medications included in the kit to verify the intended medication before use.

Additional Recommendations for Healthcare Facilities

- Add a prominent "contains tranexamic acid" auxiliary warning label to all vials and ampules that contain tranexamic acid injection.
- Add tranexamic acid injection to internal high-alert medication lists and develop procedures and policies to ensure safe use and minimize the risk of mix-up with other medications.

In Hong Kong, there are 7 registered pharmaceutical products which are tranexamic acid injectables. All products are prescription-only medicines. As of the end of October 2025, with regard to tranexamic acid, the Department of Health (DH) had received 6 cases of adverse drug reaction, but these cases were not related to medication errors. Related news was previously issued by FDA, and was reported in the Drug News Issue No. 134 and 184. The current product inserts of the locally registered tranexamic acid injectables have listed that the route of administration is for intravenous or intramuscular only. The precautions on the risk of inadvertent neuraxial administration of tranexamic acid injection is also documented in overseas reputable drug references such as

"American Hospital Formulary Service Drug Information". The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

The United States: Immune Globulin Intravenous (IGIV) and/or Immune Globulin Subcutaneous (IGSC) Lots with Increased Reports of Allergic/Hypersensitivity Reactions

On 24 October 2025, the US Food and Drug Administration (FDA) announced that the FDA Adverse Event Reporting System (FAERS) had received increased reporting of allergic/hypersensitivity type reactions following infusion of specific lots of Immune Globulin Intravenous (IGIV) and/or and Immune Globulin Subcutaneous (IGSC). Reports included serious adverse events, some of which were considered severe, requiring treatment with epinephrine, steroids, and/or admission to the emergency room or hospital. Though hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with immune globulin products, the increased reporting of hypersensitivity reactions to these lots presents heightened safety risks for patients.

The affected products are listed below:
- Asceniv (lot number: 239825; manufacturer: ADMA Biologics)
- Bivigam (lot number: 237452; manufacturer: ADMA Biologics)
- Gammaked (lot number: B03J086043; manufacturer: Grifols for Kedrion)
- Gamunex-C (lot number: B01J100623, B03J077152, B03J079503; manufacturer: Grifols)

IGIV and IGSC are used for replacement therapy in patients with primary humoral immunodeficiency.

In Hong Kong, Gamunex-C Solution For Infusion 10% 5g/50ml (HK-63147) is a pharmaceutical product registered by Luen Cheong Hong Ltd (LCH). The product is a prescription-only medicine. As confirmed with LCH, the affected lots have not been imported into Hong Kong. Asceniv, Bivigam and Gammaked are not registered pharmaceutical products in Hong Kong. As of the end of October 2025, the Department of Health (DH) had received 40 cases of adverse drug reaction with regard to human normal immunoglobulin, and 2 cases were related to allergy or hypersensitivity reactions. Related news was previously issued by the US FDA and Health Canada, and was posted on the Drug Office website on 4 March 2022, 11 March 2025, 20 June 2025 and 22 August 2025. The current product insert of the locally registered Gamunex-C already included the safety warnings on the risk of hypersensitivity. The risk of hypersensitivity of human normal immunoglobulin is also documented in overseas reputable drug references such as "British National Formulary" and "Martindale: The Complete Drug Reference". The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

European Union: Injectable tranexamic acid: serious adverse reactions when inadvertently given intrathecally

On 31 October 2025, the European Medicines Agency announced that its Pharmacovigilance Risk Assessment Committee (PRAC) agreed on a direct healthcare professional communication (DHPC) to remind healthcare professionals that extreme caution should be taken when handling and giving injectable tranexamic acid to ensure it is only given intravenously (into a vein). It must not be given intrathecally (into the fluid-filled space between the thin layers that cover the brain and spinal cord), epidurally (into the space between the wall of the spinal canal and the covering of the spinal cord), intraventricularly (into a fluid-filled cavity in the brain) or intracerebrally (into the brain).

Tranexamic acid, which blocks the breakdown of blood clots, is used in adults and children from 1 year of age to prevent and treat bleeding.

PRAC reviewed cases of medication errors, including reports from across the EU, where injectable tranexamic acid was mistakenly given either intrathecally or epidurally due to mix-ups with other medicines, mostly local anaesthetics. Intrathecal use resulted in serious side effects, including severe pain in the back, buttock and legs, seizures and cardiac arrhythmias (abnormal or irregular heartbeat), and in some cases death.

Healthcare professionals should take measures to prevent potential mix-ups between injectable tranexamic acid and other injectable medicines, especially those given intrathecally, that may be used during the same procedure, such as local anaesthetics.

To reduce the risk of medication errors, syringes containing tranexamic acid should be clearly

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labelled for intravenous use only. It is also advised to store injectable tranexamic acid separately from local anaesthetics.

The product information of injectable tranexamic acid medicines, including the outer packaging, will be updated to strengthen the warnings that these medicines must only be given intravenously.

The DHPC for injectable tranexamic acid will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). When adopted, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.

In Hong Kong, there are 7 registered pharmaceutical products which are tranexamic acid injectables. All products are prescription-only medicines. As of the end of October 2025, with regard to tranexamic acid, the Department of Health (DH) had received 6 cases of adverse drug reaction, but these cases were not related to medication errors. Related news was previously issued by FDA, and was reported in the Drug News Issue No. 134 and 184. The current product inserts of the locally registered tranexamic acid injectables have listed that the route of administration is for intravenous or intramuscular only. The precautions on the risk of inadvertent neuraxial administration of tranexamic acid injection is also documented in overseas reputable drug references such as "American Hospital Formulary Service Drug Information". The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

Drug Recall

On 24 October 2025, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Aspen Pharmacare Asia Limited O/B Aspen Pharmacare Asia Limited (Aspen) to recall a total of six batches of the following two products from the market as a precautionary measure due to the potential quality issue.

Name of product	Hong Kong registration number	Batch number
Mivacron Inj 0.2%	HK-37866	XPC19
Nimbex Inj 2mg/mL	HK-42333	XP1SQ
		XPC1G
		XPC6W
		XP1V5
		XP1VF

The DH received notification from Aspen that investigation by the overseas manufacturer of the products revealed deficiencies in manual visual inspection. According to the investigation, potentially not all glass particles in the ampoules have been detected during inspection of the above batches.

As a precautionary measure, Aspen voluntarily recalls the affected batches of the two products from the market. Mivacron Inj 0.2%, containing mivacurium and Nimbex Inj 2mg/mL, containing cisatracurium, are prescription medicines used for adjunct to general anesthesia. According to Aspen, the above batches of products have been imported into Hong Kong. Mivacron Inj 0.2% has been supplied to both the Hospital Authority and private hospitals, and Nimbex Inj 2mg/mL has been supplied to private hospitals.

As of the end of October 2025, the DH had not received any adverse reaction reports in connection with the above batches of products. A notice was posted in the Drug Office website on 24 October 2025 to alert the public of the product recall. The DH will closely monitor the recall.

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of $100,000 and two years' imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a $50,000 fine and one year's imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of $500,000 and 2 years' imprisonment.

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.
Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/

Useful Contact

Drug Complaint:
Tel: 2572 2068
Fax: 3904 1224
E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:
Tel: 2319 2920
Fax: 2319 6319
E-mail: adr@dh.gov.hk
Link: http://www.drugoffice.gov.hk/adr.html
Post: Clinical Trials and Pharmacovigilance Unit,
Drug Office, Department of Health,
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street,
Kwun Tong, Kowloon

The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.

https://www.elections.gov.hk/legco2025/eng/index.html


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