



Pfizer Limited  
Walton Oaks, Dorking Road,  
Tadworth, Surrey,  
KT20 7NS, UK  
Telephone: +44 (0) 1304 616161

30<sup>th</sup> April 2026

***Tranexamic acid intravenous formulations – Serious including fatal adverse reactions due to inadvertent intrathecal administration***

Dear Healthcare professional,

Pfizer Limited on behalf of all concerned Marketing Authorisation Holders listed and in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

**Summary**

- **Intrathecal, epidural, intraventricular and intracerebral use of tranexamic acid solution for injection is contraindicated.**
- **Serious, including fatal, adverse reactions have been reported after inadvertent intrathecal administration due to mix-ups, mostly with injectable local anaesthetics.**
- **Extreme caution should be taken when storing, handling and administering intravenous formulations of tranexamic acid to ensure the correct route of administration. This includes clearly labelling syringes containing tranexamic acid for intravenous use only and storing tranexamic acid injectables separately from injectable local anaesthetics.**

**Background on the safety concern**

Tranexamic acid is an antifibrinolytic indicated in adults and children from one year of age in prevention and treatment of haemorrhages due to general or local fibrinolysis. Specific indications include:

- Haemorrhage caused by general or local fibrinolysis such as:
  - o Menorrhagia and metrorrhagia
  - o Gastrointestinal bleeding
  - o Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear Nose Throat surgery (adenoidectomy, tonsillectomy, dental extractions)
- Gynaecological surgery or disorders of obstetric origin

- Thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery
- Management of haemorrhage due to the administration of a fibrinolytic agent.

Tranexamic acid solution for injection **must not** be administered intrathecally, epidurally, by intraventricular injection or by intracerebral application. Cases of medication errors have been identified, including cases reported in the EU, where tranexamic acid injection was inadvertently administered intrathecally or epidurally. Most of these cases involved mix-ups of vials or ampoules resulting in erroneous administration of tranexamic acid instead of the intended injectable local anaesthetic (e.g. bupivacaine, levobupivacaine, prilocaine).

When administered intrathecally, serious patient harms were reported including prolonged hospitalisation and death. Serious adverse reactions following inadvertent intrathecal administration included severe back, gluteal and lower limb pain, myoclonus and generalised seizures and cardiac arrhythmias.

Healthcare professionals should take extreme care to ensure correct route of administration of tranexamic acid. Healthcare professionals should be aware of the potential for a mix-up between tranexamic acid and other injectable products, including intrathecally administered injectable products that may be used during the same procedure as tranexamic acid.

In order to reduce the risk of fatal medication errors due to incorrect route of administration, syringes containing tranexamic acid should be clearly labelled for identification and correct route of administration.

It is also advised to store tranexamic acid injectables separately from injectable local anaesthetics to prevent accidental mix-up.

The product information of injectable tranexamic acid products, including the outer packaging, will be updated to strengthen the warnings that tranexamic acid injection must not be administered intrathecally, epidurally, via intracerebral application or intraventricular injection.

### **Call for reporting**

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website (<https://yellowcard.mhra.gov.uk>)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates and product brand name.

Suspected adverse drug reactions may also be reported via the company contact points listed below.



### Company contact point








This letter is being sent to you on behalf of the group of companies listed below, who are Marketing Authorisation holders for intravenous formulations containing tranexamic acid. If you require additional information, please contact the medical information services of the individual company.

Company	Medical information contact details
<b>Pfizer Limited</b>	Pfizer Medical Information at <a href="http://www.pfizermedicalinformation.co.uk">www.pfizermedicalinformation.co.uk</a> ,  Telephone: 01304 616161 or,  Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS
<b>Accord Healthcare Limited</b>	Email: <a href="mailto:medinfo@accord-healthcare.com">medinfo@accord-healthcare.com</a>  Telephone: 01271 385257
<b>Eugia (UK) Limited</b>	Eugia (UK) Limited medical information  Email: <a href="mailto:MEDINFO@aurobindo.com">MEDINFO@aurobindo.com</a>  Telephone: +44 (0)208 845 8811(option 1)  1 Roundwood Avenue, Stockley Park, Uxbridge, UB11 1AF, United Kingdom
<b>Farmak Pharmaceuticals UK Ltd</b>	Email: <a href="mailto:med.info@farmak.uk">med.info@farmak.uk</a>  Telephone: +44 (0) 1482 738200  First Floor, 47 Queen Street, Hull, HU1 1UU

<b>Fresenius Kabi Limited</b>	<ul style="list-style-type: none"> <li>• Email: <a href="mailto:Medical.Information-UK@fresenius-kabi.com">Medical.Information-UK@fresenius-kabi.com</a></li> <li>• Telephone: 01928 533 575</li> <li>• Website: <a href="http://www.fresenius-kabi.co.uk">www.fresenius-kabi.co.uk</a></li> </ul>
<b>Ibigen S.r.l.</b>	<p>Bowmed Ibisqus Limited (on behalf of Ibigen S.r.l.)                  Email: <a href="mailto:medinfo@bowmed.com">medinfo@bowmed.com</a>                  Tel: (+44) 01483 212151                  Website: <a href="http://www.bowmed.com">www.bowmed.com</a></p>
<b>Mercury Pharmaceuticals Limited and Focus Pharmaceuticals Limited (ADVANZ PHARMA Group)</b>	<p>Email: <a href="mailto:medicalinformation@advanzpharma.com">medicalinformation@advanzpharma.com</a>                  Telephone: +44 (0) 208 588 9131</p>
<b>Stragen UK</b>	<p>Sarah Parsons                  JensonR+ Limited Medical Information,  <a href="mailto:medicalinformation@jensongroup.com">medicalinformation@jensongroup.com</a>                  Telephone: 01271 334 609                  Unit C1 Fishleigh Court, Fishleigh Road, Barnstaple, Devon, EX31 3UD</p>
<b>Tillomed Laboratories Ltd.</b>	<p>220 Butterfield, Great Marlings, Luton, LU2 8DL, United Kingdom.                  Telephone: +44 (0)1480 402 400                  Email - <a href="mailto:medical.information@tillomed.com">medical.information@tillomed.com</a></p>

*Yours sincerely*

Company	Signed
Pfizer Limited	<p><b>Seema Patel</b>                      Medical Director</p> <p>Signed by:                        224F8FB693AD465...</p>
Accord Healthcare Limited	<p><b>Arletta Werynska</b>                      UK QPPV</p> <p>Signed by:                        DF06F240D7854C5...</p>

<p>Bowmed Ibisqus Limited (on behalf of Ibigen S.r.l.)</p>	<p><b>Signed by:</b>    <b>Louise Crosbie</b>                  Technical and Quality Manager, RPI/RP                  Bowmed Ibisqus Limited</p>
<p>Eugia (UK) Limited</p>	<p><b>Signed by:</b>    <b>Dr. Parveen Begum</b>                  Deputy. QPPV/RPP</p>
<p>Farmak Pharmaceuticals UK Ltd</p>	<p><b>Signed by:</b>    <b>Sharan Patel</b>                  National Contact Person for Pharmacovigilance</p>
<p>Fresenius Kabi Limited</p>	<p><b>Signed by:</b>    <b>Dr. Mankanwar Khurana</b>                  Head of Pharmacovigilance, UK QPPV</p>
<p>Mercury Pharmaceuticals Limited and Focus Pharmaceuticals Limited (ADVANZ PHARMA Group)</p>	<p><b>Signed by:</b>    <b>Nowel Redder,</b>                  Director and QPPV, Patient Safety</p>
<p>Stragen UK</p>	<p><b>Signed by:</b>    <b>Toufik TAIB,</b>                  UKQPPV</p>
<p>Tillomed Laboratories Ltd.</p>	<p><b>Signed by:</b>    <b>Nayan Monpara</b>                  UK QPPV</p>