

# Safety review to begin on topiramate

Topiramate is used for the treatment of epilepsy and migraine. It is used specifically:

- to prevent migraine headaches in adults after consideration of possible other treatments
- alone to treat seizures in adults and children older than age 6 years
- with other medicines to treat seizures in adults and children aged 2 years and above

It should only be prescribed under the supervision of a healthcare professional.

Topiramate is already known to harm the way an unborn baby grows and develops if it is used during pregnancy. Therefore, women should already be advised to use highly effective birth control while on topiramate and to avoid becoming pregnant while using this medicine.

There are other treatments for use in pregnancy that are safer for the baby such as lamotrigine and levetiracetam. Information shows that these medicines do not increase the risk of physical birth abnormalities compared with the general population.

A safety review is today being initiated into topiramate following an observational study suggesting a potential increased risk of neurodevelopmental disabilities (including autism spectrum disorder and effects on learning and development) in children exposed to topiramate during pregnancy.

Women on topiramate who are planning a pregnancy should speak to their doctor about other treatment options, but they should not stop taking topiramate without first discussing it with a healthcare professional.

Topiramate is available as tablets, a liquid oral solution, or as capsules that can be swallowed whole or sprinkled on soft food. The brand name of topiramate is Topamax.

## **Previous reviews of topiramate and harms in pregnancy**

Following a review by the Commission on Human Medicines into the safety of antiepileptic drugs in pregnancy, including topiramate, in January 2021 we published new safety advice in [Drug Safety Update](#) with [patient advice](#), and a [Public Assessment Report](#).

Topiramate use in pregnancy is linked to an increased risk of birth defects and an increased risk of the baby being born of low birth weight and small for gestational age (fetal growth restriction).

## Scope of this review

The Medicines and Healthcare products Regulatory Agency (MHRA) routinely undertakes reviews of the safety of medicines, seeking independent expert advice from the Commission on Human Medicines. The MHRA is responsible for the safety, efficacy and quality of medicines and so this safety review focuses on the regulatory position in the UK.

The scope of the review is:

1. To evaluate information from all Marketing Authorisation Holders and available sources, including relevant stakeholders (patients, patient representatives, healthcare professionals, healthcare organisations, researchers, charity and patient organisations) on the possible harms associated with the use of topiramate during pregnancy.
2. To consider whether further regulatory action is required to minimise risk and ensure awareness of the risks.
3. To consider the impact of the available information considered as part of this review on the balance of benefits and risks of topiramate.
4. To consider what research could be undertaken to further elucidate the long-term impact on children of exposure to topiramate during pregnancy.
5. To make recommendations to the Commission on Human Medicines to improve the balance of benefits and risks for topiramate, to raise awareness of the associated risks and for further research to evaluate the risks.

Following completion of this safety review, a report of the CHM's conclusions and recommendations will be published on this website and will also be sent to those who have indicated that they would like to receive notifications.

## Timeframes for the review

Safety review initiated	Thursday 21 July
Responses due from companies	September
Assessment circulated to CHM	October
CHM consideration	October

After the CHM has considered the review, the MHRA will take forward the recommendations and update the timelines for the review where necessary.

If you would like to receive notifications in relation to this safety review please contact [MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk) to register your details. We will only use these details to notify you about this review.

Information on opportunities to contribute to the review will be published on this webpage as they arise and notifications will be sent to individuals who have indicated they wish to receive them.

## Advice for patients

Patients are advised to not stop taking topiramate without discussing with

your doctor.

If you are taking topiramate for epilepsy or migraine and are planning a pregnancy, urgently talk to your doctor – there are treatments for use in pregnancy which are safer for the baby.

For epilepsy, consult our information on [epilepsy medicines and pregnancy](#), including that lamotrigine (brand name Lamictal) and levetiracetam (brand name Keppra) are safer for the baby during pregnancy since they do not increase the risk of physical birth abnormalities compared with the general population.

## Advice for healthcare professionals

Continue to advise patients on the already known risks associated with topiramate during pregnancy. See [article in the MHRA's Drug Safety Update](#) from July 2022 for a reminder of current advice.

Before starting topiramate in a woman of childbearing potential, fully inform the patient of the risks and the need to use highly effective contraception throughout treatment with topiramate.

Do not prescribe topiramate during pregnancy for migraine prophylaxis. Specialist advice should be sought for patients with epilepsy who are pregnant.

## Reporting suspected side effects to topiramate

We continuously monitor the safety of medicines in the UK using information from various sources including the [Yellow Card scheme](#).

If you suspect that you have experienced a side effect with use of topiramate, we encourage you to submit a report. Anyone in the UK can submit a report to the [Yellow Card scheme](#).

If you have any questions about this review please contact us at [MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)

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## [June 2022 Transaction Data](#)

News story

This data provides information about the number and types of applications that HM Land Registry completed in June 2022.



Image credit: NicoElNino/Shutterstock.com

Please note this data shows what HM Land Registry has been able to process during the time period covered and is not necessarily a reflection of market activity.

In June:

- HM Land Registry completed more than 1,839,110 applications to change or query the Land Register
- the South East topped the table of regional applications with 433,271

HM Land Registry completed 1,839,118 applications in June compared with 1,983,661 in May and 1,944,893 last June 2021, of which:

- 341,908 were applications for register updates compared with 374,672 in May
- 970,694 were applications for an official copy of a register compared with 1,064,783 in May
- 239,495 were search and hold queries (official searches) compared with 235,827 in May
- 15,942 were postal applications from non-account holders compared with 15,905 in May

## Applications by region and country

Region/country	April applications	May applications	June applications
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<b>Region/country</b>	<b>April applications</b>	<b>May applications</b>	<b>June applications</b>
South East	416,705	465,741	433,271
Greater London	315,971	366,243	328,559
North West	200,963	223,007	210,768
South West	170,684	195,283	180,421
West Midlands	145,566	166,826	154,776
Yorkshire and the Humber	137,836	152,418	144,885
East Midlands	126,524	145,726	133,895
North	84,798	95,723	90,354
East Anglia	74,659	83,057	79,765
Isles of Scilly	42	57	36
Wales	78,518	89,461	82,294
England and Wales (not assigned)	97	119	94
<b>Total</b>	<b>1,752,363</b>	<b>1,983,661</b>	<b>1,839,118</b>

## **Top 5 local authority areas**

### **June 2022 applications**

#### **Top 5 Local authority areas June applications**

Birmingham	26,068
Leeds	21,930
City of Westminster	20,705
Buckinghamshire	19,025
Cornwall	18,139

### **May 2022 applications**

#### **Top 5 local authority areas May applications**

Birmingham	28,242
City of Westminster	23,404
Leeds	22,731
Buckinghamshire	20,630
Cornwall	19,738

## **Top 5 customers**

### **June 2022 applications**

<b>Top 5 customers</b>	<b>June Applications</b>
Infotrack Limited	138,726
Enact	46,821
O'Neill Patient	28,464

Top 5 customers	June Applications
Optima Legal Services	26,301
TM Group (UK) Ltd (Search Choice)	20,468

### May 2022 applications

Top 5 customers	May applications
Infotrack Limited	143,597
Enact	51,228
O'Neill Patient	34,270
Optima Legal Services	30,114
TM Group (UK) Ltd (Search Choice)	22,712

[Access the full dataset on our Use land and property data service.](#)

### Next publication

Transaction Data is published on the 15th working day of each month. The July data will be published at 11am on Friday 19 August 2022.

Published 21 July 2022

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## [Inspection Report Published: An inspection of the initial processing of migrants arriving via small boats at Tug Haven and Western Jet Foil December 2021 – January 2022](#)

Three years into the small boats crisis, the Independent Chief Inspector of Borders and Immigration has found the Home Office response is both ineffective and inefficient, exposing gaps in security procedures and leaving vulnerable migrants at risk.

In 2021, 28,526 people arrived on the south coast in small boats, according to Home Office statistics – a significant increase from 236 in 2018.

An inspection of the Tug Haven processing facilities, which have since closed, along with those at Western Jet Foil, both in Dover, found the Home Office's response to the challenge of increasing numbers of migrants was poor, particularly in terms of systems, processes, resources, data collection

and accurate record keeping. A new processing centre for migrants opened in January 2022 at a former Ministry of Defence site at Manston, also in Kent, and further facilities are also due to open later this year at Western Jet Foil.

David Neal, the Independent Chief Inspector of Borders and Immigration (ICIBI), said:

These migrants crossed the Channel in dire circumstances. Many were vulnerable and at risk, including children and women on their own, and when they arrived in Dover the way they were dealt with was unacceptable. This is because the Home Office has failed over the past three years to move from a crisis response to having better systems and procedures in place and treating this as business as usual.

Data, the lifeblood of decision-making, is inexcusably awful. Equipment to carry out security checks is often first-generation and unreliable. Biometrics, such as taking fingerprints and photographs, are not always recorded.

The Home Office told our inspectors that 227 migrants had absconded from secure hotels between September 2021 and January 2022, and not all had been biometrically enrolled. Over a five-week period alone, 57 migrants had absconded – two-thirds of whom had not had their fingerprints and photographs taken.

Put simply, if we don't have a record of people coming into the country, then we do not know who is threatened or who is threatening.

To move migrants quickly through Tug Haven, effective safeguarding was sacrificed because of the large numbers of migrants from small boats coming into the country. There was limited reflection by staff at all grades of the connection between vulnerability and security – that identifying a trafficking victim could feed the intelligence cycle and reveal intelligence about organised criminal gangs. The ability of staff to identify and safeguard vulnerable migrants was also hindered by the fact that no interpreters were used in the procedures carried out at Tug Haven.

Many of the issues identified were also picked up in a [separate inspection](#) undertaken last year by [Her Majesty's Chief Inspector of Prisons](#), which found that migrants were being held in unsatisfactory conditions, with weak Home Office systems relating to governance, accountability and safeguarding.

Mr Neal added that the Home Office team charged with responding to the crisis, the Clandestine Channel Threat Command, is pulled between day-to-day operations and developing a deterrent, as well as responding to the constant requests for strategic briefings. The majority of its Campaign Plan objectives focus on strategic effects at the expense of delivering security and dealing humanely with the here and now. In simple terms, the focus on the

'Prevent' function has eclipsed the need to do simple things well on the quayside in Dover.

He added that although staff were doing their very best, they were tired, and high volumes of migrants led to poor record keeping and data collection and processes that do not work.

The workforce can do no more. They have responded with enormous fortitude and exceptional personal commitment, which is humbling, and they are quite rightly proud of how they have stepped up. However, we found there was a lack of effective and visible leadership.

This is not about rank and file staff working hard on the quayside at Dover, this is about effective leadership, grip and the ability to bring in systems that work. Border Force and Immigration Enforcement officers at home and overseas are doing a great job on a daily basis.

He added:

A new model for Borders and Enforcement is desperately required if our border is to be secured and vulnerability effectively addressed. There needs to be a strategic approach by the Home Office to regularise their response to small boats, as this has become business as usual and moved beyond an emergency response.

The inspection was undertaken between December 2021 and January 2022 and the report made four recommendations, all of which the Home Office has accepted, with priority placed on ensuring that staff received training and updated guidance by March 2022 in security matters, including how the Biometric Recording Stations are operated.

By June 2022 further improvements needed to have been made, including identifying migrants who are vulnerable such as children, single women and families, and ensuring information is properly recorded and acted upon. Further detailed recommendations call for the improvement of overall data quality and resourcing needs.

Our recommendations are not intended to supersede those provided by Her Majesty's Chief Inspector of Prisons and the Home Office's own Joint Review, but clearly point to a need for the Home Office to urgently implement all recommendations as a priority.

We will reinspect the processing facilities later this year.

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# [AAIB Report: DA 40 NG \(G-CTSB\), Aircraft stalled and struck the ground shortly after takeoff.](#)

News story

On takeoff from Cranfield Airport an aircraft loaded with five containers of de-icing fluid stalled and struck the ground, 12 December 2020.



The aircraft, a DA 40 NG (G-CTSB), stalled and struck the ground shortly after takeoff from a height of about 100-200 ft. The pilot survived but sustained serious injuries.

The aircraft had been loaded with five containers of de-icing fluid, contrary to the approved training organisation's prohibition on the carriage of cargo and dangerous goods. One container, loaded in the front right footwell close to the flying controls, limited the forward movement of the control stick. The aircraft was near its maximum permitted takeoff weight and aft centre of gravity limit when it departed. This, together with the limited control authority available, caused the accident.

The investigation also found that aspects of the management of the Approved Training Organisation may have contributed to the accident. The de-icing fluid was probably incorrectly classified by the manufacturer as a non-dangerous good, with incorrect safety information supplied.

One Safety Recommendation is made regarding the use of recording facilities on digital flight instrument systems.

[Read the report.](#)

Media enquiries call: 01932 440015 or 07814 812293

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## Grocer banned for abusing £50,000 government loan

Abbas Abo Kifayah (37), of Kingsbury, northwest London, was the sole director of Al-Amir Ltd. The company traded as a grocer and butchers from premises on Forty Avenue, Wembley, in northwest London.

The company, however, went into creditors' voluntary liquidation in July 2021, which triggered an investigation by the Insolvency Service.

Investigators uncovered that Abbas Kifayah successfully secured a £50,000 bounce back loan for Al-Amir Ltd in August 2020. However, Abbas Kifayah exaggerated the company's turnover to secure a higher value loan than Al-Amir Ltd was entitled to.

Further enquiries found that once the £50,000 loan was placed into the company's bank account, £43,200 was transferred into Abbas Kifayah's personal account, while just over £3,000 was transferred to a third party and £2,250 was withdrawn in cash.

When Abbas Kifayah was questioned about these transactions, he stated that £12,000 was used to pay his salary and the remainder for his backdated salary and personal use. However, investigators could not find any evidence that any of the money was used for the benefit of the company.

On 30 June 2022, the Secretary of State for Business, Energy and Industrial Strategy accepted a 10-year disqualification undertaking from Abbas Kifayah after he did not dispute that he obtained a £50,000 Bounce Back Loan which the company was not entitled and failed to use the funds received for the economic benefit of Al-Amir Ltd.

Effective from 21 July 2022, Abbas Kifayah is banned from directly, or indirectly, becoming involved in the promotion, formation or management of a company, without the permission of the court.

Al-Amir Ltd's Liquidator is considering the bounce back loans and recovery of funds.

Lawrence Zussman, Deputy Head of Insolvent Investigations, said:

Bounce back loans were available to support viable businesses through the pandemic. Abbas Kifayah, however, abused the government's support when he inflated his company's turnover in order to receive the maximum loan before squandering the money rather than use it to benefit his business.

10 years is a significant amount of time to be removed from the

corporate arena and Abbas Kifayah's disqualification should serve as a clear warning that we will take decisive action to protect the public and the taxpayer".

Abbas Abo Kifayah is from Kingsbury, North-West London and his date of birth is November 1984.

Al-Amir Ltd (Company Reg no. 09398002).

Disqualification undertakings are the administrative equivalent of a disqualification order but do not involve court proceedings. Persons subject to a disqualification order are bound by a [range of other restrictions](#).

[Further information about the work of the Insolvency Service, and how to complain about financial misconduct](#).

You can also follow the Insolvency Service on: