



PHARMACOVIGILANCE **NEWSLETTER**



EDITOR'S NOTE

Dear Readers

Welcome to another edition of the BoMRA Pharmacovigilance Newsletter! At BoMRA, we remain committed to ensuring the safe and effective use of medicines and vaccines for all people in Botswana. Through strong partnerships with healthcare professionals, patients and communities, our national pharmacovigilance system continues to grow fostering a culture where medicine safety is everyone's responsibility.

In this issue, we reflect on efforts to strengthen regional pharmacovigilance activities, enhance vaccine safety monitoring, and promote greater awareness about adverse drug reaction reporting. We also share updates and safety information aimed at supporting informed clinical decisions and empowering the public to use medicines safely.

We extend heartfelt appreciation to all our partners and healthcare professionals for their continued collaboration and vigilance. Your dedication plays a vital role in protecting patients and improving health outcomes across the country.

Together, let's keep building a safer, healthier Botswana.

Editorial Team

Ms Kemo Ntlhayakgosi

Ms Lydia Makwana

Botswana National Pharmacovigilance System Overview

The National Pharmacovigilance System, coordinated by the Botswana Medicines Regulatory Authority (BoMRA), operates through a network of regional centers called Adverse Drug Reaction Monitoring Centers (AMCs) across the country to enhance medicine safety monitoring and reporting.

To date, 15 AMCs have been established, with 9 currently staffed by dedicated Pharmacovigilance Associates. These centers form an essential part of BoMRA's efforts to promote awareness and encourage the reporting of side effects to strengthen patient safety.

These regional Pharmacovigilance Centers contribute to the majority of Adverse Drug Reaction (ADR) reports submitted annually, accounting for over 90% of total reports received by the National Pharmacovigilance Center. In addition, regional centers are instrumental in capturing ADRs from rural and peri-urban areas, helping to ensure national representation in pharmacovigilance data.

Botswana's National Pharmacovigilance system's performance over the past 5 years

The chart shows the number of ADR and Adverse Events Following Immunization (AEFI) reports received from 2019 to 2025. ADR reporting has shown a steady increase over the years, reflecting growing awareness and improved participation in pharmacovigilance reporting.

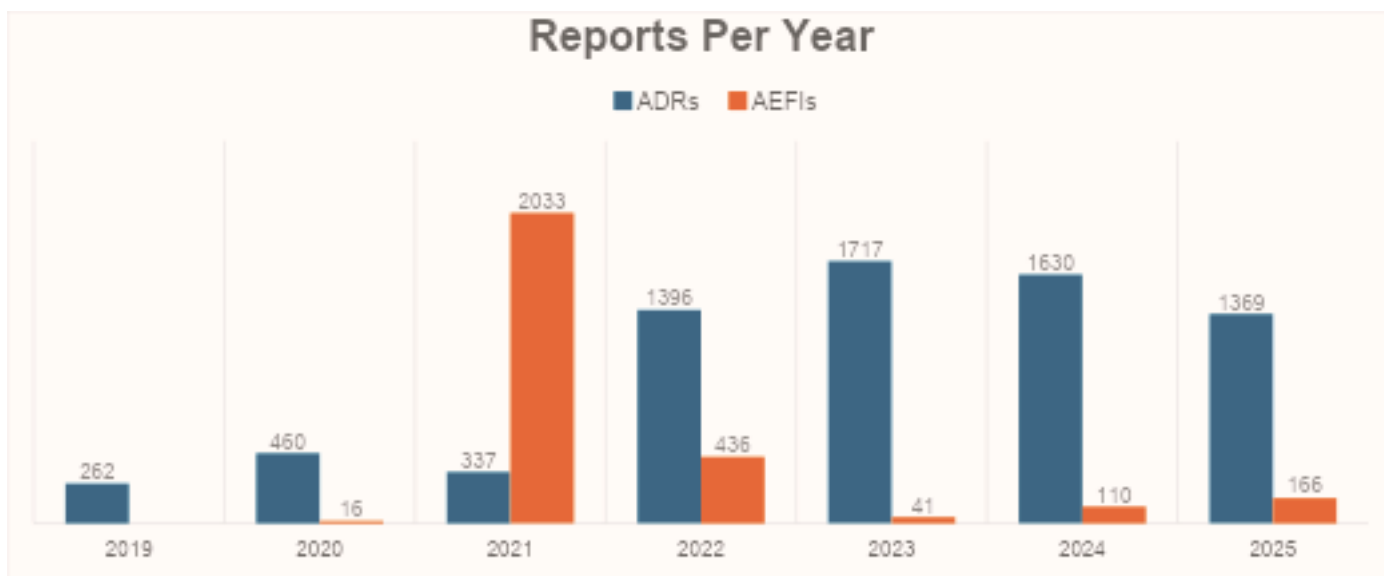


Figure 1: Presentation of the number of reports yearly



Adverse Drug Reaction (ADR) Reporting Summary: April 2025 - February 2026

During the period April 2025 to February 2026, the National Pharmacovigilance Center received a total of 1369 Adverse Drug Reaction (ADR) reports. Of these, 68% were submitted for female patients, while 32% involved male patients. The majority of reports (70%) were classified as non-serious events, reflecting increased awareness and proactive reporting of mild to moderate adverse reactions. According to Figure 2, the top three therapeutic categories most frequently associated with reported adverse reactions were.

- Antiretrovirals (ARVs)
- Antihypertensives
- Antidiabetic medicines

REPORTS PER PRODUCT

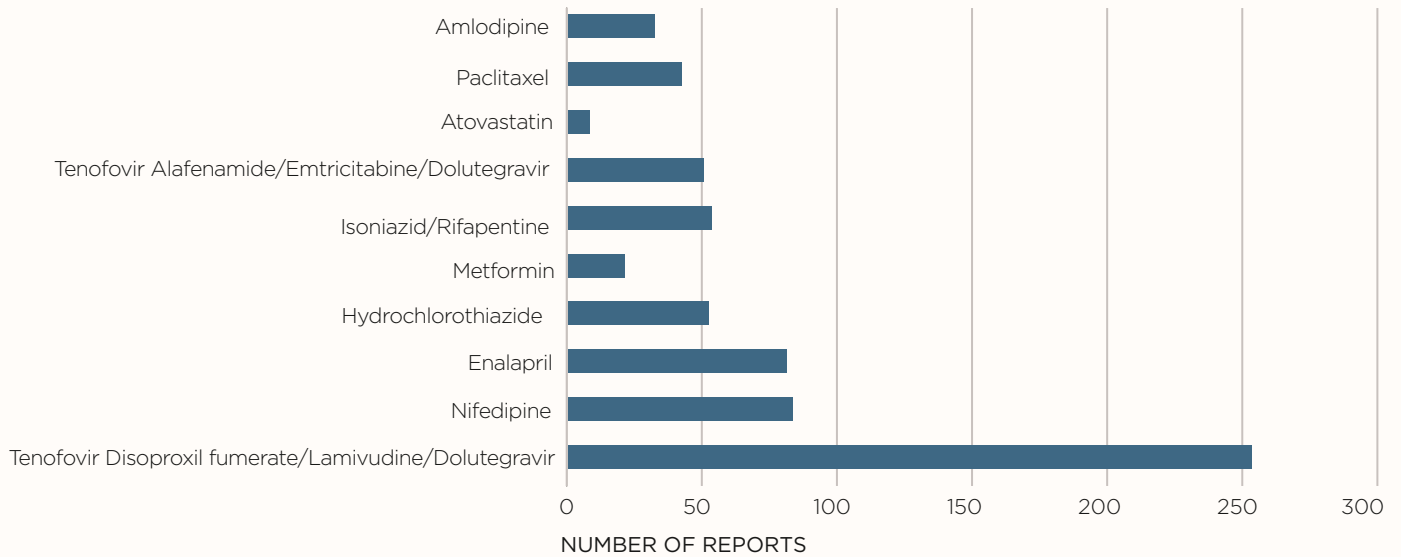
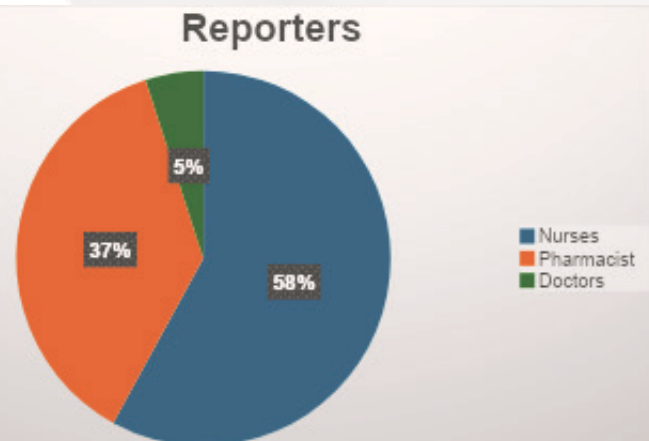


Figure 2: Top 10 medicines with the most commonly reported adverse reactions.

The nursing profession continues to lead in ADR reporting, contributing 58% of all reports received between April and February 2026. Pharmacists followed with 37%, while medical doctors accounted for 5% of the total reports (**Figure 3**)

Figure 3: Categories of reporting healthcare professionals



RE A LEBOGA!

BoMRA extends its sincere appreciation to all healthcare professionals for their continued commitment to patient safety through the reporting of suspected ADRs to their nearest AMC.

Your active participation greatly contributes to strengthening the national safety monitoring system. Together, we can ensure safer use of medicines and better health outcomes for all patients. The table below presents the total number of reports received from various regions, highlighting the top five healthcare facilities with the highest number of submissions per district.

Region	Health Facilities	Number of Reports
Southern	Athlone Hospital, Woodhall Clinic, Tsopeng Clinic, Sbrana Psychiatric Hospital, Goodhope Hospital	321
North-west	Maun General Clinic, Sedie Clinic, Maun Clinic, Matshwane Clinic, Disaneng Clinic	312
South-East	Police College, Bamalete Lutheran Hospital, Princess Marina Referral Hospital, UB Clinic	209
Central	Newton Clinic, Kadimo Clinic, Orapa Mining Hospital, Serowe Clinic	279
Kweneng	A.S Dada Kumakwane Clinic, Scottish Living, Thamaga Primary Hospital, Kopong Clinic, Lentsweletau Clinic, Salajwe Clinic	261
North East	Nyangabgwe Hospital, Donga Diabetics Clinic, Jubilee Psychiatric Clinic, Boikhutso clinic, Boikhutso clinic	342

Table 1 represents the top 5 Healthcare facilities that submitted reports to BoMRA between the period April 2025 - February 2026

Adverse Events Following Immunization (AEFI) Surveillance Strengthened Through Targeted Training

Recognizing the need to strengthen AEFI surveillance across the country, the Department of Pharmacovigilance and Clinical Trials launched a targeted program to support districts with lower reporting activity.

Through this initiative, healthcare workers received focused AEFI training designed to empower healthcare professionals through hands-on AEFI training and inspire a stronger culture of vaccine safety reporting.

Following targeted training efforts across the country, **811** healthcare professionals were equipped with the skills and knowledge to detect and report AEFIs. This initiative led to a significant rise in reports submitted to BoMRA. **166** AEFI reports were received during the April 2025 - February 2026 period - an increase from just **110** reports during the

same period in the year 2024-2025. The improvement reflects a growing commitment to vaccine safety monitoring nationwide.

From the 166 reports, **75%** of the reports were non-serious and **25%** were categorized as serious. According to World Health Organization (WHO), a serious AEFI is an adverse event that resulted in hospitalization/prolonged hospitalization, birth defect, death, life threatening and persistent or significant disability.



Figure 4: One on one engagements with healthcare professionals

STAKEHOLDER ENGAGEMENTS

Effective collaboration with key stakeholders at the district level is crucial to strengthening public health initiatives and emphasizing the importance of medicine safety monitoring. Our AMCs continue to play a vital role in this effort through active participation in strategic events and public outreach.

World Kidney Day 2026 (Francistown)

The Nyangabgwe Hospital ADR Monitoring Centre proudly took part in World Kidney Day activities hosted by the Office of the District Commissioner in Francistown, from the 2nd to the 4th of February 2026. The Event under the theme “United by Unique – placing people at the centre of care and exploring new ways of making a difference”. The Center set up an educational stall aimed at raising awareness about the critical role of pharmacovigilance, particularly in patients with kidney disease who may be at increased risk of adverse drug reactions. Activities included mall activation, community outreach, and the main commemorative event, where various stakeholders provided health education and screening services to the public.



Figure 5: World Kidney Day-Francistown

Through these targeted engagements two hundred and thirty-five (235) members of the public were sensitised, six (6) ADR reports and one (1) AEFI were successfully collected from chemotherapy patients/ public. These reports included reactions associated with anticancer therapies, supportive medications and covid 19 vaccination.

Encouraging healthcare professionals and patients to actively report medicine safety concerns helps strengthen the culture of reporting. Such initiatives not only increase public awareness but also support the ongoing mission to ensure the safe and effective use of medicines for everyone. They also demonstrate how incorporating pharmacovigilance activities into public health campaigns can enhance medicine safety monitoring and surveillance.

World Patient Safety Day

World Patient Safety Day, observed on 17 September, is a global initiative launched by the World Health Organization (WHO) in 2019 to raise awareness and drive action to prevent harm in healthcare. It was established in recognition of the fact that unsafe care is a major cause of avoidable injury and death worldwide. The day aims to promote global solidarity, engage patients and healthcare workers, and encourage policies and practices that

improve safety across health systems. At its core, it calls for making healthcare safer for everyone, everywhere by placing patient safety at the heart of health care delivery.

BoMRA joined the global community in commemorating World Patient Safety Day 2025 under the theme “Safe Care for Every Newborn and Every Child.” This year’s campaign called for urgent action to eliminate avoidable harm in child and newborn care, while empowering families and caregivers through education and active engagement.



Figure 6: World Patient Safety Day in Lobatse district

Figure 7: The community of Mabeleapudi addressed on how to ensure best care for the little ones.

MedSafety Day

This year’s Medsafety week marked the 10th year anniversary, and it was commemorated under the theme “We can all make medicines safer”, emphasizing the role everyone plays in reporting side effects and contributing to medication safety. As an initiative to spread awareness country wide, celebrations were carried out in AMC located in Gaborone, Lobatse, Mololepolole, Serowe, Francistown and Maun.

Activities included an internal stakeholder Engagement, where BoMRA staff were reminded on the importance of medicine safety through reporting of adverse events. Other activities included mall activations, clinic sensitizations and interviews with our local broadcasting service providers.



Figure 8: The CEO and Acting CRO celebrating MedSafety Week at BoMRA head office

Figure 9: An Interview with BTV during Maun Mall Activation

Figure 10: CME for Maun HCPs in the private sector

* This publication is meant to provide updates on medication safety issues to health care professionals, and not as a substitute for clinical judgement

LAUNCH OF NEW ADVERSE DRUG REACTION MONITORING CENTERS

The Authority officially launched 3 new Adverse Drug Reaction Monitoring Centers, expanding its regional coverage to Tsabong and Selibe Phikwe, also covering both public and private health sector.



Sidilega Private Hospital, Gaborone

Official Launch Date: 04 November 2025
Number of Healthcare professionals trained: **86**

Tsabong Primary Hospital, Tsabong

Official Launch Date: 30th January 2026
Number of Healthcare professionals trained: Clinicians: **92**

Selibe Phikwe Government Hospital, Phikwe

Official Launch Date: 30th January 2026
Number of Healthcare professionals trained: Clinicians: **142**

KNOW YOUR REGION

Regional Centers for adverse drug reaction reporting

Region	Contact Details
Lobatse	Sbrana Psychiatric Hospital – Morgan Gibson Email: mgibson@bomra.co.bw Tel: +267 76 879 184
Gaborone	Princess Marina Referral Hospital – Boago Mmusi Email: bmmusi@bomra.co.bw Tel: +267 73 385 509
Molepolole	Scottish Livingstone Hospital – Adoniah Lebakeng Email: alebakeng@bomra.co.bw
Serowe	Sekgoma Memorial Hospital – Kefilwe Lopang Email: kloping@bomra.co.bw Tel: +267 73 599 171
Maun	Letsholathebe II Memorial Hospital – Annah Sibi Email: asibi@bomra.co.bw Tel: +267 71 357 250
Selebi Phikwe	Selebi Phikwe Government Hospital – Lucky Mokwaleng Email: lmokwaleng@bomra.co.bw Tel: +267 73 529 813
Ghanzi	Ghanzi Primary Hospital - Pusoetsile Pusoetsile Email: ppusoetsile@bomra.co.bw
Tsabong	Tsabong Primary Hospital- Thato Rampesu Email: trampesu@bomra.co.bw Tel: +267 73 385 517
North East	Nyangabwe Referral / Tati River Hospital – Amanda Solotata Email: asolotata@bomra.co.bw

Please contact the relevant representative above or reach out to BOMRA Headquarters for general enquiries

SAFETY COMMUNICATIONS

Safety Update on Fluconazole Use During Pregnancy – Important Information for Healthcare Professional

Introduction

The BoMRA is committed to ensuring the safe and effective use of medicines within Botswana. Following a thorough review of the latest safety data and recommendations from the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC), BoMRA is issuing this safety communication to inform healthcare professionals about important updates concerning the use of fluconazole during pregnancy. This update aims to enhance patient safety by highlighting the potential risks of fluconazole to the developing foetus and providing clear guidance for clinical practice.

Key Safety Concerns

Risk of Spontaneous Abortion and Congenital Malformations

- Emerging evidence shows fluconazole use during pregnancy is linked with an increased risk of spontaneous abortion and birth defects.
- These risks have been reported not only with high-dose, long-term treatments but also with lower doses and single-dose use.

Teratogenic Effects and Timing of Exposure

- Fluconazole exposure during the first and second trimesters carries the highest risk for the developing baby.
- Exposure during this time may interfere with organ development, increasing the likelihood of facial, skeletal, and heart abnormalities.

Recommendations for Practice

- Avoid prescribing fluconazole during pregnancy unless absolutely necessary. Evaluate alternative treatments first.
- Women who are pregnant, suspect pregnancy, or planning pregnancy should be informed about the potential risks of fluconazole use.
- There is a risk with single-dose treatment, and with longer courses of treatment, therefore;
- After a single dose of fluconazole, women should wait at least one week before attempting to conceive.
- Advise women of childbearing potential to use effective contraception throughout treatment and for at least one week after the final dose.

“Your vigilance protects patients — please report all suspected side effects or adverse reactions to BoMRA through our reporting channels.”

Finasteride and dutasteride: Risk of Suicidal Ideation

BoMRA urges healthcare professionals to exercise increased vigilance when prescribing finasteride, as new evidence suggests a potential link between treatment and suicidal thoughts. This communication highlights practical measures to support early detection of mood changes and strengthen patient counselling.

Finasteride and dutasteride taken by mouth have a known risk of psychiatric side effects, including depression. Suicidal ideation has also recently been added as a possible side effect of unknown frequency in the product information. Finasteride (oral 1 mg tablet and skin solution) is used to treat the early stages of androgenic alopecia in men aged 18 to 41 years. Finasteride (oral 5 mg tablet) and dutasteride (0.5 mg capsules) are used to treat men with benign prostatic hyperplasia (BPH). These two products are registered for use in Botswana.

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Background & Regulatory Findings

- Following a comprehensive review of post-marketing data, EMA's Pharmacovigilance Risk Assessment Committee has confirmed suicidal ideation (suicidal thoughts) as a possible side effect of finasteride 1 mg and 5 mg tablets.
- The frequency is unknown, meaning current data do not allow reliable estimation of how often this occurs.
- In several reports, symptoms of depression or low mood appeared before the onset of suicidal ideation

Advice for Practice

Patient Assessment & Monitoring

- Before initiating finasteride, it is important to assess each patient's psychiatric history, especially for depression or previous suicidal ideation.
- During treatment, patients are to be monitored for changes in mood, depressive symptoms, suicidal thoughts, or worsening mental health.
- Be particularly vigilant during the early months of treatment, when emergence of new psychiatric symptoms may be more likely.

Patient Counselling

- Inform patients of the potential risk of mood changes and suicidal thoughts, even in those without previous psychiatric history.
- Advise patients to stop taking finasteride and seek medical help immediately if they experience suicidal ideation, severe mood changes, or worsening depression.
- Educate patients that sexual dysfunction (e.g. reduced libido, erectile dysfunction) may accompany finasteride use and might contribute to mood changes; they should report these symptoms promptly



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Updated Safety Alert: Risk of Neurodevelopmental Disorders in Children of Fathers Treated with Sodium Valproate

Introduction

In 2023, BoMRA published a safety communication informing the public of the risks of Sodium Valproate in women of childbearing potential associated with congenital malformations in the newborn. The article covered warnings and precautions alerting healthcare professionals to the risk of Sodium valproate linked to congenital malformations (approximately 10%) and neurodevelopmental disorders NDDs (up to 30–40%) in children born to women exposed during pregnancy.

In light of this, the public is alerted to new information from a recent study suggesting a possible risk of NDDs in children fathered by men treated with valproate within three months before conception.

Registered valproate products in Botswana include Epilim, Epivulex, Epiproate, Valparin, and Valprowin, used to treat epilepsy and bipolar disorder.

Safety Concern

In 2024, results from a retrospective observational post authorisation safety study (PASS) conducted in Europe, initiated a change in recommendations for valproate use. This study suggests that there may be an increased risk of neuro-developmental disorders (NDDs) in children born to men treated with valproate in the 3 months before conception compared to those born to men treated with lamotrigine or levetiracetam. Because this study had some limitations, this risk has not been confirmed but considered possible.

As a precautionary measure, BoMRA is requesting all healthcare professionals to inform male patients about the possible infertility and testicular toxicity which may cause NDD in their children.

Advice to Healthcare Professionals

- Do not start valproate in patients under 55 unless two specialists independently consider and document that there is no other effective or tolerated treatment or the risk of infertility or potential risk of testicular toxicity are not applicable.
- Inform male patients about potential infertility and testicular toxicity risks and make sure they understand.
- Inform male patients about potential infertility and testicular toxicity risks and make sure they understand.
- Continue pregnancy prevention measures for female patients and ensure contraception during and up to 3 months after treatment.
- Advise men not to donate sperm during treatment and for 3 months after stopping valproate.
- Review male patients regularly.
- Discuss alternative treatments with patients planning to conceive.

Advice to Patients

- Do not stop taking valproate on your own. Stopping suddenly may cause serious health problems. Always talk to your doctor first.
- If you plan to have a child, tell your doctor before trying to conceive. Your treatment may need to be reviewed.
- Men taking valproate should not donate sperm during treatment or for at least 3 months after stopping the medicine.
- Inform your doctor immediately if you or your partner become pregnant or suspect pregnancy.
- Discuss contraception options with your healthcare provider to prevent unplanned pregnancy while using valproate.



Every report counts! - Please report all suspected side effects or adverse reactions to BoMRA through our reporting channels.

Updated Safety Alert: Topiramate Use in Pregnancy

BoMRA wishes to share a safety update on the use of topiramate-containing medications in pregnancy.

Topiramate is a broad-spectrum antiepileptic drug indicated as adjunctive therapy and monotherapy for adults and paediatric patients. It has shown efficacy in the treatment of several other neurological and psychiatric diseases, including binge eating disorder, bulimia, and essential tremors.

Previously, topiramate was contraindicated in pregnancy and lactation, as topiramate is teratogenic in animals, however, there was no adequate data on humans. This safety alert follows an epidemiological study published in May 2022. The study investigated the risk of neurodevelopmental disorders in children exposed to antiseizure medications. The study investigated the risk of neurodevelopmental disorders in children exposed to antiseizure medications. The Nordic register-based study of antiepileptic drugs in pregnancy (SCAN-AED) was a population-based cohort study using health register and social register data from Denmark, Finland, Iceland, Norway, and Sweden (1996-2017). The study included 4,494,926 participants from 4,702,774 live-born children with available mother-child identities and maternal prescription data. Approximately 24,825 children were prenatally exposed to antiseizure medications, and 16,170 of them were born to mothers with epilepsy.

The study revealed that the adjusted hazard ratios (aHRs) for autism spectrum disorder and intellectual disability after exposure to topiramate were 2.8 (95% CI, 1.4-5.7)

and 3.5 (95% CI, 1.4-8.6), respectively, and after valproate exposure were 2.4 (95% CI, 1.7-3.3) and 2.5 (95% CI, 1.7-3.7). The adjusted hazard ratios were increased with higher doses of antiseizure medication compared with children from the general population. The study demonstrated a dose-dependent association between prenatal exposure to topiramate, valproate, and several duotherapies with increased risks of neurodevelopmental disorders. There was a 2.77-fold increase in the risk of autism spectrum disorder and a 3.47-fold increase in the risk of intellectual disability in children with an epileptic mother taking topiramate during pregnancy compared to those with epileptic mothers not taking any antiepileptic treatment during pregnancy, Bjørk et.al (2022). To this end, BoMRA has received the following adverse drug reactions: levetiracetam (n=0), carbamazepine (n=6), lamotrigine (n=2), and topiramate (n=0). All ADRs were reported by adults of childbearing age (18 years and above), with 6 cases from females and 2 from males.

Marketing authorization holders will be requested to revise the **contraindication, warnings, and precautions section** of the **product information, patient information leaflet**, and other relevant information to reflect the new safety evidence

Despite these findings, the benefit-risk balance remains favourable when topiramate is used appropriately for epilepsy under specialist supervision.

New Safety Information

Topiramate is now contraindicated in:

- Women of childbearing potential unless Pregnancy Prevention Programme (PPP) requirements are met.
- Pregnant women for migraine prevention.
- Pregnant women with epilepsy, unless no safer alternative is available

Advice to Healthcare Professionals

- Avoid prescribing topiramate in pregnancy unless the benefits outweigh the risks.
- Do not use topiramate for migraine prevention during pregnancy.
- Perform pregnancy testing before starting treatment.
- Ensure women of childbearing potential use highly effective contraception during therapy and for four weeks after stopping topiramate. ([Refer to the product leaflet on the possible risk of Topiramate interaction with hormonal contraceptives](#)).
- Inform and counsel patients on potential risks to the unborn child and the need for pregnancy prevention.
- Refer women who become or plan to become pregnant while on topiramate for specialist advice.
- Review treatment annually for all women of childbearing potential taking topiramate or similar antiseizure medications.

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Advice for Patients and Caregivers

- Do not stop taking topiramate without telling your doctor or pharmacist first.
- Tell your doctor immediately if you are pregnant or planning to become pregnant.
- Use effective contraception while on treatment and for at least 4 weeks after stopping.
- Be aware that topiramate can harm an unborn baby's growth and development if taken during pregnancy.

All information about the safe use of medicines should be read together with the product information and patient information leaflet found in the box of each medical product.

REPORTING TOOLS

It is very important to report suspected adverse drug reactions (ADRs)



1. ADR Reporting Forms

- Download the forms from <https://www.bomra.co.bw/?s=reporting+form>
- Email the completed form to reportadr@bomra.co.bw



2. E-Reporting (Online Form)

- Use the Primary eReporting (who-umc.org) link on the BoMRA website
- Complete the online ADR reporting form



3. BRIMS Portal

- Access from: www.bomra.co.bw or directly at
- <https://brims.bomra.co.bw>



4. MedSafety App

- Download the MedSafety App
- Available on the Apple App Store and Google Play Store

5. Phone Reporting

- Call BoMRA directly at: 373 1727 / 373 1720

Need More Information?

For details about medicines or vaccines, contact the National Medicines Information Centre:

- nmic@bomra.co.bw
- 373 1788 / 373 1771