

**TEVA MIGRAINE PREGNANCY REGISTRY**  
**ADVERSE EVENTS AND SPECIAL SITUATIONS REPORT FORM**

IRB Approved at the  
 Protocol Level  
 Dec 23, 2020

Registry Phone Number: 833-927-2605    Registry Fax Number: 800-800-1052  
 301 Government Center Drive, Wilmington, NC 28403  
 TevaMigrainePregnancyRegistry@syneoshealth.com

Patient Name : _____ Patient ID #: _____  Form Completion Date: _____ <div style="text-align: center;">dd      mmm      yyyy</div>	For Office Use Only Data collected by phone: <input type="checkbox"/> Yes <input type="checkbox"/> No Date data received: _____ <div style="text-align: center;">dd      mmm      yyyy</div>
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**ALL ADVERSE EVENTS AND SPECIAL SITUATIONS MUST BE REPORTED:**

**SOME ADDITIONAL SPECIAL SITUATIONS THAT MUST BE REPORTED FOR PATIENTS TAKING MIGRAINE MEDICATIONS**

1. **Breastfeeding:** Suspected adverse reactions that occur in infants following exposure to a medicinal product from breast milk.
2. **Lack of efficacy:** Unexpected failure of a drug to produce the intended effect as determined by a previous scientific investigation.
3. **Transmission or suspected transmission of an infectious agent via a medicinal product:** Suspected transmission of infectious agents, any organism, virus, or "infectious particle." Relevant for biological products including vaccines (e.g., live attenuated vaccines) or blood products.
4. **Abuse of a medicinal product:** Persistent or sporadic, intentional excessive use of medicinal products that is accompanied by harmful physical or psychological effects [DIR2001/83/EC Art 1(16)].
5. **Medication error:** An unintended failure in the drug treatment process that leads to or has the potential to lead to harm to the patient.
6. **Misuse:**
  - a. Situations where the medicinal product is intentionally and inappropriately used not in accordance with the authorized product information.
  - b. Misuse for illegal purposes is misuse with the additional connotation of an intention of misusing the medicinal product to cause an effect in another person. This includes, among others: the sale, to other people, of medicines for recreational purposes and use of a medicinal product to facilitate assault.
7. **Off-label use:** Situations where a medicinal product is intentionally used for a medical purpose not in accordance with the authorized product information.
8. **Overdose:** Administration of a quantity of a medicinal product given per administration or cumulatively that is above the maximum recommended dose according to the authorized product information. Clinical judgement should always be applied.
9. **Occupational exposure to a medicinal product:** An exposure to a medicinal product (as defined in [DIR Art (1),(2)]) as a result of one's professional or non- professional occupation.
10. **Unexpected beneficial effect:** When a product improves a condition different from that for which it has been prescribed.

1. Adverse Event/Special Situation: \_\_\_\_\_
2. Start Date: \_\_\_\_\_ ☐ Unknown ☐ Not Applicable  

dd/mmm/yyyy

 Start Time: \_\_\_\_\_ ☐ AM ☐ PM ☐ Unknown ☐ Not Applicable  

hh/mm
3. End Date: \_\_\_\_\_ ☐ Ongoing ☐ Unknown ☐ Not Applicable  

dd/mmm/yyyy

 End Time: \_\_\_\_\_ ☐ AM ☐ PM ☐ Unknown ☐ Not Applicable  

hh/mm
4. Severity: ☐ Mild ☐ Moderate ☐ Severe ☐ Unknown ☐ Not Applicable

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5. Was The Event Serious? ☐ Yes    ☐ No    ☐ Not Applicable

6. Serious Adverse Event Due To:

- |  |  |
|--|--|
| <input type="checkbox"/> Death of Patient                            | <input type="checkbox"/> Life-Threatening                                |
| <input type="checkbox"/> Inpatient Hospitalization                   | <input type="checkbox"/> Prolongation of Hospitalization                 |
| <input type="checkbox"/> Congenital Anomaly/Birth Defect             | <input type="checkbox"/> Persistent or Significant Disability/Incapacity |
| <input type="checkbox"/> Important Medical Event (Medically Serious) | <input type="checkbox"/> Not Applicable                                  |

7. Death of Patient:

- ☐ Yes  
☐ No

Death Date: \_\_\_\_\_ ☐ Not Applicable  
dd/mm/yyyy

Autopsy Performed: ☐ Yes    ☐ Unknown  
☐ No    ☐ Not Applicable

Cause of Death: \_\_\_\_\_ ☐ Not Applicable

8. Hospitalization:

Admission Date: \_\_\_\_\_ ☐ Unknown    ☐ Not Applicable  
dd/mm/yyyy

Discharge Date: \_\_\_\_\_ ☐ Unknown    ☐ Not Applicable  
dd/mm/yyyy

9. Protocol Defined Adverse Event of Special Interest ☐ Yes    ☐ No    ☐ Not Applicable

- ☐ Severe Hypersensitivity Reaction  
☐ Moderate/Severe Ophthalmic Adverse Event  
☐ Anaphylaxis Related To Adverse Event

10. Relationship to Study Drug: ☐ Yes    ☐ No    ☐ Not Applicable

- ☐ Reasonable Possibility  
☐ No Reasonable Possibility

11. Additional Contributing Factors:

- ☐ Decreased Access Due To Medications/Health Care Provider And/Or Avoidance Of Seeking Medical Care  
☐ Other Reasons Due To Pre-Existing Medical Condition  
☐ None  
☐ Not Applicable

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12. Action Taken Regarding Study Medication:

- ☐ Dose Not Changed
- ☐ Dose Reduced
- ☐ Dose Increased
- ☐ Drug Interrupted
- ☐ Drug Withdrawn
- ☐ Unknown
- ☐ Not Applicable

13. If Suspect Drug Was Stopped, Was The Event Recovered?

- ☐ Yes
- ☐ No
- ☐ Not Applicable
- ☐ Unknown

14. If Suspect Drug Was Stopped And Restarted, Did The Event Reappear?

- ☐ Yes    Specify Product Name: \_\_\_\_\_
- ☐ No
- ☐ Not Applicable
- ☐ Unknown

15. Batch Number (all medications): \_\_\_\_\_

- ☐ Unknown
- ☐ Not Applicable

16. Outcome:

- ☐ Fatal
- ☐ Recovering/Resolving
- ☐ Recovered/Resolved With Sequelae
- ☐ Recovered/Resolved
- ☐ Not Recovered/Not Resolved
- ☐ Unknown
- ☐ Not Applicable

17. Treatment of Adverse Event:

- ☐ None
- ☐ Concomitant Medication
- ☐ Other- Specify \_\_\_\_\_
- ☐ Not Applicable

18. Did This Adverse Event Result In Discontinuation Of The Patient From The Study?

- ☐ Yes
- ☐ No
- ☐ Unknown
- ☐ Not Applicable

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19. Relevant Laboratory/Diagnostic Information

Test	Results (specify units and normal range)	Date (dd/mmm/yyyy)	Normal	Clinically Significant
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

20. Case Narrative (Please provide full details of the event):

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[NOT ENTERED IN REGISTRY DATABASE]

Provider's Signature \_\_\_\_\_

Date \_\_\_\_\_

Provider's Printed Name \_\_\_\_\_

dd                      Mmm                      yyyy

Name/Title of Person Completing Form If Other Than Provider \_\_\_\_\_