

Medicine Shortage Communication

<date>

<TOPAMAX® / TOPIMAX® / EPITOMAX® / TOPAMAC®> (topiramate, <presentation>, film-coated tablets): supply shortage

Dear Healthcare Professional,

Johnson & Johnson Innovative Medicine <affiliate to include country specific information to reflect global or local company name> is notifying healthcare professionals about a shortage of **<TOPAMAX® / TOPIMAX® / EPITOMAX® / TOPAMAC® (topiramate, <presentation>, film-coated tablets)>**.

Overview of situation

- **Following a routine assessment at a manufacturing site, a need to modify engineering controls and internal environmental technologies was identified, resulting in a temporary interruption of production and leading to a shortage.**
- **The shortage affects some of the EU countries where the product is marketed including Austria, Belgium, Croatia, Cyprus, Germany, Hungary, Italy, Netherlands, Portugal, Spain.**
- **This shortage is expected to continue through Q4 2026.**
- **The shortage is not due to any safety, efficacy or quality concerns with <TOPAMAX® / TOPIMAX® / EPITOMAX® / TOPAMAC®> (topiramate) film-coated tablets.**

Mitigation measures

In order to manage the shortage, Johnson & Johnson Innovative Medicine <affiliate to include country specific information to reflect global or local company name>". is engaging with the European Medicines Agency and the <National Competent Authority> on mitigation measures.

During the shortage, healthcare professionals should:

- **Where necessary, ensure that patients who are already taking <TOPAMAX® / TOPIMAX® / EPITOMAX® / TOPAMAC®> or for whom there are no suitable alternatives are prioritised for use of the available supply.**
- **Consider prescribing alternative medicines or formulations for new patients or where supply is unavailable. Depending on the indication and the patient's age, these may include, but are not limited to:**

- **Other Topiramate Formulations:** <generic topiramate tablets, topiramate hard capsules, topiramate sprinkle capsules or topiramate oral solutions>.
- **Other medicines that are currently approved for the same indications and patient groups.**
- **For additional information consult EMA's shortage catalogue, your country's shortage register (if available) or your national competent authority.**

Background on the shortage

<TOPAMAX® / TOPIMAX® / EPITOMAX® / TOPAMAC®> (topiramate) film-coated tablets, 25 mg, 50 mg, 100 mg and 200 mg, are indicated as per local labelling:

- <Monotherapy in adults, adolescents and children over 6 years of age with partial seizures with or without secondary generalised seizures, and primary generalised tonic-clonic seizures.>
- Adjunctive therapy in children aged 2 years and above, adolescents and adults with partial onset seizures with or without secondary generalisation or primary generalised tonic-clonic seizures and for the treatment of seizures associated with Lennox-Gastaut syndrome.
- In adults for the prophylaxis of migraine headache after careful evaluation of possible alternative treatment options. Topiramate is not intended for acute treatment.>

Following a routine assessment at a manufacturing site, a need to modify engineering controls and internal environmental technologies was identified, resulting in a temporary interruption of production and leading to a shortage.

These targeted modifications do not affect product quality or safety; there is no risk to products currently on the market or to finished inventory held for future distribution.

Johnson & Johnson is working with regulators and supply partners to restore supply as quickly as possible.

Call for reporting

<Please add language about safety and lack of efficacy reporting according to local regulations>

<Details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Yours faithfully,

[Insert medical affairs representative or regulatory affairs representative as appropriate with your local regulations]

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN		
Medicinal product(s)/active substance(s)	Topamax / Topimax / Epitomax / Topamac topiramate, 25 mg, 50 mg, 100 mg and 200 mg, film-coated tablets	
Marketing authorisation holder(s)	Johnson & Johnson Innovative Medicine <affiliate to include country specific information to reflect global or local company name>	
Purpose of the communication	To inform healthcare professionals about a shortage in supply affecting Member States.	
MSC recipients	Prescribing physicians (neurologists, neuropediatricians, psychiatrists, pedopsychiatrists, general practitioners), and pharmacists. The target group should be further defined at national level, in agreement with the respective national competent authority.	
Member States where the MSC will be distributed	In agreement with the national competent authorities.	
Timetable		Date
MSC and communication plan (in English) agreed by SPOC WP		7 May 2026
MSC and communication plan (in English) agreed by MSSG		28 May 2026
Submission of translated MSCs to the national competent authorities for review		12 June 2026
Agreement of translations by national competent authorities		According to the timelines set by NCAs
Dissemination of MSC		Within 10 business days after

MSC COMMUNICATION PLAN

respective national
competent
authorities
approval