Ipramax®
Topiramate

RISK AWARENESS FORM
PART A
PHYSICIAN COPY

Risk Awareness Form for female children and women who are able to become pregnant while treated with topiramate (PART A- Physician COPY)

Patient details		
Name of patient:		Date of birth:
Patient ID (or Hospital file number):		
Date:		

Part A- To be completed <and signed> by the treating physician. Use it with the healthcare guide.

- This form ensures patients and caregivers understand the risks of Topiramate during pregnancy.
- Fill it out at the start of treatment, annual reviews, and if pregnancy is planned or occurs.
- Keep a copy with the patient's name and ID, and caregiver's name if needed.

Part A- The need for Topiramate treatment for the patient named above has been evaluated. The following points have been discussed with the patient and/or their parent/caregiver:

☐ Risks to children exposed to topiramate during pregnancy	☐ Pregnancy test before treatment initiation (if the patient has already reached menarche)
☐ Need for highly effective contraception during treatment and 4 weeks after discontinuation	
☐ Importance to contact physician in case of (suspected) pregnancy	☐ Provision of patient guide/Card
☐ Importance of pregnancy planning	☐ Need for regular (at least annually) review by a specialist
IN CASE OF PREGNANCY:	
☐ Need for prenatal monitoring of the child	☐ Evaluation of alternative treatment or treatment change

- Report any suspected adverse reactions to the SFDA and Tabuk Pharmaceuticals (contact info on the packaging leaflet).
- This document is approved by the Saudi Food and Drug Authority (SFDA).

Name of physician:..... Name of Patient/Caregiver:.....

Signature:..... Signature:.....

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RISK AWARENESS FORM
PART B
PATIENT COPY

Risk Awareness Form for female children and women who are able to become pregnant while treated with topiramate (PART B – PATIENT COPY)

Part B- To be completed <and signed> by the Patient or Caregiver.

- Fill out this form with your doctor at the start of treatment, during annual visits, and if you are planning or are pregnant.
- This helps confirm you understand the risks of Topiramate during pregnancy.
- Keep a signed copy

Part A- I discussed the following with my doctor:

☐ Why I need Topiramate rather than another medicine.	☐ Why I need a negative pregnancy test before treatment with Topiramate is started.
☐ Topiramate can cause serious harm to an unborn baby if taken by a mother during pregnancy.	
☐ That I must use highly effective contraception without interruption during the entire duration of my treatment with Topiramate and for four weeks after stopping treatment.	
☐ That the doctor is informed as soon as a girl experiences her first period during treatment with Topiramate.	☐ Need for regular (at least annually) review by a specialist.
☐ The need to consult my doctor if I plan to become pregnant, to evaluate if it is possible to switch to alternative treatment before I stop my contraception.	☐ That I should promptly talk to my doctor if I think I am pregnant.
☐ I have received a copy of the patient guide/Card.	☐ Need for regular (at least annually) review by a specialist.
IN CASE OF PREGNANCY:	
☐ That I need appropriate monitoring of my unborn child.	

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- This document is approved by the Saudi Food and Drug Authority (SFDA).

Name of physician:.....

Signature:.....

Name of Patient/Caregiver:.....

Signature:.....

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