Topiramate▼ Pregnancy Prevention Programme

Annual Risk Awareness Form

Epilepsy

▼ *This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. You can talk to your doctor, pharmacist or nurse or you can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.*

Information for Patients

Topiramate is one of a range of effective medicines for the treatment of epilepsy. As with all medicines it has risks as well as benefits.

If you take topiramate when pregnant it can seriously harm the baby.

Children whose mothers take topiramate during pregnancy have a higher risk of:

- Being born with birth defects
- Having mental development and learning problems, such as autism spectrum disorder and attention deficit hyperactivity disorder (ADHD)
- Being smaller and weighing less than expected at birth.

Due to these risks, patients who can get pregnant must use effective birth control (contraception) at all times while taking topiramate. They must also follow the requirements of the Pregnancy Prevention Programme.

This Annual Risk Awareness Form is to make sure you or your "responsible person" are aware of the risks of taking topiramate during pregnancy. A responsible person may be a parent/legal guardian or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision. Your specialist will go through this form with you. You will receive a copy of the completed form – please keep the copy safe.

Information for the Specialist Prescriber

Topiramate should not be used in patients of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled. This form outlines the condition of the topiramate Pregnancy Prevention Programme and when these must be fulfilled. This form should be used to support and record the prescribing decision.

You must complete this form for **all patients of childbearing potential.** Step 1 is completed by you in discussion with the patient or their responsible person (if applicable). Step 2 is completed by you and the patient (or responsible person) – this part records the discussions about the risks associated with the use of topiramate during pregnancy and the measures needed to minimise those risks. Once completed, give a copy of the form to the patient (or responsible person) and store it in their medical notes. It should also be shared with all healthcare professionals listed in the table below.

WARNING: Prescribing topiramate to a patient of childbearing potential without the Pregnancy Prevention Programme conditions being fulfilled is contraindicated and represents an unlicensed use of topiramate. This is the case even when treatment is based on an informed choice made by the patient.

Name of patient:	**Patient's date of birth:**
Patient's NHS/CHI number:	**Patient's hospital number:**
Name and contact details of specialist prescriber:	**Role and unique identifier:**
Signature of specialist prescriber:	**Date of signature:**
Name and address of patient's GP:	
Date form completed:	

Step 1: Establish whether the patient is at risk of the reproductive harms of topiramate

- The risks apply to all patients who can get pregnant (from when first period occurs to menopause) and are taking any medicine containing topiramate.
- If there is a possibility of pregnancy, patients will need to follow the conditions of the Pregnancy Prevention Programme.
- If the potential for pregnancy may be subject to change (e.g. the patient has not had their first period), the risks should be discussed at subsequent annual reviews or sooner if their circumstances change.
- Patients who have not had their first period DO NOT need to follow the requirements of the Pregnancy Prevention Programme, but they and their responsible person need to be aware of the risks for the future. Provide a copy of the Patient Guide and remind the responsible person to contact their specialist or Prescriber to arrange for review of treatment as soon as the patient's first period occurs.

If you consider there is a compelling reason that indicates there is no potential for pregnancy, tick which reason applies and record here. In this event, step 2 does not need to be completed.

To be completed by the specialist prescriber when they consider the topiramate Pregnancy Prevention Programme (PPP) is not needed	
☐	The absence of pregnancy risk is permanent for the following reason (insert reason):
☐	There are other reasons that conditions of the topiramate Pregnancy Prevention Programme are not applicable (insert reason):
☐	The patient has not had their first period at the time of this appointment, I have asked the patient and their family to inform their prescriber if this changes before their next annual review
Signature of patient (or responsible person) to confirm PPP is not required at this time:	**Date:**

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Step 2: Explain the risks to the patient and document awareness

Specialist prescribers and patients (or responsible persons) must both complete this section of the form. This records that you have discussed the risks of taking topiramate during pregnancy and the measures needed to reduce the risks. The patient (or responsible person) must also sign the form to confirm they are aware of these risks.

Information to be discussed with the patient	Specialist Prescriber to initial to confirm you have discussed	Patient (responsible person) to initial to confirm you are aware
Their medication should be reviewed regularly (at least once a year). At this review, your specialist prescriber will decide with you whether topiramate continues to be the best treatment for you. This will take into account any change in your circumstances.		
Topiramate can cause serious harm to an unborn baby if taken by a mother during pregnancy. For babies of mothers who take topiramate while pregnant the risks are: • Around 4 to 9 babies in every 100 will have birth defects, this compares with 1 to 3 babies in every 100 born to mothers in the general population. • A 2-3 times higher risk of autism spectrum disorder, attention deficit hyperactivity disorder and intellectual disabilities compared with women without epilepsy not taking epilepsy medicines. • Around 18 in 100 babies will be born small for gestational age; this compares with around 5 in 100 babies of mothers in the general population.		
Need for a pregnancy test to exclude pregnancy before starting topiramate. Further pregnancy tests may be needed during treatment.		
Need to use effective birth control (contraception) at all times while taking topiramate and for four weeks after stopping topiramate.		
The importance of contacting their GP for referral to the specialist as soon as they are thinking about becoming pregnant. This is to make sure that there is time to switch to another treatment before the child is conceived and before birth control (contraception) is stopped.		
The need to contact their GP immediately, to be referred to the specialist for an urgent review of their treatment, if they think they may be pregnant.		
Risks of stopping topiramate for epilepsy without medical advice. They should not stop taking topiramate or change their dose unless they are told to do so by their specialist. This is because their condition may become worse, including an increase in seizures.		
A copy of the Patient Guide has been offered		
Signature of Specialist Prescriber:	**Date**	
Name of patient:		
Name of responsible person (if applicable):		
Signature of Patient (or responsible person, if applicable)	**Date:**	

MHRA approval date: 31 May 2024