Topiramate▼ Pregnancy Prevention Programme

Annual Risk Awareness Form

Prophylaxis of Migraine

▼ *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 prevention of migraine. 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
- Mental development and learning problems, such as autism spectrum disorder and attention deficit hyperactivity disorder
- Being smaller and weighing less than expected at birth (small for gestational age)

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 know about the risks of taking topiramate during pregnancy. Your healthcare professional will go through this form with you. You will receive a copy of the completed form – please keep the copy safe.

Information for the healthcare professional

Topiramate should not be used in patients of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled. This form outlines the conditions of the topiramate Pregnancy Prevention Programme and when these must be fulfilled. The 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. Step 2 is completed by you and the patient – 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 and store it in their medical notes.

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 healthcare professional:	**Role and unique identifier:**
Signature of healthcare professional:	**Date of signature:**
Name and address of patient's GP*:	
Date form completed:	

*** If applicable**

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 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 healthcare professional 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):
Signature of patient to confirm that PPP is not needed at this time	**Date**

Step 2: Explain the risks and document awareness

Healthcare professionals and patients 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 must also sign the form to confirm they are aware of these risks.

Information to be discussed with the patient	**Healthcare professional to initial to confirm you have discussed**	**Patient to initial to confirm you are aware**
Their medication should be reviewed regularly (at least once a year). At this review your healthcare professional 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 compared with 1 to 3 babies in 100 of mothers in the general population. • A 2-3 times higher risk of autism spectrum disorder, attention deficit hyperactivity disorder and intellectual disabilities compared with babies born to women without epilepsy not taking epilepsy medicines. • Around 18 babies in every 100 will be born small for gestational age compared with around 5 in every 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 during treatment with topiramate and for four weeks after stopping topiramate.		
The importance of discussing any plans for a pregnancy with their healthcare professional as soon as they are planning pregnancy to ensure timely discussion.		
In case of suspected or unplanned pregnancy, and patient is only taking topiramate to prevent migraine, they need to: • stop taking topiramate straight away. • contact their healthcare professional.		
A copy of the Patient Guide has been offered		
Signature of healthcare professional:	**Date**	
Signature of Patient:	**Date**	

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