

Annual Risk Awareness Form

Topamax▼ (topiramate) and Risks in Pregnancy

Part A: To be completed and signed by the treating doctor

This form is intended to facilitate the annual reassessment of your female patients, to make sure that female patients (or their parents/legal guardians*) have been fully informed about and understand the risks related to the use of topiramate during pregnancy.

- Complete this form with your patient at initiation, at annual review, when your patient plans a pregnancy or has become pregnant.
- This form should be used together with the healthcare professional guide, which contains detailed information.
- The completed form should be recorded according to local institutional practice. It is recommended that a copy is kept as part of the patient's medical record and a copy is provided to the patient.

Name of patient

MRN (if applicable)

The need for topiramate treatment has been evaluated for the above-named patient.

The following points have been discussed with the patient (and/or parent/legal guardian*):

- | | |
|--|--|
| <input type="checkbox"/> Tick | <input type="checkbox"/> Tick |
| <input type="checkbox"/> Risks to children exposed to topiramate during pregnancy | <input type="checkbox"/> Need for highly effective contraception throughout treatment and for at least 4 weeks after discontinuation |
| <input type="checkbox"/> (If applicable:) Risk of untreated epilepsy to mother and to an unborn child | <input type="checkbox"/> Importance of pregnancy planning |
| <input type="checkbox"/> Pregnancy test before treatment initiation (if the patient has already reached menarche) | <input type="checkbox"/> Importance of contacting her doctor immediately in case of (suspected) pregnancy |
| <input type="checkbox"/> Need for regular (at least annual) review by a doctor experienced in management of migraine or epilepsy | <input type="checkbox"/> Provision of Patient Guide [†] |

In case of pregnancy:

- | | |
|---|--|
| <input type="checkbox"/> Tick | <input type="checkbox"/> Tick |
| <input type="checkbox"/> Risks to children exposed to topiramate during pregnancy | <input type="checkbox"/> When used to prevent migraine: Importance of immediately stopping treatment. |
| <input type="checkbox"/> Need for prenatal monitoring of the baby | <input type="checkbox"/> Provision of Patient Guide [†] |
| <input type="checkbox"/> When used for epilepsy: Evaluation of alternative treatment options or treatment change | |

Name of doctor

Signature

Date

* For patients who are minors or without the capacity to make an informed decision.

[†] Patient Guide and patient card can be found online at www.hpra.ie by entering "Topamax" or topiramate in the 'Find a medicine' search box and then clicking on "EdM" next to any of the medicines that appear. It is also available on www.medicines.ie by searching for Topamax.

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Part B: To be completed and signed by the patient (or her parent / legal guardian*).

Read and complete this form during a visit with your doctor: at treatment start, at the annual visit, when you are planning a pregnancy or if you are pregnant. This is to make sure that you have discussed with your doctor and understand the risks related to the use of topiramate during pregnancy. Keep a copy of this form in case you want read to it again.

I have discussed the following points with my doctor and I understand:

Tick

- Why I need topiramate rather than another medicine.
- That children whose mothers take topiramate during pregnancy:
 - have a higher risk of birth defects (3-fold)
 - have a higher risk of being smaller and weigh less than expected at birth
 - may have a higher risk of developmental problems (2-3 fold)
- That I should visit a doctor regularly (at least annually) to review whether topiramate remains the best treatment option for me.
- (If you take topiramate for epilepsy:) That untreated epilepsy can also put me and my unborn child at risk.
- Why I need a negative pregnancy test before treatment with topiramate is started.
- The reasons why I must use highly effective contraception without interruption during the entire duration of my treatment with topiramate and for four weeks after stopping treatment.
- The need to consult my doctor if I plan to become pregnant and before I stop my contraception. This is to evaluate if it is possible to switch to another treatment.
- That I talk urgently with my doctor if I think I am pregnant.
- (If applicable) The need to consult her doctor as soon as she has her first periods during treatment with topiramate.
- I have received a copy of the Patient Guide.†

* For patients who are minors or without the capacity to make an informed decision.

† Patient Guide and patient card can be found online at www.hpra.ie by entering "Topamax" or topiramate in the 'Find a medicine' search box and then clicking on "EdM" next to any of the medicines that appear. It is also available on www.medicines.ie by searching for Topamax.

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In case of pregnancy, I have discussed the following points with my doctor and I understand:

Tick

The risks of topiramate use in pregnancy.

For patients with epilepsy: The options for switching treatment.

For patients with migraine: That I should stop treatment immediately.

That I need appropriate monitoring of my baby.

I have received a copy of the Patient Guide.†

Name of patient

Signature of patient

Date

If applicable, name of person signing with/on behalf of patient (parent/legal guardian*)

Name

Relationship to patient

Signature

Date

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