accord

ACH-TERIFLUNOMIDE PATIENT EDUCATION BROCHURE: CANADA

This patient education brochure is supplement to the patient card; it provides details on key safety risks for the patient.

Risk of haematological effects

ACH-TERIFLUNOMIDE may cause decreased white blood cells.

Patients should have their complete blood cell count checked by their healthcare provider before treatment and during treatment.

Patients should check for symptoms of decreased white blood cells such as infections, fatigue, fever, aches, pains and flu-like symptoms.

Risk of hypertension

ACH-TERIFLUNOMIDE may cause hypertension.

Patients should have their blood pressure checked by their healthcare provider before treatment and during treatment.

Patients should check for symptoms of hypertension such as shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations.

Risk of liver effects

ACH-TERIFLUNOMIDE may cause liver disorders. Severe liver injury including fatal liver failure occurred rarely in patients treated with teriflunomide. The risk for severe liver disorder may be increased if you take ACH-TERIFLUNOMIDE when you already have liver disease or if you are taking other drugs that affect the liver. Your healthcare professional should do blood tests to check your liver function:

- within 6 months before treatment initiation
- every month, for at least 6 months after you starting treatment

Patients should check for symptoms of liver effects such as yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite and contact their doctor immediately if any develop.

Risk of serious infections including progressive multifocal leukoencephalopathy (PML)

ACH-TERIFLUNOMIDE may cause serious infections.

Patients should contact their healthcare professional immediately if they have any signs or symptoms of an infection. Patients should also inform their healthcare professional if they are prescribed or taking any other medicines that affect the immune system.

Risk of birth defects

Do not take ACH-TERIFLUNOMIDE if you are pregnant. If used during pregnancy, ACH-TERIFLUNOMIDE may cause major birth defects and even death to your baby. Pregnancy must be avoided by using effective birth control when a man or woman is on ACH-TERIFLUNOMIDE. Continue birth control for two years after you stop taking ACH-TERIFLUNOMIDE to make sure your blood levels of ACH-TERIFLUNOMIDE are low enough. Your healthcare professional can prescribe a medicine to help lower your blood levels of ACH-TERIFLUNOMIDE more quickly. Your healthcare professional can inform you when it is safe to get pregnant or to father a child.

If you are a woman of childbearing age, you should have a pregnancy test before you start taking ACH-TERIFLUNOMIDE. If you become pregnant, are late starting your period or have any reason to suspect pregnancy while taking ACH-TERIFLUNOMIDE or within 2 years after stopping it, tell your healthcare professional right away.

If you become pregnant while taking ACH-TERIFLUNOMIDE, you or your healthcare professional can enroll you in the ACH-TERIFLUNOMIDE Pregnancy Registry Study. Information on this study is available at www.accordhealth.ca or is available by calling 1-866-296-0354.

Suspected adverse reactions should be reported to Accord Healthcare Inc at 1-866-296-0354 or at safety@accordhealth.ca.

Suspected adverse drug reactions (ADRs) can also be reported to the Health Canada at **https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.**

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.