

Depalept – Patient safety information card

The information in this patient safety information card is intended for women who have been prescribed Depalept and can become pregnant (are of childbearing age). Read this patient safety information card along with the patient insert within the drug's package and if you have any questions, consult a doctor or a pharmacist.

• **Keep the patient information safety card. You may have to read it again.**

Risks to the fetus

When taken by a pregnant woman Depalept may harm the fetus.

If you are a woman of childbearing age, the doctor shall prescribe Depalept for you only if no other drug can benefit you.

Before you receive a prescription for this drug, the doctor will explain to you what might happen to your baby if you become pregnant while taking Depalept.

If at a later stage you decide that you would like to become pregnant, do not stop taking your drug until you have discussed it with your doctor and have together decided on a plan to replace this drug with a different one, if possible.

It seems that when taken during pregnancy Depalept poses a higher risk compared to other anti-epileptic drugs, whether as monotherapy or with another anti-epileptic. The higher the dosage, the higher the risks, but there is a risk with any dosage.

The drug may cause severe congenital malformations and can interfere with the child's developmental process when he grows up.

Congenital malformations include *spina bifida* (when the bones in the spine do not develop correctly); face and skull abnormalities, heart, kidneys, urinary tract and genitalia abnormalities; limbs malformations.

If you take Depalept during pregnancy, you will be at a higher risk compared to other women for giving birth to a child with congenital malformations which require medical attention. Since Depalept has been used for many years, it is known that 11 out of 100 babies of women taking Depalept will suffer from congenital malformations, compared to 2-3 babies out of each 100 born among the rest of the population.

It is estimated that 30-40% of preschool-age children whose mothers took Depalept during pregnancy may suffer from developmental problems at the tender age. These children may suffer from a delay in starting to walk and talk, from lower intelligence and from difficulties in language and memory.

Autistic Spectrum Disorders and Childhood Autism are more often diagnosed in children exposed to Depalept, and there is some evidence that the children might be at an increased risk to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).

Before and during treatment with Depalept

• **You should ensure that you are using an effective contraceptive.**

• **Tell the doctor immediately if you are pregnant or think that you might be pregnant.**

Your doctor will explain to you the risks to the fetus, in case you become pregnant.

If you considering trying to become pregnant, do not stop taking Depalept or stop using a contraceptive until you have consulted with the doctor that prescribed the drugs for you. You should consult with your doctor as much in advance as possible before you become pregnant, so that you will be able to take several measures for your pregnancy to go as smoothly as possible and the risks to you and your fetus are reduced as much as possible.

The doctor may have to adjust Depalept's dosage or to substitute the therapy with another drug before you begin trying to become pregnant. If you become pregnant, you will be monitored very closely for treatment of your epilepsy/bipolar disorder as well as for following the development of your fetus.

Ask your doctor regarding taking folic acid while trying to become pregnant. Folic acid may reduce the risk for early termination which exists in any pregnancy and the risk for *spina bifida*.

However, it is unlikely that it will reduce the risk of congenital malformations associated with Depalept use.