Valproate Patient Information Leaflet

SANOFI

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PATIENT INFORMATION BOOKLET – VALPROATE / DEPAKINE®

The information in this booklet is for women who are being prescribed valproate and are able to get pregnant (of child-bearing age). Read this leaflet along with the patient information leaflet which comes in the medicine box and if you have any questions talk to your doctor or pharmacist.

There is a lot of information and it is recommended that you show this booklet to friends and family to help you discuss and understand your treatment. This booklet was last updated on (14/MAY/2015). Keep this booklet. You may need to read it again.

RISKS TO THE UNBORN CHILD

Valproate can be harmful to unborn children when taken by a woman during pregnancy.

Whether taken on its own or with another epilepsy medicine, valproate seems to carry a higher risk if taken during pregnancy than other epilepsy medicines. The higher the dose, the higher the risks but all doses carry a risk.

It can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects include spina bifida (where the bones of the spine are not properly developed); facial and skull malformations; heart, kidney, urinary tract and sexual organ malformations; limb defects.

If you take valproate during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. Because valproate has been used for many years we know that in women who take valproate around 10 babies in every 100 will have birth defects. This compares to 2-3 babies in ever 100 born to women who don't have epilepsy.

It is estimated that up to 30-40% of preschool children whose mothers took valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, intellectually less able than other children, and have difficulty with language and memory.

Autistic spectrum disorders and childhood autism are more often diagnosed in children exposed to valproate and there is some evidence children may be more likely to be at risk of developing symptoms of Attention Deficit Hyperactivity Disorder (ADHD).

Ask your doctor about taking folic acid when trying for a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it it unlikely that it will reduce the risk of birth defects associated with valproate use.

If you are a woman capable of becoming pregnant your doctor should only prescribe valproate for you if nothing else works for you.

Before prescribing this medicine to you, she or he will have explained what might happen to your baby if you become pregnant whilst taking valproate. If you decide later you want to have a child you should not stop taking your medicine until you have discussed this with your doctor and agreed a plan for switching you onto another product if this is possible.

FIRST PRESCRIPTION

If this is the first time you have been prescribed valproate your doctor will have explained the risks to an unborn child if you become pregnant. Once you are of childbearing age, you will need to make sure you use an effective method of contraception throughout your treatment. Talk to your doctor or family planning clinic if you need advice on contraception.

Key messages:

- **Make sure you are using an effective method of contraception**
- **Tell your doctor at once if you are pregnant or think you might be pregnant.**

CONTINUING TREATMENT AND NOT TRYING FOR A BABY

If you are continuing treatment with valproate but you don't plan to have a baby make sure you are using an effective method of contraception. Talk to your doctor or family planning clinic if you need advice on contraception.

Key messages:

- **Make sure you are using an effective contraception**
- **Tell your doctor at once if you are pregnant or think you might be pregnant.**

CONTINUING TREATMENT AND CONSIDERING TRYING FOR A BABY

If you are continuing treatment with valproate and you are now thinking of trying for a baby you must not stop taking either your valproate or your contraceptive medicine until you have discussed this with your prescriber. You should discuss with your doctor well before you become pregnant so that you can put several actions in place so your pregnancy goes as smoothly as possible and any risks to you and your unborn child are reduced as much as possible.

Your doctor may need to change the dose of valproate or switch you to another medicine before you start trying for a baby. If you become pregnant, you will be monitored very closely both for the management of your epilepsy/ bipolar disorder as well to check how your unborn child is developing.

Ask your doctor about taking folic acid when trying for a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it it unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:

- **Do not stop using your contraception before you have talked to your doctor and worked together on a plan to ensure your epilepsy/ bipolar disorder is controlled and the risks to your baby are reduced**
- **Tell your doctor at once when you know or think you might be pregnant.**

AN UNPLANNED PREGNANCY WHILST CONTINUING TREATMENT

Babies born to mothers who have been treated with valproate are at risk of birth defects and problems with early development which can be debilitating. If you are taking valproate and you think you are pregnant or might be pregnant contact your doctor at once. Do not stop taking your epilepsy/ bipolar disorder medicine until your doctor tells you to.

Ask your doctor about taking folic acid. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it it unlikely that it will reduce the risk of birth defects associated with valproate use.

Key messages:

- **Tell your doctor at once if you know you are pregnant or think you might be pregnant.**
- **Do not stop taking valproate unless your doctor tells you to.**

For side effect reporting:

To report any side effect, kindly contact Saudi Food & Drug Authority "SFDA" and/or SANOFI company through the following telephone numbers and e-mails:-

To report any side effect (s):

Saudi Food & Drug Authority "SFDA":-
National Pharmacovigilance and Drug safety Center (NPC)
Fax: + 966-11-205-7662
Tel.: +966-11-2038222 Ext.: 2356-2317-2354-2334-2340-2353
Toll-free: 8002490000
E-mail: npc.drug@sfda.gov.sa
Web: www.sfda.gov.sa/npc

SANOFI

Fax: + 966-11-4627914, + 966-12-6636191
Tel.: + 966-11-4633190, + 966-12-6693318
Mobile: + 966-54-428-4797
E-mail: ksa_pharmacovigilance@sanofi.com

If you have a question related to an emergency, please consult your doctor or the emergency unit
If you need further information or if you have a concern with personal health conditions, medical issues relate to Sanofi's prescription products, you should consult your healthcare professional.

"this medication is only prescribed under the strict supervisison of the doctors ,In case of the persistance, worseneing of the disease conditions or if you experience any side effects please contact your doctor or the emergency unit"