

VALPROATE* GUIDE FOR MALE PATIENTS

Read this guide along with the patient information leaflet
for complete product information

Valproate* (▼ Orfiril, Orfiril long, Orfiril retard)

What you should know

This guide contains key information about the potential risk of valproate* when used by male patients in the 3 months before conception of a child. Talk to your doctor or pharmacist if you have any questions.

KEEP THIS GUIDE. YOU MAY NEED TO READ IT AGAIN.

▼ This medicine is subject to special monitoring to detect new safety information as quickly as possible. You can contribute by reporting any incorrect side effects, see www.dmp.no/pasientmelding.

Information about the use of valproate in male patients can also be found online at felleskatalogen.no.*

*Valproate also known as Orfiril, Orfiril long, Orfiril retard.

What are the risks of taking valproate* when conceiving a child

A study suggests a possible risk of movement and mental developmental disorders (problems with early childhood development) in children born to fathers treated with valproate* in the 3 months before conception.

In this study, around 5 children in every 100 had such disorders when born to fathers treated with valproate*, as compared to around 3 children in every 100 when born to fathers treated with lamotrigine or levetiracetam (other medicines that can be used to treat your disease).

However, the study has limitations and therefore it is not entirely clear if the increased risk for movement and mental developmental disorders suggested by this study is caused by valproate*.

A wide range of movement and mental developmental disorders were investigated in the study. However, the study was not large enough to show which particular type of disorder children may be at risk of developing.

For example, problems with your child's movement and mental development as they grow up may include:

- Movement problems
- Lower intelligence than other children of the same age
- Poor speech and language skills
- Autism or autistic spectrum problems
- Attention Deficit and/or Hyperactivity Disorder

The risk for children born to fathers who stopped valproate* treatment 3 months (the time needed to form new sperm) or longer before conception is not known.

*Valproate also known as Orfiril, Orfiril long, Orfiril retard.

PLEASE REFER TO THE PATIENT INFORMATION LEAFLET FOR MORE DETAILED INFORMATION

What does this mean for me?

As a precautionary measure, your doctor will discuss with you the potential risk in children born to fathers treated with valproate* in the 3 months before conception.

Your doctor will also discuss with you:

- The need to consider **effective contraception** (birth control) for you and your female partner during valproate* use and for 3 months after stopping valproate* (the time needed for new sperm to be formed).
- The need to consult your doctor when you **are planning to conceive a child** and before stopping contraception (birth control).
- The possibility of **other treatments** that can be used to treat your disease, depending on your individual situation.

Do not donate sperm when taking valproate* and for 3 months after stopping valproate* treatment.

Talk to your doctor if you are thinking about having a baby.

If your **female partner becomes pregnant** while you used valproate* in the 3 months before conception and you have questions, **contact your doctor**.

Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may become worse.

You should **get regular appointments** with your prescriber.

During this visit your doctor will discuss with you the precautions associated with valproate* use and the possibility of other treatments that can be used to treat your disease, depending on your individual situation.

*Valproate also known as Orfiril, Orfiril long, Orfiril retard.

PLEASE REFER TO THE PATIENT INFORMATION LEAFLET FOR MORE DETAILED INFORMATION