

Reporting Adverse Events

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

In the United Kingdom, side effects can be reported to MHRA via the Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help us by providing more information on the safety of this medicine.

You may also report your pregnancy and any adverse event to medinfo.uk@merckgroup.com

PATIENT CARD

Pregnancy prevention measures if you are taking Ogsiveo▼ (nirogacestat)

This patient card is approved by the MHRA and fulfils the conditions of the Marketing Authorisation. Please also carefully read the patient information leaflet in your pack for further information.

Pregnancy risks and Pregnancy testing

- Nirogacestat may cause harm to an unborn baby, including loss of the pregnancy, if taken during pregnancy.
- Do not take nirogacestat if you are pregnant. If you can become pregnant, your doctor will check if you are pregnant before you start treatment with nirogacestat.

- You will also have pregnancy tests during your treatment if you have stopped having periods or have unusual menstrual bleeding.

Contraception requirements

- If you are a woman who can become pregnant or a man with a partner who can become pregnant, you must use at least one highly effective method of contraception (such as an intrauterine device) or two complementary forms of contraception including a barrier method (such as condoms in combination with spermicide) during treatment with nirogacestat and for 1 week after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.

If you think you are pregnant

- If you suspect that you may be pregnant, tell your doctor or nurse straight away. If you are pregnant, you must stop taking nirogacestat.

You should carry this card at all times.

Patient name:

Doctor Name and Contact: