

Package leaflet: Information for the patient

Ogsiveo 100 mg film-coated tablets

Ogsiveo 150 mg film-coated tablets

nirogacestat

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ogsiveo is and what it is used for
2. What you need to know before you take Ogsiveo
3. How to take Ogsiveo
4. Possible side effects
5. How to store Ogsiveo
6. Contents of the pack and other information

1. What Ogsiveo is and what it is used for

Ogsiveo is a medicine that contains the active substance nirogacestat which inhibits a protein called gamma-secretase. Gamma-secretase inhibitors treat cancer by stopping the activity of certain proteins that are involved in the growth of cancer cells.

Ogsiveo is used in adults to treat progressing desmoid tumours (soft tissue tumours that form in fibrous (connective) tissue, usually in the arms, legs or abdomen, that do not spread to other locations). It is used in adults who require treatment with a medicine given by mouth or injection (systemic therapy).

2. What you need to know before you take Ogsiveo

Do not take Ogsiveo:

- If you are allergic to nirogacestat or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant (see Pregnancy section below)
- If you are able to become pregnant and are not using highly effective contraception (birth control) (see Contraception in men and women section below).
- If you are breast-feeding (see Breastfeeding section below).

Warnings and precautions

Talk to your doctor or nurse if any of the following happen to you while you are taking Ogsiveo (see also section 4: Possible side effects).

- **If you experience severe diarrhoea or diarrhoea that lasts longer than two days** and does not respond to treatment, stop taking the medicine and seek medical advice straight away. Your doctor may pause treatment with Ogsiveo until your symptoms improve, give you other medicines, lower the dose or tell you to drink more fluids.
- **If you experience a rash** tell your doctor or nurse as soon as possible. Your doctor may give you a medicine to treat these or may pause treatment with Ogsiveo or lower the dose.
- **Ovarian problems.** You may experience symptoms such as hot flashes, night sweats, vaginal dryness and menstrual cycle changes, including irregular periods or no periods. These side effects went away in the majority of women while they were still on treatment and in all women who stopped taking Ogsiveo.

Examinations:

- Your doctor will do blood tests to check your electrolytes (salts) and liver function during treatment.
- **Skin cancers.** Certain types of skin cancer, called basal cell carcinoma and squamous cell carcinoma, have been reported in patients taking Ogsiveo. Your doctor should perform regular examinations of your skin during treatment with Ogsiveo. Tell your doctor or nurse if you have any new or changing skin lesions such as a small white or flesh coloured bump, a scaly red patch, an open sore, or a wart that may crust or bleed easily.

Children and adolescents

Do not give Ogsiveo to children and adolescents aged under 18 years as the safety and efficacy have not been established in this population. Ogsiveo may be detrimental to bone growth in growing children.

Other medicines and Ogsiveo

Tell your doctor if you are taking, have recently taken or might take any other medicines, including herbal medicines, while receiving Ogsiveo.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Clarithromycin, erythromycin - used to treat bacterial infections
- Itraconazole, ketoconazole, fluconazole - used to treat serious fungal infections
- Cyclosporine, tacrolimus - used to prevent transplant rejection
- Fostamatinib - used to treat low blood platelet count
- Ritonavir, atazanavir, efavirenz and etravirine - used to treat HIV infections/AIDS
- Diltiazem - used to treat high blood pressure and chest pain
- Hormonal contraceptives agents (birth control medicines) (see Contraception in men and women section below)
- Rifampicin - used to treat tuberculosis (TB)
- Carbamazepine, phenytoin, phenobarbital - used to treat epilepsy
- St. John's wort (*Hypericum perforatum*) - a herbal medicine used for depression
- Midazolam used for anaesthesia, sedation or to decrease anxiety
- Digoxin, dofetilide - used to treat heart conditions or correct irregular heartbeats
- Warfarin - used to thin your blood
- Antacids (short acting medicines containing minerals such as calcium, magnesium, aluminium or bicarbonate that neutralise the acid in your stomach) These medicines may interfere with

Ogsiveo absorption and reduce how well it works. Take Ogsiveo 2 hours before or 2 hours after taking the antacid.

- H2 blockers (such as famotidine and cimetidine), and proton pump inhibitors (such as omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole) - used to reduce acid in the stomach. These medicines may interfere with Ogsiveo absorption and reduce how well it works and you should not take these during treatment with Ogsiveo.

Ogsiveo with food and drink

Avoid consuming grapefruit and grapefruit juice when taking Ogsiveo as this may increase the likelihood and or severity of side effects.

Pregnancy

Do not take Ogsiveo if you are pregnant. If you can become pregnant, your doctor will check if you are pregnant before you start treatment with Ogsiveo. You will also have pregnancy tests during your treatment if you have stopped having periods or have unusual menstrual bleeding. If you suspect that you may be pregnant, tell your doctor or nurse straight away. If you are pregnant, you must stop taking Ogsiveo. Ogsiveo may cause harm to the unborn baby if taken during pregnancy.

Contraception in men and women

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 Ogsiveo and for 1 week after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.

Breast-feeding

It is not known if Ogsiveo passes into breast milk. Do not breast-feed during treatment with Ogsiveo and for 1 week after the last dose.

Fertility

Based on findings in animal studies, Ogsiveo may impair female and male fertility. There are no data concerning fertility in humans.

Women who can get pregnant should not donate eggs (oocytes) during treatment and for 1 week after the last dose of Ogsiveo.

Men should not donate sperm during treatment with Ogsiveo and for 1 week after the last dose.

Driving and using machines

Ogsiveo has no or negligible influence on the ability to drive or capacity to use machines, however, since fatigue and dizziness may occur in patients taking nirogacestat, exercise caution if you experience these side effects.

Ogsiveo contains lactose

Ogsiveo contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Ogsiveo contains sodium

Each film-coated tablet contains less than 23 mg sodium (main component of cooking/table salt). This means Ogsiveo is essentially sodium-free.

Ogsiveo contains sunset yellow FCF (E 110)

Ogsiveo contains sunset yellow FCF (E 110) which may cause allergic reactions.

3. How to take Ogsiveo

Always take this medicine exactly as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended dose is 150 mg to be taken two times a day, one dose in the morning and one dose in the evening.

Taking Ogsiveo

- Swallow the tablet whole.
- Do not break, crush or chew the tablet. The tablet can be taken with or without food.
- Do not consume grapefruit or grapefruit juice while taking Ogsiveo.
- If your doctor has told you to take antacid medicine, take Ogsiveo 2 hours before or 2 hours after taking the antacid (see section 2 “Other medicines and Ogsiveo”).

If you take more Ogsiveo than you should

If you have taken more tablets than you should, contact your doctor, pharmacist or nurse straight away. You may experience diarrhoea, nausea, vomiting, and nosebleeds.

If you forget to take Ogsiveo

Skip the missed dose and take your next dose at your regular time. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- **If you experience severe diarrhoea or diarrhoea that lasts longer than two days and does not respond to treatment, stop taking the medicine and seek medical advice straight away.** Very common (may affect more than 1 in 10 people).
- **If you experience a rash, small painful lumps in your groin, armpits, buttocks or under your breasts, or pimples around the base of your hairs, tell your doctor or nurse as soon as possible.** Very common (may affect more than 1 in 10 people).

Other side effects

Talk to your doctor if you get any of the following side effects:

Very common (may affect more than 1 in 10 people):

- nausea
- mouth sores or pain (stomatitis)
- dry mouth
- dry skin
- itchiness (pruritus)
- hair loss (alopecia)
- inflammation of hair follicles (folliculitis)
- low levels of phosphate (hypophosphataemia) and potassium seen in blood tests (hypokalaemia)
- headache
- dizziness
- changes in protein (proteinuria) and sugar levels in your urine (glycosuria)
- increase in the number of a type of white blood cells (eosinophilia)

- abnormal laboratory values for liver function (alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased)
- ovarian problems such as hot flashes, night sweats, vaginal dryness and menstrual cycle changes, including irregular periods or no periods (ovarian toxicity).
- cough
- upper respiratory tract (nose and throat) infections (upper respiratory tract infections)
- difficulty breathing (dyspnoea)
- nosebleeds (epistaxis)
- tiredness (fatigue)
- flu-like symptoms (influenza-like illness)

Common (may affect up to 1 in 10 people):

- painful skin condition that causes lumps and abscesses in areas with sweat glands, such as the groin and armpits (hidradentitis)
- skin cancer (basal cell carcinoma, squamous cell carcinoma). Symptoms may be small white or flesh coloured bump, a scaly red patch, an open sore, or a wart that may crust or bleed easily.
- kidney problems (renal tubular disorder)
- bone fracture

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Ogsiveo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Store this medicine below 25°C.

Do not throw away your medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ogsiveo contains

The active substance is nirogacestat (as nirogacestat dihydrobromide).

Ogsiveo 100 mg film-coated tablets

Each film-coated tablet contains 100 mg of nirogacestat (as nirogacestat dihydrobromide).

Ogsiveo 150 mg film-coated tablets

Each film-coated tablet contains 150 mg of nirogacestat, (as nirogacestat dihydrobromide).

The other ingredients are:

Core tablet: cellulose microcrystalline, lactose monohydrate, sodium starch glycolate, and magnesium stearate.

Coating: Macrogol polyvinyl alcohol graft copolymer (E 1209), talc (E553b), titanium dioxide (E171), glycerol monocaprylocaprate type 1/mono/diglycerides (E471), polyvinyl alcohol - partially

hydrolysed (E1203), FD&C yellow #6/sunset yellow FCF aluminium lake (E110), iron oxide yellow (E172)

See section 2 “Ogsiveo contains lactose, sodium and sunset yellow”.

What Ogsiveo looks like and contents of the pack

Ogsiveo 100 mg film-coated tablets are round and light orange, debossed with “100” on one side, and are 10 mm in diameter.

Ogsiveo 150 mg film-coated tablets are oval and yellow orange, debossed with “150” on one side, and are 8.5 x 17.5 mm in size.

The tablets are supplied in cartons containing 56 film-coated tablets in clear PVC/PVDC blisters containing 14 tablets per blister.

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