

Package leaflet: information for the patient

Varenicline Glenmark 0.5 mg film-coated tablets

Varenicline Glenmark 1 mg film-coated tablets

varenicline

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Varenicline Glenmark and what is it used for?

Varenicline Glenmark contains the active substance varenicline. Varenicline Glenmark is a medicine that can help adults stop smoking.

Varenicline Glenmark can relieve the craving for a cigarette and withdrawal symptoms associated with quitting smoking.

Varenicline Glenmark can also reduce the enjoyment of smoking cigarettes when you smoke during treatment.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

There have been reports of depression, suicidal thoughts and behavior, and suicide attempts in patients using varenicline. If you are using Varenicline Glenmark and

develop agitation, depressed mood, or behavioral changes that concern you or your family, you should stop using Varenicline Glenmark and contact your doctor immediately for an assessment of the treatment. This also applies if you are using Varenicline Glenmark and develop suicidal thoughts or behaviors.

The effects of quitting smoking

The changes in your body caused by quitting smoking, with or without treatment with Varenicline Glenmark, can change the way other medicines work. Therefore, in some cases, a dosage adjustment may be necessary. For details, refer to the section 'Are you using any other medicines?' below.

In some people, quitting smoking, with or without treatment, has been associated with an increased risk of experiencing changes in thinking or behavior, feelings of depression and anxiety, and may be associated with the worsening of a psychiatric illness. If you have a history of psychiatric illness, you should discuss this with your doctor.

Heart symptoms

New or worsening existing heart or blood vessel problems (cardiovascular problems) have mainly been reported in people who already have cardiovascular problems. Tell your doctor if you experience changes in your symptoms during treatment with Varenicline Glenmark. Seek immediate medical attention if you experience symptoms of a heart attack or stroke.

Seizures

Tell your doctor if you have had seizures before starting Varenicline Glenmark treatment. Some people have reported seizures while using varenicline.

Hypersensitivity reactions

Stop using Varenicline Glenmark and inform your doctor immediately if you experience any of the following signs and symptoms that may indicate a serious allergic reaction: swelling of the face, lips, tongue, gums, throat, or body and/or difficulty breathing, wheezing.

Skin reactions

Potentially life-threatening skin rashes (Stevens-Johnson syndrome and erythema multiforme) have been reported with the use of varenicline. If you develop a rash or if your skin begins to peel or blister, you should stop using Varenicline Glenmark and seek urgent medical attention.

Children and adolescents under 18 years

Varenicline Glenmark is not recommended for use in children, as efficacy has not been demonstrated.

Are you taking any other medicines?

If you are taking other medicines in addition to Varenicline Glenmark, have you recently done or is there a possibility that you will soon use other medicines? Then tell your doctor or pharmacist.

In some cases, due to quitting smoking, with or without Varenicline Glenmark, an adjustment of the dose of other medicines may be required. Examples include theophylline (a medicine for the treatment of respiratory problems), warfarin (a medicine to reduce blood clotting), and insulin (a medicine for the treatment of diabetes). Consult your doctor or pharmacist if you are unsure.

If you have a severe kidney disorder, you should avoid the simultaneous use of cimetidine (a medicine for the treatment of stomach problems) and Varenicline Glenmark, as this can cause high blood levels of varenicline.

The use of Varenicline Glenmark in combination with other treatments to quit smoking. Consult your doctor before using Varenicline Glenmark in combination with other treatments to quit smoking.

What should you pay attention to with food and drink?

There have been some reports of an increased toxic effect of alcohol in patients who use varenicline. However, it is not known whether varenicline actually worsens alcohol intoxication.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. It is preferable to avoid the use of Varenicline Glenmark when you are pregnant. Consult your doctor if you want to become pregnant.

Although it has not been studied, varenicline may be excreted in breast milk. You should ask your doctor or pharmacist for advice before taking Varenicline Glenmark.

Driving and using machines

Varenicline Glenmark may be associated with dizziness, drowsiness, and transient loss of consciousness. You should not drive, operate complex machinery, or engage in other potentially dangerous activities until you know whether this medicine affects your ability to perform these activities.

Varenicline Glenmark contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always take this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

You have a greater chance of quitting smoking if you are motivated to stop. Your doctor and pharmacist can advise, support, or provide further information to ensure your attempt to quit smoking will be successful.

Before starting your Varenicline Glenmark course, you usually need to choose a date in the second week of treatment (between day 8 and day 14) on which you will stop smoking. If you do not want to or are unable to set a planned stop date within 2 weeks, you can choose your own planned stop date within 5 weeks after starting the treatment. Write this date on the packaging as a reminder.

Varenicline Glenmark is supplied in white tablets (0.5 mg) and light blue tablets (1 mg). You start with the white tablets and then usually switch to the light blue tablets. The dosage instructions that you must follow from Day 1 are listed in the table below.

Week 1	Dosage
Day 1-3	From day 1 to day 3, you should take one white Varenicline Glenmark film-coated tablet of 0.5 mg once a day.
Day 4-7	From day 4 to day 7, you should take one white Varenicline Glenmark film-coated tablet of 0.5 mg twice a day, once in the morning and once in the evening, at approximately the same time each day.

Week 2	Dosage
Day 8-14	From day 8 to day 14, you should take one light blue Varenicline Glenmark film-coated tablet of 1 mg twice a day, once in the morning and once in the evening, at approximately the same time each day.

Week 3-12	Dosage
Day 15 - end of the treatment	From day 15 until the end of the treatment, you should take one light blue Varenicline Glenmark film-coated tablet of 1 mg twice a day, once in the morning and once in the evening, at approximately the same time each day.

If you have stopped smoking after 12 weeks of treatment, your doctor may advise you to undergo another 12 weeks of treatment with Varenicline Glenmark film-coated tablets of 1 mg twice daily, to help prevent you from starting to smoke again.

If you cannot or do not want to stop smoking immediately, you should reduce smoking during the first 12 weeks of treatment and stop at the end of that treatment period. You should then take one Varenicline Glenmark film-coated tablet of 1 mg twice daily for another 12 weeks for a total treatment duration of 24 weeks.

If you experience side effects that you cannot tolerate, your doctor may decide to temporarily or permanently reduce your dose to 0.5 mg twice daily.

If you have kidney problems, you should discuss this with your doctor before using Varenicline Glenmark. You may need a lower dosage.

Varenicline Glenmark is for oral use.

The tablets should be swallowed whole with water and can be taken with or without food.

The bottle contains a desiccant. Do not swallow the desiccant!

Have you used too much of this medicine?

If you accidentally take more Varenicline Glenmark than your doctor has prescribed, you should seek medical help immediately or go to the emergency department of the nearest hospital. Take the box of tablets with you.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose. It is important that you take Varenicline Glenmark regularly at the same time of day. If you forget to take a dose, take it as soon as you remember. If it is 3-4 hours before your next dose, do not take the missed tablet.

If you stop using this medicine

Clinical studies have shown that your chances of quitting smoking increase when you take all doses of your medication at the correct times and for the recommended duration of treatment as described above. Therefore, it is important to continue taking Varenicline Glenmark according to the instructions described in the table above, unless your doctor tells you to stop the treatment.

In the treatment for smoking cessation, the risk of relapse to smoking may be increased in the period immediately after stopping the treatment. You may temporarily experience increased irritability, a tendency to smoke, depression, and/or sleep disorders when you stop taking Varenicline Glenmark. Your doctor may decide to gradually reduce your Varenicline Glenmark dosage at the end of the treatment.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them.

Quitting smoking, with or without treatment, can cause various symptoms. These symptoms may include mood swings (such as feeling depressed, irritable, frustrated, or anxious), insomnia, difficulty concentrating, decreased heart rate, and increased appetite or weight gain.

You should be aware of the possible occurrence of serious neuropsychiatric symptoms such as agitation, depressed mood, or behavioral changes during an

attempt to quit with or without Varenicline Glenmark, and you should contact your doctor or pharmacist if you experience these symptoms.

Serious side effects sometimes or rarely occurred in people trying to quit smoking with Varenicline Glenmark: seizure, stroke, heart attack, suicidal thoughts, loss of contact with reality and inability to think clearly or judge (psychosis), changes in thinking or behavior (such as aggression and abnormal behavior). Serious skin reactions have also been reported such as erythema multiforme (a type of skin rash) and Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, around the eyes, or genitals) and severe allergic reactions including angioedema (swelling of the face, mouth, or throat).

- Very common: occur in more than 1 in 10 users
 - o Inflammation of the nose and throat, abnormal dreams, sleep problems, headache
 - o Nausea

- Common: occur in less than 1 in 10 users
 - o Chest infection, inflammation of the sinuses (sinusitis)
 - o Weight gain, decreased appetite, increased appetite
 - o Drowsiness, dizziness, changes in taste
 - o Shortness of breath, cough
 - o Heartburn, vomiting, constipation, diarrhea, bloating, abdominal pain, toothache, indigestion, flatulence, dry mouth
 - o Rash, itching
 - o Joint pain, muscle pain, back pain
 - o Pain on the chest, fatigue

- Sometimes: occur in less than 1 in 100 users
 - o Fungal infection, viral infection
 - o Panic attack, difficulty thinking, restlessness, mood swings, depression, anxiety, hallucinations, changes in sexual desire (libido changes)
 - o Epileptic seizure, tremor, slowness, less sensitive to touch
 - o Conjunctivitis, eye pain
 - o Tinnitus
 - o Tight, painful feeling in the chest (angina pectoris), rapid heartbeat palpitations, accelerated heart rate
 - o Increased blood pressure, hot flush
 - o Inflammation of the nose, sinuses, and throat, blocked nose, throat and lungs, hoarseness, hay fever, throat irritation, blocked sinuses, excessive nasal mucus discharge which
 - o coughing causes, runny nose
 - o Red blood in stool, irritated stomach, change in bowel habits, belching, mouth ulcers, painful gums
 - o Redness of the skin, acne, increased sweating, night sweats
 - o Muscle cramps, painful chest wall

- o Abnormally frequent urination, nighttime urination
 - o Increased menstrual volume
 - o Breast complaints, flu-like illness, fever, feeling weak or unwell
 - o High blood sugar level
 - o Heart attack
 - o Suicidal thoughts
 - o Changes in thinking or behavior (such as aggression)
- Rare: occur in less than 1 in 1000 users
- o Excessive thirst
 - o Feeling unwell or unhappy, slowed thinking
 - o Stroke
 - o Increased muscle tension, difficulty speaking, difficulty with coordination, reduced taste, altered sleep pattern
 - o Disturbed vision, discoloration of the eyeball, dilated pupils, sensitivity to light, nearsightedness, watery eyes
 - o Irregular heartbeat or arrhythmias
 - o Sore throat, snoring
 - o Blood in vomit, abnormal stools, coated tongue
 - o Stiff joints, pain in the rib area
 - o Sugar in urine, more frequent urination
 - o Vaginal discharge, change in sexual performance
 - o Feeling cold, cyst
 - o Diabetes
 - o Sleepwalking
 - o Loss of contact with reality and inability to think clearly or judge (psychosis)
 - o Abnormal behavior
 - o Severe skin reactions such as erythema multiforme (a type of skin rash) and Stevens-Johnson syndrome (a serious disease with blistering of the skin, mouth, around the eyes, or genitals)
 - o Severe allergic reactions including angioedema (swelling of the face, mouth, or throat)
- Not known:
- o Transient loss of consciousness

The reporting of side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via: the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You will find it on the blister pack or box after EXP. It includes a month and a year. The last day of that month is the expiry date.

This medicine does not require any special storage conditions.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is varenicline.
- Each film-coated tablet of 0.5 mg contains 0.5 mg varenicline (as tartrate).
- Each film-coated tablet of 1 mg contains 1 mg varenicline (as tartrate).
- The other substances in this medicine are:

Tablet core – Varenicline Glenmark 0.5 mg and 1 mg film-coated tablets

Ascorbic acid

Microcrystalline cellulose

Anhydrous dibasic calcium phosphate

Sodium croscarmellose

Colloidal anhydrous silica

Magnesium stearate

Tablet coating – Varenicline Glenmark 0.5 mg film-coated tablets

Hypromellose

Titanium dioxide (E171)

Macrogol 400

Tablet coating – Varenicline Glenmark 1 mg film-coated tablets

Hypromellose

Titanium dioxide (E171)

Macrogol 400

Indigo carmine aluminum lake (E132)

What does Varenicline Glenmark look like and how much is in a package?

- Varenicline Glenmark 0.5 mg film-coated tablets are white to off-white, film-coated, capsule-shaped, biconvex film-coated tablets, with the inscription "0.5" on one side and blank on the other side.
- Varenicline Glenmark 1 mg film-coated tablets are light blue, capsule-shaped, biconvex film-coated tablets, with the inscription "1.0" on one side and blank on the other side.

Varenicline Glenmark is available in the following packages:

Varenicline Glenmark 0.5 mg film-coated tablets

- Bottle, with a child-resistant closure and desiccant (silica) canister, in a box, with 56 film-coated tablets.
- Blister packs in a package with 28 or 56 film-coated tablets in a wallet.
- Blister packs in a package with 11 or 56 film-coated tablets in a box.

Varenicline Glenmark 1.0 mg film-coated tablets

- Bottle, with a child-resistant closure and desiccant (silica) canister, in a box, with 56 film-coated tablets.
- Blister packs in a package with 28 or 56 film-coated tablets in a card (wallet).
- Blister packs in a package with 28, 42, 56, 112, or 140 film-coated tablets in a box.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder
Glenmark Arzneimittel GmbH
Industriestrasse 31
D-82194 Gröbenzell
Germany

Manufacturer
Combino Pharm Malta, Ltd.
HF60 Hal Far Industrial Estate
Birzebbugia BBG3000
Malta

Registered under:

RVG 132947 Varenicline Glenmark 0.5 mg film-coated tablets
RVG 132948 Varenicline Glenmark 1 mg film-coated tablets

This medicine is registered in member states of the European Economic Area under the following names:

Germany:	Vareniclin Glenmark 0.5 mg Filmtabletten Vareniclin Glenmark 1 mg Filmtabletten
Finland:	Varenicline Glenmark 0.5 mg tablet, film-coated Varenicline Glenmark 1 mg tablet, film-coated
Malta:	Varenicline Glenmark 0.5 mg film-coated tablets

Netherlands:	Varenicline Glenmark 1 mg film-coated tablets Varenicline Glenmark 0.5 mg film-coated tablets
Czech Republic:	Varenicline Glenmark 1 mg film-coated tablets Varenicline Glenmark Varenicline Glenmark
Sweden:	Varenicline Glenmark 0.5 mg film-coated tablet Varenicline Glenmark 1 mg film-coated tablet

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Transtoyou