

VARENICLINE SANDOZ®

Varenicline citrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Varenicline Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Varenicline Sandoz against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Varenicline Sandoz is used for

Varenicline Sandoz is a medicine to help adults stop smoking. It can help to reduce craving and withdrawal symptoms that may happen while you stop smoking.

People giving up smoking are often affected by nicotine withdrawal. Symptoms of nicotine withdrawal can include craving for tobacco, irritability, frustration, feeling angry, sleep problems, depressed mood, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, increased appetite or weight gain. Not everybody is affected by symptoms of nicotine withdrawal.

Although it is not recommended that you smoke after your quit date, Varenicline Sandoz will reduce your

enjoyment of cigarettes if you do smoke while on treatment.

How Varenicline Sandoz works

Varenicline Sandoz contains the active ingredient varenicline and works by blocking the effects of nicotine in your body. There are receptors for nicotine in the brain. When cigarette smoke is inhaled, nicotine attaches to these receptors. This sends a message to a different part of the brain to release a chemical called dopamine. Dopamine gives a feeling of pleasure which only lasts for a short time. The body wants to repeat this feeling reinforcing the need to keep smoking. It is believed that Varenicline Sandoz works by activating these receptors and blocking nicotine from attaching to them. Varenicline Sandoz does not contain nicotine and it is not addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Varenicline Sandoz is only available with a doctor's prescription.

Use in children

Available information does not support the use of this medicine in children under the age of 18 years.

Deciding to stop smoking

Varenicline Sandoz helps you give up smoking. Other things you need include:

- willpower
- a quit plan
- support from your family and friends
- counselling, advice or additional support
- changes in your behaviour, so you avoid situations where you are likely to smoke.

Most people are unable to quit smoking without support. Your doctor and pharmacist can give you advice, support and sources of information to help you stop smoking. You can also get free advice and support from Quitline by calling 0800 778 778 or online at www.quit.org.nz.

Before you take Varenicline Sandoz

When you must not take it

Do not use Varenicline Sandoz if you have an allergy to:

- any medicine containing varenicline citrate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Varenicline Sandoz after the expiry date printed on the

pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor if you are not sure whether you should take this medicine.

Before you start to take it

Tell your doctor if you have or have had feelings of low mood, anxiety, disturbances in thinking, emotional reactions or behaviour that has interfered or interferes with your everyday life.

For some people, stopping smoking, with or without treatment, has been associated with changes in behaviour, thinking or mood that are not typical for them e.g. developing suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion.

Some people had these symptoms when they began taking varenicline, and others developed them after several weeks of treatment or after stopping varenicline.

Your family, friends, or carers should be asked to monitor any changes in your behaviour, thinking or mood that are not typical for you e.g. if you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion.

Discuss with your doctor the benefits and risks of taking Varenicline Sandoz to decide if it is right for you.

Tell your doctor if you have or have had any of the following medical conditions:

- **mental health conditions such as depression, thoughts of suicide or self-harm**
- **kidney problems**
- **repeated fits or convulsions (epilepsy)**

Some people have reported convulsions or fits while taking varenicline

- **heart and blood vessel problems such as heart attack, chest pain or stroke.**

Tell your doctor if you are pregnant, become pregnant or are breast-feeding.

- it is not recommended that you take Varenicline Sandoz while you are pregnant or breast-feeding
- if you plan to become pregnant, your treatment should be timed so that you have completed the course before becoming pregnant.

If you have not told your doctor about any of the above, tell him/her before you start taking Varenicline Sandoz.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you can buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

This includes other medicines to help you stop smoking such as:

- nicotine replacement therapy (NRT), which includes patches, gum, lozenges, sublingual tablets and inhalers (such as Nicorette, Nicabate, QuitX)
- bupropion (e.g. Zyban).

Taking Varenicline Sandoz in combination with other smoking cessation therapies is not recommended.

The safety and benefits of taking Varenicline Sandoz in combination with other medicines to stop smoking have not been studied.

Tell your doctor or pharmacist if you are being treated with the following:

- insulin
- theophylline, a medicine used to treat asthma
- warfarin, a medicine used to thin the blood

The effects of changes in your body resulting from stopping smoking, with or without Varenicline Sandoz, may alter the way these medicines work. In some cases, an adjustment of dose may be necessary.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Varenicline Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to start

There are 3 ways to quit smoking with Varenicline Sandoz:

1. Choose a quit date when you will stop smoking.

- **Make a note of this date. You can write this date on the carton of the Initiation Pack as a reminder.**
- **Start taking Varenicline Sandoz 1 to 2 weeks (7 to 14 days) before your quit date.**
- You can keep smoking during this time
- **Make sure that you try to stop smoking on your quit date. If you slip-up and smoke, try again.**

2. Start taking Varenicline Sandoz.

- Choose a quit date when you will stop smoking between days 8 and 35 of starting Varenicline Sandoz,
- Make a note of this date. You can write this date on the carton of the Initiation Pack as a reminder.
- Make sure that you try to stop smoking on your quit date. If you slip-up and smoke, try again.

3. Start taking Varenicline Sandoz.

- Reduce the number of cigarettes you smoke each day during the first 12 weeks of taking Varenicline Sandoz.
- Stop smoking on the last day of the 12 week treatment period.-This is your quit date
- Continue taking Varenicline Sandoz 1 mg tablets for a further 12 weeks.

How much to take

Start with the white 0.5 mg tablet and then increase the dose up to the light blue 1 mg tablet.

Starting with a low dose helps your body get used to Varenicline Sandoz.

If you have severe kidney disease your doctor may prescribe a different dose.

The usual dosage instructions are listed below.

- Days 1-3: Take one white 0.5 mg tablet once a day.
- Days 4-7: Take one white 0.5 mg tablet in the morning and one in the evening.
- Weeks 2-4: Take one light blue 1 mg tablet in the morning and one in the evening.
- Weeks 5-12: Take one light blue 1 mg tablet in the morning and one in the evening.
- Weeks 13-24: Take one light blue 1 mg tablet in the morning and one in the evening.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

This will have the best effect and help you remember when to take it.

It does not matter if you take Varenicline Sandoz before or after food.

Some people find it helpful to take varenicline with food.

How long to take it

If options 1 or 2 are the selected way to quit smoking, take Varenicline Sandoz for 12 weeks.

Your doctor may advise you to take Varenicline Sandoz for a further 12 weeks after your first treatment. This may increase your chances of stopping in the long term.

If option 3 is the selected way to quit smoking, take Varenicline Sandoz for 12 weeks.

You must then take Varenicline Sandoz for an additional 12 weeks (24 weeks in total).

If you do not stop smoking during the first 12 weeks of treatment or if you start smoking again after treatment, you can make another attempt to stop smoking.

However, before you make another attempt, you should try to understand the reasons why your attempt to stop smoking failed, so that your next attempt has a better chance of success.

If you forget to take it

If it is less than 6 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or contact the Poisons Information Centre for advice (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Varenicline Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Take your tablets with you to hospital.

While you are taking Varenicline Sandoz

Make sure you try to stop smoking on your quit date.

If you slip up and smoke, try again.

Things you must do

Stop taking Varenicline Sandoz and tell your doctor immediately if you or your family, friends or carers notice agitation, hostility, depression or changes in behaviour, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion.

All mentions of suicide or violence must be taken seriously. These are very serious side effects. You may need urgent medical attention or hospitalisation.

It is not known whether these changes are related to Varenicline Sandoz as it is known that mood

changes can also be due to the effects of stopping smoking.

If you have existing heart or blood vessel problems, tell your doctor as soon as possible if you notice any changes in symptoms while taking Varenicline Sandoz.

Your doctor may check your blood pressure and blood glucose levels from time to time to make sure you have not developed any unwanted side effects.

It is important to keep all of your doctor's appointments so that your progress can be checked.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Varenicline Sandoz.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not take Varenicline Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they are also trying to stop smoking.

Things to be careful of

Be careful driving or operating machinery until you know how Varenicline Sandoz affects you.

Varenicline Sandoz may cause dizziness, sleepiness, blackouts, seizures or difficulty concentrating in some people. You should not drive, operate complex machinery or do anything else that could be dangerous until you know whether this medicine

affects your ability to perform these activities.

Be careful if drinking alcohol while you are taking this medicine.

There have been reports of increased feelings of being drunk while taking varenicline. Drinking alcohol while taking Varenicline Sandoz may also increase your risk of experiencing changes to your behaviour, thinking or mood that are not typical for you e.g. developing suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Varenicline Sandoz.

Giving up smoking with or without treatment can cause various symptoms. These could include changes of mood, sleeplessness, difficulty concentrating, decreased heart rate, increased appetite or weight gain. This medicine helps many people give up smoking, but it may have unwanted side effects in some people. All medicines can have side effects. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Stop taking Varenicline Sandoz if...

Stop taking Varenicline Sandoz and tell your doctor immediately if you or your family, friends or carers notice agitation, hostility, depression or changes in behaviour, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations,

hallucinations, paranoia or confusion.

Some people have had changes in behaviour, thinking or mood that are not typical for them when they start taking varenicline. These may include suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion.

These symptoms have occurred in people with previous mental health problems, as well as those with no previous history.

Tell your doctor if...

Tell your doctor or pharmacist if you have nausea (feel sick) while taking Varenicline Sandoz and it worries you.

Around 3 in 10 people experience nausea, usually starting in the first week. Most people who have nausea are able to keep taking the medicine. Some people find it helpful to take Varenicline Sandoz with food.

Ask your doctor or pharmacist for advice if you notice any of the following and they worry you:

- stomach or bowel problems
 - constipation
 - diarrhoea
 - feeling bloated
 - indigestion
 - wind
 - nausea, vomiting
 - stomach discomfort
- dry mouth, toothache
- headache
- dizziness
- sleep problems
 - difficulty sleeping
 - sleepiness
 - abnormal dreams
 - sleep walking
- feeling tired, fatigue
- signs and symptoms of a cold
- change in appetite, weight gain
- changes in taste
- muscle or joint pain.

These are the more common side effects of varenicline. They are usually mild.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- trembling, fits or convulsions
- problems with your vision or pain in your eyes
- red blood in stools
- stomach pain
- excessive thirst, having a dry mouth and skin, pass large amounts of urine.

This list includes serious side effects which may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital and stop taking Varenicline Sandoz if you experience any of the following:

- self-harm or thoughts of self-harm
- changes in behaviour, thinking or mood that are not typical for you e.g. if you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion
- rash or sudden severe itchy swellings on the skin
- severe painful red blisters on the skin with chills, fever, aching muscles and generally feeling unwell
- breathing problems
 - wheezing
 - difficulty breathing
 - shortness of breath
- swelling of the face, lips, mouth, tongue, throat, hands or feet
Some people have reported swelling of parts of their face and body after taking varenicline.
- chest pain, which may spread to the neck and shoulders, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech or loss of speech, collapse
- abnormal or fast heartbeat
- blood in vomit

This list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Very serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people. Some of these side effects (for example, changes in blood pressure or blood sugar levels) can only be found when your doctor does tests to check your progress.

After taking Varenicline Sandoz

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Varenicline Sandoz or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return your unwanted medicines to your pharmacy for safe disposal.

Your doctor may tell you to stop taking this medicine or the expiry date may have passed.

Product description

What it looks like

Varenicline Sandoz is available in 2 strengths:

- Varenicline Sandoz 0.5 mg tablets are white, capsule shaped film-coated, debossed with “0.5” on one side and plain on other side.
- Varenicline Sandoz 1 mg tablets are light blue, capsule shaped film-coated, debossed with “1.0” on one side and plain on the other side.

Packs Available

The following packs are available:

- Initiation pack to start treatment, contains 11 x 0.5 mg tablets and 42 x 1 mg tablets
- Continuation pack containing 56 x 1 mg tablets to continue treatment.

Ingredients

Active Ingredients

Varenicline Sandoz 0.5 mg tablets contain the equivalent of 0.5 mg of varenicline.

Varenicline Sandoz 1 mg tablets contain the equivalent of 1 mg of varenicline.

Inactive Ingredients

Each tablet of Varenicline Sandoz contains the following inactive ingredients:

- Microcrystalline cellulose
- Pregelatinised starch
- Propyl gallate
- Citric acid
- Magnesium stearate
- Opadry Blue (1 mg tablet) or Opadry White (0.5 mg tablet)

Supplier

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