

PHARMACOR VARENICLINE

Varenicline tartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PHARMACOR VARENICLINE.

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 PHARMACOR VARENICLINE 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 PHARMACOR VARENICLINE is used for

PHARMACOR VARENICLINE contains the active ingredient varenicline tartrate.

PHARMACOR VARENICLINE is used 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, PHARMACOR VARENICLINE will reduce your enjoyment of cigarettes if you do smoke while on treatment.

How PHARMACOR VARENICLINE works

PHARMACOR VARENICLINE 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 PHARMACOR VARENICLINE works by activating these receptors and blocking nicotine from attaching to them. PHARMACOR VARENICLINE 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.

PHARMACOR VARENICLINE is only available with a doctor's prescription.

Use in children

Available information does not support the use of this medicine in children and adolescents under the age of 19 years.

Deciding to stop smoking

PHARMACOR VARENICLINE helps you give up smoking. Other things you need include:

- willpower
- a quit plan
- support from your family and friends or carers
- 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 PHARMACOR VARENICLINE

When you must not take it

Do not use PHARMACOR VARENICLINE if:

1. You are allergic to varenicline tartrate, or 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.

Always check the ingredients to make sure you can use this medicine.

Do not take PHARMACOR VARENICLINE after the expiry date printed on the pack or if the packing 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 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 PHARMACOR VARENICLINE, and others developed them after several weeks of treatment or after stopping PHARMACOR VARENICLINE.

Your family and friends 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 PHARMACOR VARENICLINE to decide if it is right for you.

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

- **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 PHARMACOR VARENICLINE

- **heart and blood vessel problems such as heart attack, chest pain or stroke.**
- **take any medicines for any other condition**
- **have allergies to any other medicines, foods preservatives or dyes.**

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

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under section 6. Are there any side effects?

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

- It is not recommended that you take PHARMACOR VARENICLINE while you are pregnant or breast feeding.

Check with your doctor if you are pregnant or intend to become pregnant.

- if you plan to become pregnant, your treatment should be timed so that you have completed the course before becoming pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Taking other medicines

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

supplements that you buy without a prescription from your pharmacy, supermarket 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 PHARMACOR VARENICLINE in combination with other smoking cessation therapies is not recommended.

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

The effects of changes in your body resulting from stop smoking, with or without PHARMACOR VARENICLINE, may alter the way some medicines work.

These medicines include:

- Insulin
- Theophylline, a medicine used to treat asthma
- Warfarin, a medicine used to thin the blood.

In some cases, an adjustment of dose may be necessary.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PHARMACOR VARENICLINE.

How to take PHARMACOR VARENICLINE

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 PHARMACOR VARENICLINE:

Option 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 PHARMACOR VARENICLINE 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.**

Option 2

- **Start taking PHARMACOR VARENICLINE.**
- **Choose a quit date when you will stop smoking between days 8 and 35 of starting PHARMACOR VARENICLINE.**
- **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.**

Option 3

- **Start taking PHARMACOR VARENICLINE.**
- **Reduce the number of cigarettes you smoke by half during the first 4 weeks (weeks 1-4)**
- **Reduce by half again the number of cigarettes you smoke in the next 4 weeks (weeks 5-8)**
- **Aim to have stopped smoking on the last day of 12 week treatment period. This is your quit date.**
- **Continue taking**

**PHARMACOR
VARENICLINE 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 PHARMACOR VARENICLINE.

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

The usual dose 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.

Follow the instructions provided and use PHARMACOR VARENICLINE until your doctor tells you to stop.

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 PHARMACOR VARENICLINE before or after food.

Some people find it helpful to take PHARMACOR VARENICLINE with food.

How long to take it

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

- Your first pack of PHARMACOR VARENICLINE will cover your first four weeks of treatment.
- Visit your doctor before the end of the fourth week that you take PHARMACOR VARENICLINE for a check-up and for a new prescription.
- At this appointment, your doctor will check your progress and give you a new prescription for the tablets you need to complete your treatment.
- Visit your doctor before the end of the eleventh week for a check-up.
- Your doctor may advise you to take PHARMACOR VARENICLINE for an additional 12 weeks. This may increase your chances of stopping smoking in the long term.

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

- Your first pack of PHARMACOR VARENICLINE will cover your first four weeks of treatment.
- Visit your doctor before the end of the fourth week that you take PHARMACOR VARENICLINE for a check-up and for a new prescription.
- At this appointment, your doctor will check your progress and give you a new prescription for the tablets to continue your treatment.
- Visit your doctor before the end of the eleventh week for a check-up and for a new

prescription.

- You must then take PHARMACOR VARENICLINE 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

PHARMACOR VARENICLINE should be used regularly at the same time each day.

If it is almost time for your next dose (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 when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you have used too much PHARMACOR VARENICLINE, you may need urgent medical attention.

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 PHARMACOR VARENICLINE. 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 PHARMACOR VARENICLINE

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 PHARMACOR VARENICLINE and tell your doctor immediately if you or your family/friends 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 PHARMACOR VARENICLINE 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 PHARMACOR VARENICLINE.

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 PHARMACOR VARENICLINE.

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 PHARMACOR VARENICLINE 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 before you drive or use any machines or tools until you know how PHARMACOR VARENICLINE affects you.

PHARMACOR VARENICLINE 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.

Tell your doctor if you drink alcohol.

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

There have been reports of increased feelings of being drunk while taking PHARMACOR VARENICLINE. Drinking alcohol while taking PHARMACOR VARENICLINE 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 PHARMACOR VARENICLINE.

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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

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

Stop taking PHARMACOR VARENICLINE if...

Stop taking PHARMACOR VARENICLINE 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 PHARMACOR 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 PHARMACOR VARENICLINE 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 PHARMACOR VARENICLINE with food.

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

Common side effects:

- 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
- change in taste
- muscle or joint pain

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

Tell your doctor as soon as possible if...

Call your doctor straight away, if you notice any of the following serious side effects.

Serious side effects:

- 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, passing large amounts of urine.

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

Go to hospital if ...

Stop taking PHARMACOR VARENICLINE and call your doctor immediately or go to Emergency Department at your nearest hospital if you experience any of these very serious side effects.

Very serious side effects:

Changes in behaviour, thinking or mood

- self-harm or thoughts of self-harm
- change 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

Skin issues

- severe painful red blisters on the skin with chills, fever aching muscles and generally feeling unwell

Allergic reactions

- rash or sudden severe itchy swellings on the skin
- 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 PHARMACOR VARENICLINE.

Heart related issues

- 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

Other

- 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 PHARMACOR VARENICLINE

Storage

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

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

Store it in a cool dry place (where the temperature stays below 25°C, Store in the original package) away from moisture, heat or sunlight.

Do not store PHARMACOR VARENICLINE or any other medicine in the bathroom or near a sink.

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

Keep it where children cannot reach it.

Disposal

If you no longer need to use this medicine or it is out of date, take it to your pharmacy for safe disposal.

Do not use this medicine after the expiry date or when your doctor tells you to stop taking PHARMACOR VARENICLINE.

Product description

What it looks like

PHARMACOR VARENICLINE is available in 2 strengths:

- PHARMACOR VARENICLINE 0.5 mg tablets are white to off white, capsular biconvex, film-coated tablets, debossed with "VC" on one side and "0.5" on the other side.
- PHARMACOR VARENICLINE 1 mg tablets are light blue, capsular biconvex, film-coated tablets, debossed with "VC" on one side and "1" on the other side.

Packs Available

The following packs are available:

- Initiation composite Pack (1-4 weeks of treatment) containing 11 x 0.5 mg tablets and 42 x 1 mg tablets in blisters within a secondary cold sealed wallet.
Note. Composite Carton containing 11 x 0.5 mg and 42 x 1 mg tablets. This carton contains two cold sealed wallets. The first cold sealed wallet consists of an initial dosing pack containing 11 x 0.5 mg tablets and 14 x 1 mg tablets. The second cold sealed wallet consists of 28 x 1 mg tablets.
- Initiation composite Pack (1-2 weeks of treatment) containing 11 x 0.5 mg tablets and 14 x 1 mg tablets in blisters within a secondary cold sealed wallet.
Note. Composite Carton containing 11 x 0.5 mg and 14 x 1 mg tablets. This carton contains single cold sealed wallet. This cold sealed wallet consists of an initial dosing pack containing 11 x 0.5 mg tablets and 14 x 1 mg tablets.
- Continuation carton pack containing 56 x 1 mg tablets in blisters within a carton.
- Continuation wallet pack containing containing 56 x 1 mg tablets in blisters in a cold sealed wallet.
- Continuation carton pack containing 28 x 1 mg tablets in blisters within a carton.
- Continuation wallet pack containing containing 28 x 1 mg tablets in blisters in a cold sealed wallet.
- HDPE Bottle Pack with desiccant (enclosed within polypropylene canister) and without desiccant containing 56 tablets (0.5 mg & 1 mg respectively).

Ingredients

Active ingredients

PHARMACOR VARENICLINE 0.5 mg tablets contain 0.855 mg of varenicline tartrate the equivalent of 0.5 mg of varenicline.

PHARMACOR VARENICLINE 1 mg tablets contain 1.71 mg of varenicline tartrate the equivalent of 1 mg of varenicline.

Inactive ingredients

Each tablet of PHARMACOR VARENICLINE contains the following inactive ingredients:

- Cellulose - microcrystalline
- Croscarmellose sodium
- Maltodextrin
- Stearic acid
- Opadry Blue (1 mg tablet), Opadry White (0.5 mg tablet) and Opadry Clear.

PHARMACOR VARENICLINE is gluten free.

Supplier

PHARMACOR VARENICLINE tablets are supplied in Australia by:

Pharmacor Pty Ltd Chatswood
NSW 2067 Australia

www.pharmacor.com.au

PHARMACOR VARENICLINE tablets are supplied in New Zealand by:

Pharmacor Limited c/- Wynn
Williams Level 25, Vero Centre 28
Shortland Street Auckland Central
AUCKLAND, 1010 New Zealand.
Ph: +64 800 172 553
Or
0800 172 553

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- PHARMACOR VARENICLINE varenicline (as tartrate) 0.5 mg and varenicline (as tartrate) 1 mg film coated tablet composite blister pack: 395134
- PHARMACOR VARENICLINE varenicline (as tartrate) 1 mg film coated tablet blister pack: 395135
- PHARMACOR VARENICLINE varenicline (as tartrate) 0.5 mg film coated tablet bottle: 395133

- PHARMACOR VARENICLINE varenicline (as tartrate) 1 mg film coated tablet bottle: 395137