VASSIX

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VASSIX?

VASSIX contains the active ingredient varenicline tartrate. VASSIX is used to help adults stop smoking. For more information, see Section 1. Why am I using VASSIX? in the full CMI.

2. What should I know before I use VASSIX?

Do not use if you have ever had an allergic reaction to varenicline tartrate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use VASSIX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VASSIX and affect how it works. Furthermore, the effects of changes in your body resulting from stopping smoking, with or without VASSIX, may alter the way some medicines work. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use VASSIX?

Your doctor will decide with you on how to use VASSIX to quit smoking. There are 3 ways to quit smoking with VASSIX.

To take VASSIX, you start with the white 0.5 mg tablet and then increase the dose up to the light blue 1 mg tablet.

More instructions can be found in Section 4. How do I use VASSIX? in the full CMI.

5. What should I know while using VASSIX?

Things you should do	• Make sure you try to stop smoking on your quit date. If you slip up and smoke, try again. • Stop taking VASSIX and call your doctor straight away if you or those around you notice changes in behaviour, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions. • Call your doctor straight away if you have existing heart or blood vessel problems and notice any changes in symptoms while taking VASSIX; or become pregnant while taking VASSIX. • Remind any doctor, dentist or pharmacist you visit that you are using VASSIX.
Things you should not do	• Do not take VASSIX 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.
Driving or using machines	• 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.
Drinking alcohol	• Drinking alcohol while taking VASSIX may increase your risk of experiencing changes to your behaviour, thinking or mood that are not typical for you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. Keep your tablets in the pack until it is time to take them.

For more information, see Section 5. What should I know while using VASSIX? in the full CMI.

6. Are there any side effects?

Common side effects of VASSIX include: stomach or bowel problems (e.g. nausea), dry mouth, toothache, headache, dizziness, sleep problems, signs and symptoms of a cold, change in appetite, weight gain, changes in taste, muscle or joint pain. Other serious side effects have also been reported: convulsions, vision problems or pain in eyes, blood in stools or vomit, stomach pain, excessive thirst, dry mouth and skin, passing large amounts of urine, changes in behaviour, thinking or mood, severe skin issues, allergic reactions, heart related issues.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

VASSIX

Active ingredient(s): *varenicline tartrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VASSIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VASSIX.**

Where to find information in this leaflet:

1. Why am I using VASSIX?
2. What should I know before I use VASSIX?
3. What if I am taking other medicines?
4. How do I use VASSIX?
5. What should I know while using VASSIX?
6. Are there any side effects?
7. Product details

1. Why am I using VASSIX?

VASSIX contains the active ingredient varenicline tartrate.

VASSIX 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, VASSIX will reduce your enjoyment of cigarettes if you do smoke while on treatment.

How VASSIX works

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

VASSIX 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.

Deciding to stop smoking

VASSIX helps you give up smoking. Other things you need include:

- willpower
- a quit plan
- support from your family, 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 13 7848 (13 QUIT) or online at www.icanquit.com.au

2. What should I know before I use VASSIX?

Warnings

Do not use VASSIX 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.

2. the expiry date printed on the pack has passed.
3. 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.

Check with 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 VASSIX, and others developed them after several weeks of treatment or after stopping VASSIX.

  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 VASSIX to decide if it is right for you.

- have or have had any other 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 VASSIX.
  - 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.

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

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?

Pregnancy and breastfeeding

It is not recommended that you take VASSIX 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.

Use in children

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

3. What if I am 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 VASSIX in combination with other smoking cessation therapies is not recommended.

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

The effects of changes in your body resulting from stopping smoking, with or without VASSIX, 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 VASSIX.

4. How do I use VASSIX?

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 VASSIX

There are 3 ways to quit smoking with VASSIX:

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 VASSIX 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 VASSIX.
- Choose a quit date when you will stop smoking between days 8 and 35 of starting VASSIX.
- 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 VASSIX.
- 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 the 12 week treatment period - this is your quit date
- Continue taking VASSIX 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 VASSIX.

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.

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

How to take VASSIX

Swallow the tablets whole with a full glass of water.

When to take VASSIX

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 VASSIX before or after food.

Some people find it helpful to take VASSIX with food.

How long to take VASSIX

- **If options 1 or 2 are the selected way to quit smoking, take VASSIX for 12 weeks.**
  - Your first pack of VASSIX will cover your first four weeks of treatment.
  - Visit your doctor before the end of the fourth week that you take VASSIX 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 VASSIX 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 VASSIX for 12 weeks.**
  - Your first pack of VASSIX will cover your first four weeks of treatment.
  - Visit your doctor before the end of the fourth week that you take VASSIX 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 VASSIX 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 use VASSIX

VASSIX 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 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 use too much VASSIX

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Take your tablets with you to hospital.

5. What should I know while using VASSIX?

Things you should do

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

If you slip up and smoke, try again.

Stop taking VASSIX and call your doctor straight away 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 VASSIX as it is known that mood changes can also be due to the effects of stopping smoking.

Call your doctor straight away if you:

- have existing heart or blood vessel problems and you notice any changes in symptoms while taking VASSIX.
  - 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.
- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are using VASSIX.

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

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.

Things you should not do

- Do not take VASSIX 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VASSIX affects you.

VASSIX 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.

Drinking alcohol

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 VASSIX. Drinking alcohol while taking VASSIX 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.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Store it in a cool dry place (where the temperature stays below 25°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

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

6. Are there any side effects?

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

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.

Stop taking VASSIX 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 VASSIX. 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 or pharmacist if you have nausea (feel sick) while taking VASSIX 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 VASSIX with food**.**

Less Serious side effects

Less Serious side effects	What to do
• stomach or bowel problems o constipation o diarrhoea o feeling bloated o indigestion, o wind o nausea, vomiting o stomach discomfort • dry mouth, toothache • headache • dizziness • sleep problems o difficulty sleeping o sleepiness o abnormal dreams o sleep walking • feeling tired, fatigue • signs and symptoms of a cold • change in appetite, weight gain • changes in taste • muscle or joint pain	**Speak to your doctor if you have any of these common side effects and they worry you.** They are usually mild.

Serious side effects

Serious side effects	What to do
• trembling, fits or convulsions • problems with your vision or pain in your eyes • red blood in stools • stomach pain	**Call your doctor straight away if you notice any of these serious side effects.**

• excessive thirst, having a dry mouth and skin, passing large amounts of urine.	You may require medical attention.

Very serious side effects

Very serious side effects	What to do
Changes in behaviour, thinking or mood • 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 **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 o wheezing o difficulty breathing o 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 VASSIX. **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.	**Stop taking VASSIX and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these 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 may be making you feel unwell.

Other side effects not listed here 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/ reporting-problems.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VASSIX contains

Active ingredient (main ingredient)	varenicline tartrate
Other ingredients (inactive ingredients)	microcrystalline cellulose maltodextrine croscarmellose sodium stearic acid **Opadry 0.5 mg 20A580008 (ID 148608)** (contains hypromellose, hyprolose, titanium dioxide and purified talc. **Opadry 1.0 mg 20A505060 Blue** (ID 148609) (contains hypromellose, hyprolose, titanium dioxide, purified talc and indigo carmine aluminium lake.

Do not take this medicine if you are allergic to any of these ingredients.

What VASSIX looks like

VASSIX is available in 2 strengths:

- 0.5 mg white to off-white, capsular biconvex, film coated tablet debossed with “C2” on one side and plain on the other side..
- 1 mg light blue, capsular biconvex, film coated tablet debossed with “C1” on one side and plain on the other side.

The following packs are available:

- Initiation Pack containing 11 x 0.5 mg film coated tablets and 42 x 1mg film coated tablets in two sealed wallets. The first wallet consists of an initial dosing pack containing 11 x 0.5 mg tablets and 14 x 1 mg tablets. The second sealed wallet consists of 28 x 1mg tablets.
- Continuation pack containing 56 x 1 mg film coated tablets in a sealed wallet

Not all pack types may be marketed

Who distributes VASSIX

Nova Pharmaceuticals Australia Pty Ltd
Suite 305, 10 Norbrik Drive
Bella Vista,
NSW 2153
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Toll free: 1800 002 171

www.novapharm.com.au

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