

QuitX[®] Chewing Gum (Freshmint and Classic flavour)

2mg & 4mg

Nicotine Chewing Gum

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about QuitX gums.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist, or a counsellor experienced with helping smokers to quit.

All medicines have risks and benefits. You need to weigh the benefits and risks of taking QuitX gum against the expected benefits it will 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 QuitX Gum is used for

QuitX Gum helps you to give up smoking by reducing cravings for nicotine thereby relieving the desire to smoke,

as well as some of the unpleasant withdrawal effects which smokers experience when they stop smoking.

Dependence on nicotine can in some cases be transferred from cigarettes to QuitX Gum but it is less harmful and easier to break than smoking.

How QuitX Gum works

To successfully become a non-smoker it is important to understand how QuitX Gum works. Smokers have both a physical dependence on nicotine (i.e. the body becomes dependent on nicotine) and a psychological (i.e. mental) dependence on the smoking habit itself.

When you give up smoking, your body will miss the effects of nicotine and you will miss the habit of smoking.

QuitX Gum helps your body to tackle the problem of missing nicotine. However, you will still need to work on breaking your habit of smoking.

It is your body's dependence on nicotine which causes withdrawal symptoms when you suddenly stop smoking.

Nicotine is an addictive. When you stop smoking, you may experience withdrawal symptoms such as:

- irritability, frustration or anger
- restlessness
- sleeplessness
- difficulty concentrating
- depression
- hunger or weight gain
- craving for cigarettes
- decreased heart rate

QuitX Gum is intended to ease nicotine withdrawal symptoms by providing your body with nicotine.

QuitX Gum releases nicotine into your saliva. The nicotine is absorbed through the lining of your mouth and enters your blood stream.

Any nicotine that is swallowed in saliva is broken down in your stomach. It is therefore wasted. So it is important to chew QuitX Gum slowly so that the nicotine is released a little at a time and absorbed through the lining of the mouth.

This nicotine is sufficient to decrease the cravings for smoking. Unlike cigarettes, QuitX Gum does not contain harmful tar and carbon monoxide.

QuitX can help you to stop smoking

QuitX Gum helps you give up smoking by relieving nicotine craving, but you will only be successful in becoming a non-smoker if you are determined to quit.

You will need to plan your stop smoking program.

You will also need the support of others, your family, your friends, your pharmacist, family doctor or any one of a number of "quit smoking" organisations.

Do not be afraid to seek support or advice.

QuitX can help you to cut down your smoking

If you are not ready to stop smoking completely, QuitX can help you to give up smoking gradually by reducing cravings for nicotine and thus relieving the desire to smoke. It will help reduce some of the unpleasant withdrawal effects which smokers experience when they give up smoking.

Before using QuitX Gum

When you must not use QuitX Gum

Do not use QuitX Gum if:

You are allergic to nicotine or to any of the ingredients listed under the Product Description at the end of this leaflet.

You are pregnant or intend to become pregnant.

Nicotine in any form may be harmful to an unborn child. If you are pregnant or intend to become pregnant, you should try to quit smoking without using nicotine products.

However, if this is not possible, your doctor may advise you to use QuitX Gum.

You are breastfeeding or intend to breastfeed.

Nicotine passes into breast milk and can affect the health of the baby. If you are breastfeeding or intend to breastfeed, you should try to quit smoking without using nicotine products. However, if this is not possible, your doctor may advise you to use QuitX Gum.

You have heart disease such as palpitations (fast or irregular heart beats) or angina.

You have had a recent heart attack or a stroke.

You are a non-smoker, or only smoke occasionally.

You are under 12 years of age.

There is not enough information about the use of QuitX Gum in children.

You should not use QuitX Gum if the expiry date printed on the carton has passed or the packaging is torn or shows signs of tampering.

If you are uncertain whether you can use QuitX Gum, speak to your doctor or pharmacist.

Do not give QuitX Gum to anyone else to use without professional advice from a doctor or pharmacist.

Before you start to use QuitX Gum

If you have any of the following, you should ask for your doctor's or pharmacist's advice before using QuitX Gum.

These medical conditions may need consideration by or

discussion with your doctor or pharmacist. You and your doctor or pharmacist can then weigh up the risk of using QuitX Gum against the benefits you will get if you stop smoking.

- any type of heart disease, including angina, heart failure
- high blood pressure
- any blood circulation disorder
- kidney disease
- stomach ulcer or pain
- hyperthyroidism (a disorder of the thyroid gland)
- diabetes controlled with insulin
- phaeochromocytoma (a tumour of the adrenal gland)
- liver disorder.

If you have dentures, dental caps or partial bridges.

QuitX Gum may stick to your dentures, dental caps or partial bridges and may cause damage to your dental work. It is important that your dental work is kept clean. You should stop chewing QuitX Gum if it is sticking to your dental work and discuss further use of QuitX Gum with your doctor and dentist.

Taking other medicines

Tell your doctor or pharmacist if you are taking any of other medicines before you start to use QuitX Gum.

This includes medicine that you buy without a prescription, in a pharmacy, supermarket or health food shop.

The following medicines may affect how QuitX works or may be affected by QuitX.

- theophylline, a medicine used for asthma
- imipramine, clomipramine and fluvoxamine (medicines used for depression)
- pentazocine, a medicine for pain relief
- clozapine, olanzapine and tacrine (medicines used for mental conditions)
- flecainide, a medicine used for irregular and/or rapid heartbeat
- ropinirole, a medicine used for restless legs syndrome
- caffeine

gone. This will take about one minute.

3. CHEW

When the tingling has gone, continue to chew the gum slowly until the tingling returns. Then again place the gum under your tongue or between your cheek and gums.

4. Chew each piece of QuitX Gum in this way (CHEW, PARK, CHEW) until you no longer experience the tingling sensation. Each piece of gum will usually last about 30 minutes.

5. Dispose of the chewed pieces of gum neatly.

Using QuitX Gum

What is the proper chewing method?

Do not chew QuitX Gum when eating or drinking.

This causes excessive swallowing of nicotine, reducing the effectiveness of QuitX Gum. Do not drink acidic beverages, such as coffee or soft drinks, for 15 minutes before chewing as they can interfere with the absorption of nicotine.

To get the full effect from QuitX Gum these steps should be followed carefully:

1. CHEW

Place one piece of QuitX Gum in your mouth and chew it slowly until you feel a slight tingling sensation.

2. PARK

When you feel the tingling (usually after about 10 chews), place the piece of gum under your tongue or between your cheek and gums until the tingling has

Proper chewing is important

QuitX Gum releases nicotine into your saliva. This nicotine is absorbed through the lining of your mouth and enters your bloodstream.

Any nicotine that is swallowed in saliva is broken down in your stomach. It is therefore wasted.

So it is important to chew QuitX Gum slowly so that the nicotine is released a little at a time and absorbed through the lining of the mouth. If QuitX Gum is chewed too quickly or for too long, a lot of saliva is produced and swallowed which reduces QuitX's ability to work effectively. Too much chewing may also produce an unpleasant strong taste, which is a useful sign that you should slow down or stop chewing. Chewing too quickly may at first irritate the throat or cause hiccups or make you feel sick. So remember that if the taste is too strong you are chewing too fast!

Which strength of QuitX Gum should I use?

You should discuss which strength of QuitX Gum you should use with your pharmacist. QuitX Gum is available from a pharmacy in 2 mg and 4 mg strengths.

Usually, the 4 mg strength is recommended if you smoke 20 or more cigarettes in a day or are a smoker who has not been able to quit smoking using the 2 mg strength.

Otherwise, you should use the 2 mg strength.

How much QuitX Gum should I use?

The amount of QuitX Gum you chew each day depends on your former smoking habits. Usually, it is recommended that a piece of QuitX Gum should be used when the urge to smoke is felt.

Because nicotine is released from QuitX Gum at a slower rate than from a cigarette, it is important that you do not try to delay chewing in the hope that the urge to smoke will go away. QuitX Gum needs extra time to work and be effective.

Adolescents (12 years and over)

QuitX gums should not be used in adolescents unless they are under the supervision of a doctor or pharmacist.

The recommended duration of QuitX treatment is 12 weeks.

Weeks 1 to 8

Chew 1 piece of 2mg or 4mg gum when there is an urge to smoke or every 2 to 3 hours.

Do not use more than 20 pieces of the 2mg QuitX gum or more than 10 pieces of the 4mg QuitX gum a day.

Weeks 8 to 12

Gradually reduced to 1 to 2 pieces a day and then stop use.

If the adolescent continues to smoke after 12 weeks, continue to seek advice from a pharmacist or doctor.

Adults (18 +)

A) IF YOU HAVE DECIDED TO STOP SMOKING IMMEDIATELY

Use QuitX 2mg gum if you smoke less than 20 cigarettes per day.

Weeks 1 to 12

Chew 1 piece of gum when there is an urge to smoke or every 1 to 2 hours (maximum 20 gums/day).

Most smokers need about 8 to 12 pieces a day.

After 12 weeks

Gradually reduce to 1 to 2 pieces of gum a day and then stop use.

Use QuitX 4mg gum if you smoke 20 or more cigarettes per day.

Weeks 1 to 12

Chew 1 piece of gum when there is an urge to smoke or every 1 to 2 hours (maximum 10 gums/day).

Most smokers need about 4 to 6 pieces a day.

After 12 weeks

Gradually reduce to 1 to 2 pieces of gum a day and then stop use.

B) IF YOU HAVE DECIDED TO CUT DOWN SMOKING

Use QuitX 2mg gum if you smoke less than 20 cigarettes per day.

Gradually increase gum use (maximum 20 gums/day) for up to 6 months, while cutting down smoking. Stop smoking completely when you are ready. Continue using gum as per directions for Instruction 1) **IF YOU HAVE DECIDED TO STOP SMOKING IMMEDIATELY.**

If you have not cut down smoking in 6 weeks or quit smoking after 9 months, contact your doctor or pharmacist for advice.

Use QuitX 4mg gum if you smoke 20 or more cigarettes per day.

Gradually increase gum use (maximum 10 gums/day) for up to 6 months, while cutting down smoking. Stop smoking completely when you are ready. Continue using gum as per directions for Instruction 1) **IF YOU HAVE DECIDED TO STOP SMOKING NOW.**

If you have not cut down smoking in 6 weeks or quit smoking after 9 months, contact your doctor or pharmacist for advice.

C) COMBINATION TREATMENT

If you have previously relapsed with use of one form of nicotine replacement therapy (NRT), combination use with a nicotine patch NRT may help.

You should discuss the use of combination therapy (nicotine gum and nicotine patches) with your doctor or pharmacist before starting combination therapy.

Your doctor or pharmacist can advise you on which products (and strength) to use.

When to start using QuitX Gum

Set a Stop Smoking Day so that you can plan to be ready. This allows you to:

- Pick the right day - set a quit date that is likely to be stress free.
- Quit with a friend- you can help each other stick to your plan.
- Remove any temptation – make home and work cigarette-free zones.
- Take one day at a time - everyday without a cigarette makes you a winner.
- Keep yourself busy – do something you enjoy.
- Think cash, not ash - your money will no longer be going up in smoke.
- Avoid putting on weight - start a gentle exercise regimen.

If at first you don't succeed don't give up. Successful quitters keep trying.

When your Stop Smoking Day arrives, stop smoking completely on that day and begin your QuitX treatment.

When to stop using QuitX Gum

It is recommended that QuitX Gum be used for 12 weeks to help you get over your psychological desire to smoke. After 12 weeks, you should gradually reduce the number of pieces of QuitX Gum chewed each day. It should take another 4 weeks to step down to using 1 to 2 pieces per day. Don't be discouraged by this, it is all part of the quitting process.

When you reach this stage you can call yourself an ex-smoker, but there is still the chance that you may lapse back to your smoking habit, so always carry some QuitX Gum just in case you feel an urge to smoke. The use of QuitX Gum beyond one year is not recommended.

If you take too much (overdose)

Stop smoking completely when you start using QuitX Gum. Symptoms of nicotine overdose can occur if you smoke at the same time as you use QuitX Gum or if many pieces of QuitX Gum are chewed at the same time or rapidly one after the other.

Signs of overdose or poisoning include:

- nausea and vomiting
- salivating
- diarrhoea
- abdominal pain
- sweating
- headache
- dizziness
- disturbed hearing
- weakness, faintness and fatigue
- breathing difficulties
- loss of consciousness
- weak, rapid or irregular pulse

Keep QuitX Gum out of the reach of children. Seek medical advice immediately if a young child chews, swallows or sucks any quantity of QuitX Gum.

Children have a greater risk of poisoning from QuitX Gum if accidentally chewed, swallowed or sucked. **Young children can be poisoned by small amounts of nicotine.**

In the event of yourself or another adult chewing or swallowing large quantities of QuitX Gum, seek medical advice.

Immediately telephone your doctor or Poisons Information Centre for advice (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital.

Side effects

Nicotine like all other medicines may cause unwanted side-effects in some people.

Seek professional advice from your doctor or pharmacist as soon as possible if you do not feel well while you are using QuitX Gum.

Do not smoke or use QuitX Gum or other nicotine medicines and see your doctor as soon as possible if you get:

- chest pain or
- bad indigestion or
- an irregular (uneven) heart beat

Most of the undesirable effects reported by users of QuitX Gum occur during the first weeks after beginning treatment and may be due to chewing incorrectly or to the effects of nicotine. Some are minor and temporary but others may need medical attention.

The most common side effects are:

- headache
- nausea and vomiting
- indigestion
- hiccups
- sore mouth or throat
- jaw muscle ache

- skin irritation, itching or redness

These may diminish during the first weeks of using QuitX Gum.

Seek professional advice if you are not sure.

Some effects, such as dizziness, headache, sleeplessness and mouth ulcer may be withdrawal symptoms due to low nicotine levels.

If any of these effects do not go away, or you have any other undesirable effects during use, tell your pharmacist or doctor.

REMEMBER - that QuitX Gum is not intended as an alternative to smoking and that your aim is to overcome your need for nicotine by the end of the treatment period.

After using QuitX Gum

Storage

The expiry date of QuitX Gum is on the label of the carton and on the foil of the blister strip.

Do not use QuitX Gum if the expiry date has passed. Leave all pieces in the blister pack until immediately before use.

Store QuitX Gum in a cool place where the temperature stays below 25°C. Exposure to temperatures greater than 25°C (e.g. if carried in a shirt pocket or stored in a car glove box for long periods) may cause deterioration of the Gum.

KEEP QuitX GUM OUT OF REACH OF CHILDREN.

Disposal

When QuitX Gum is no longer needed, dispose of it carefully, where children or animals cannot get it.

Product Description

What QuitX Gum looks like

QuitX Gum is available in two flavours; freshmint flavour and classic flavour.

Freshmint coated gums

The freshmint coated gums are square, biconvex shaped pieces of chewing gum available in two strengths; 2mg and 4mg.

The 2mg gums are white and the 4mg gums are light peach in colour.

Both are available in packs of 30 and 100 pieces.

Classic uncoated gums

The classic uncoated gums are square, biconvex shaped pieces of chewing gum available in two strengths; 2mg and 4mg.

The 2mg gums are off white to tan and the 4mg gums are yellowish in colour.

Both are available in packs of 30 and 100 pieces.

Each pack of QuitX gum are labelled with the Australian Registration numbers:

Freshmint 2mg: AUST R 192915

Freshmint 4mg: AUST R 192914

Classic 2mg: AUST R 225886

Classic 4mg: AUST R 225888

QuitX Freshmint and Classic gum CMI 210714

Ingredients

The active ingredient in QuitX Gum is nicotine polacrilex.

Other ingredients in the Freshmint gum are:

- chewing gum base
- xylitol
- sodium carbonate anhydrous
- sodium bicarbonate
- magnesium oxide light
- menthol
- menthol flavour
- natural toothpaste flavour
- acacia
- hydroxypropylcellulose
- acesulfame potassium
- titanium dioxide
- carnauba wax
- sunset yellow (4mg strength only)

Other ingredients in the Classic gum are:

- chewing gum base
- sorbitol
- sodium carbonate
- sodium bicarbonate
- acesulfame potassium
- butylated hydroxytoluene
- menthol
- carnauba wax
- Mint Fruit Flavour
- talc
- quinolone yellow (4mg strength only)
- Brown Lake Blend colour (4mg strength only)

Distributor

QuitX is distributed in Australia by:

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