

QuitX® Coated Chewing Gum

(Nicotine)

Consumer Medicine Information

IMPORTANT - Please read this leaflet very carefully BEFORE you start to use the chewing gum. After reading, if you have any questions, consult your pharmacist or doctor.

1. Identification

QuitX Coated Chewing Gum is available in 2 nicotine dosage strengths, with each dosage strength available in 2 flavours, namely Freshmint and Classic.

QuitX 2 mg Coated Chewing Gum is available in Classic or Freshmint flavour.

QuitX 4 mg Coated Chewing Gum is available in Classic or Freshmint flavour.

There are 2 pack sizes for each flavour, containing either 24 or 96 pieces of QuitX Coated Chewing Gum.

QuitX Coated Chewing Gum contains nicotine, chewing gum base (containing butylated hydroxytoluene), acesulfame potassium, calcium carbonate, carnauba wax, gelatin, glycerol, mannitol, menthol, polacrillin, saccharin, saccharin sodium, sodium bicarbonate, sodium carbonate anhydrous, sorbitol, talc, titanium dioxide, water - purified, xylitol. Flavours: Freshmint Gums - eucalyptus oil, peppermint oil, Classic Gums - fruit flavour.

The gums are sugar-free and have no added colour.

Each gum contains sorbitol, xylitol and mannitol with a combined total of 0.4g per piece. For the 2mg strength, this is equivalent to 8g per maximum dose of 20 pieces. For the 4mg strength, this is equivalent to 4g per maximum dose of 10 pieces. Please note that products containing sorbitol may have a laxative effect or cause diarrhoea.

Each gum contains 11.5 mg or 0.5 mmol sodium (for the 2 mg gum, this is equivalent to 230 mg or 10 mmol/ maximum dose of 20 gums; for the 4 mg gum, this is equivalent to 115 mg or 5 mmol/ maximum dose of 10 gums) which should be taken into account by those on a low sodium diet.

2. What QuitX Coated Chewing Gum is used for

QuitX Coated Chewing Gum can help you stop smoking by relieving the desire to smoke as well as some of the unpleasant withdrawal effects which smokers may experience when they stop smoking. Dependence on nicotine can in some cases be transferred from cigarettes to QuitX Coated Chewing Gum, but it is less harmful and easier to break than smoking. You probably know that smoking is a very difficult habit to break. There are two sides to quitting smoking.

The first is the psychological dependence on cigarettes. You have probably smoked for many years and smoking has become an important part of your life.

The other side is a physical addiction to nicotine. Cigarettes contain nicotine, and your body has become dependent on nicotine. QuitX Coated Chewing Gum can reduce your desire to smoke by providing some of the nicotine that you used to inhale from cigarettes. This helps you to resist smoking.

When chewed, nicotine is released slowly from the gum and absorbed through the lining of the mouth. The amount of nicotine in the gum can also reduce some of the unpleasant effects that often happen when giving up smoking, such as feeling ill or irritable. QuitX Coated Chewing Gum does not act as quickly as smoking.

Nicotine can also be replaced using patches containing nicotine. The patches provide a constant level of nicotine by simply being applied each day. If you want to know more about nicotine patches, talk to your doctor or pharmacist.

QuitX Coated Chewing Gum works most effectively when you have a strong personal commitment to stop smoking. You cannot rely on QuitX alone to break the habit. You are more likely to quit smoking when using the product with help from your pharmacist, doctor, a trained counselor or a support program.

Counseling is available from various groups such as Quit For life. To get the best out of QuitX, we encourage you to enrol in a supportive group.

3. Before Using QuitX Coated Chewing Gum

When you must not use it

Do not use QuitX Coated Chewing Gum if:

- Your mouth or throat is sore
- You are under 12 years old
- You are a non-smoker
- You are an occasional smoker
- You are allergic to nicotine or any of the other ingredients in the gums
- The expiry date printed on the carton or blister platform has passed
- The packaging is torn or shows signs of tampering.

There are no health benefits to smoking. It is always better to give up smoking and using QuitX can help. In general, any possible side effects associated with NRT are far outweighed by the well established dangers of continuing to smoke.

If you are in hospital because of a heart attack, severe heart rhythm disorders or a stroke, you should try to quit smoking without using NRT unless your doctor tells you to use it. Once you are discharged from the hospital, you may use NRT in consultation with your doctor.

If you have had allergic reactions that involve swelling of the lips, face and throat (angioedema) or itchy skin rash (urticaria), using NRT can sometimes trigger this type of reaction.

Before you use it

Consult your doctor if you have any of the following conditions and ask for his/her advice before using QuitX Coated Chewing Gum:

- Any type of heart disease, including angina
- Arrhythmia (irregular heartbeat)
- Stroke or heart attack at any time in the past
- High blood pressure or any circulation disorder

Tell your doctor or pharmacist if you have any of the following conditions and ask for his/her advice before using QuitX Coated Chewing Gum:

- You are pregnant or breastfeeding
- Kidney or liver problems
- Stomach ulcer or persistent stomach upset
- Hyperthyroidism (a disorder of the thyroid gland)
- Diabetes
- Pheochromocytoma (a tumour of the adrenal gland)
- Inability to tolerate fructose (as the gums contain sorbitol, which is a source of fructose).

QuitX Coated Chewing Gum may be used by adolescents between the ages of 12 and 18 years.

NRT should only be used in this age group if a counseling program is used at the same time. QuitX Coated Chewing Gum should be used for no longer than 12 weeks in this age group except on the advice of a doctor or pharmacist.

If you have diabetes you should monitor your blood sugar levels more often than usual when starting QuitX Coated Chewing Gum as you may find your insulin or other medication requirements alter.

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription.

Your doctor or pharmacist will be able to advise you if stopping smoking may affect the way these medicines work.

If you are pregnant or breastfeeding then you should try to quit smoking without the use of QuitX Coated Chewing Gum if possible.

However it is better to stop smoking using NRT than to continue smoking.

If you are pregnant

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.

Smoking during pregnancy has risks such as poor growth of your baby before birth, premature birth or still birth. Stopping smoking is the best way to improve both your health and that of your baby. The earlier you stop smoking, the better.

Ideally, if you are pregnant, you should stop smoking without using NRT. However, if you have tried and this hasn't worked, NRT may be recommended to help you stop smoking. This is because it is better for your developing baby than if you carry on smoking. The decision to use NRT should be made as early on in your pregnancy as possible and you should aim to use it for only 2-3 months.

Products that are taken intermittently, such as gum, are preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness.

Your doctor can discuss the benefits and risks of using QuitX Coated Chewing Gum during pregnancy should you need further help.

If you are breastfeeding

Tell your doctor or pharmacist if you are breastfeeding.

Tobacco smoking causes breathing difficulties and other problems in babies and children. If you need to use NRT to help you quit, the amount of nicotine your baby may receive is much smaller and less harmful than breathing in second hand smoke. Do not use patches while breastfeeding. You should use NRT products that are taken intermittently (e.g. gum) and breastfeed just before you use the product. This allows as long a time between NRT use and breastfeeding, and will help your baby to get the smallest amount of nicotine possible.

Be careful if you have dentures, dental caps or partial bridges.

As with other gums, QuitX Coated Chewing Gum may stick to your dentures, dental caps or partial bridges and may damage them. You should stop using the gum if it sticks to your dental work and discuss further use with your dentist.

Driving or operating machinery whilst using QuitX Coated Chewing Gum

There is no evidence of any risk associated with driving or operating machinery if QuitX Coated Chewing Gum is taken according to the recommended dose but remember that smoking cessation can cause behavioural changes.

4. How to Use QuitX Coated Chewing Gum

How to get started

QuitX Coated Chewing Gum is not like ordinary chewing gum. You must stop smoking completely while you are using it.

It is probably best to nominate a specific day that you will stop smoking. It may be helpful for you to:

- Try to choose a day when you will not be where others are smoking
- Choose a day with as little stress as possible
- Choose a day not too far in the future.

Tell your family and friends that you have set this target "quit day".

This is the day you take control of your habit and become a non-smoker.

Prepare to stop smoking by trying to reduce the number of cigarettes you smoke each day.

How to commence using QuitX Coated Chewing Gum

At the beginning of the "quit day", start to use QuitX Coated Chewing Gum before any cigarettes have been smoked.

The appropriate dose will depend on your previous smoking habits. You should use QuitX 4mg Gum if:

You are a heavy smoker i.e. smoking 20 or more cigarettes a day

You have previously failed to stop smoking with QuitX 2mg Gum

Otherwise QuitX 2mg Gum should be used. If, while using the 2 mg gum, your withdrawal symptoms remain so strong as to threaten relapse, then you should use the 4 mg gum.

Chew one piece of gum when you feel the urge to smoke.

Follow these steps:

- Chew slowly until the taste becomes strong
- Rest the piece of chewing gum between your gum and cheek
- Chew again when the taste has faded

- Repeat the chewing routine for about 30 minutes
- Do not chew more than one piece at a time.

Chew slowly.

The nicotine in QuitX Coated Chewing Gum is released a little at a time and absorbed through the lining of your mouth into your bloodstream. If you chew too quickly or for too long, you will swallow the nicotine with your saliva. It will be broken down in your stomach and wasted.

Do not drink coffee or soft drinks for 15 minutes before chewing the gum.

They may keep the nicotine in the gum from being absorbed properly.

Do not use more than 20 pieces of the 2 mg gum or 10 pieces of the 4 mg gum in a day. Most people use 8-12 pieces of the 2 mg gum or 4-6 pieces of the 4 mg gum in a day.

How long to use it

After about 3 months, gradually cut down the number of pieces of QuitX Coated Chewing Gum you chew each day. When you are down to only 1-2 pieces of gum per day, you can stop using it. Stopping the gum completely should be possible within 6 months from the start of treatment.

If you find that you still need to use QuitX Coated Chewing Gum after 9 months from the start of treatment, consult a doctor or pharmacist for further advice.

5. Combination Therapy

How to combine use of QuitX Patches and QuitX 2mg Coated Chewing Gum

You can use combination therapy if you have relapsed in the past or if you experience cravings using a single form of nicotine replacement therapy.

The combination is more effective than either product alone in people who have been unable to quit smoking using a single NRT method, increasing your chances of successfully quitting.

Each morning apply a QuitX 21mg/day (Step 1) Patch to an intact area of skin. The QuitX Patch should be removed the following morning and a new patch applied to a different area from the original site. After applying the QuitX Patch use QuitX 2mg Coated Chewing Gum whenever a craving occurs.

For best results try to chew at least 4 pieces of 2mg gum every day. The maximum number of gums that can be taken in conjunction with the QuitX Patch in any given day is 12 pieces.

The combination of QuitX Patch and Gum should be used in this way for 12 weeks. After this time, if required, you can wean yourself off therapy by either of the following methods:

1. Use the QuitX 14mg/day (Step 2) patch for 3-4 weeks and then use the QuitX 7mg/day (Step 3) patch for a further 3-4 weeks while using the same number of pieces of QuitX 2mg gum in a day that you have routinely used. Then when a Patch is no longer needed, gradually reduce the number of pieces of gum until you no longer need them, OR
2. Stop use of the QuitX 21mg/day (Step 1) Patch and then gradually reduce the number of pieces of QuitX 2mg gum that are used until you no longer need them.

6. While you are using QuitX Coated Chewing Gum

Things you must do

Stop smoking completely while using QuitX Coated Chewing Gum.

You may have increased side effects if you continue to smoke while chewing the gum.

Use QuitX Coated Chewing Gum as instructed.

If you follow these recommendations you should get the full benefit of the QuitX Support Program.

Tell your doctor or pharmacist if you continue to smoke while you are using QuitX Coated Chewing Gum.

If you become pregnant while you are using QuitX Coated Chewing Gum, tell your doctor immediately.

Your doctor will discuss the benefits and risks of using QuitX Coated Chewing Gum during pregnancy and help you decide whether or not you should continue using it.

Tell any doctors, dentists and pharmacists who are treating you that you are using QuitX Coated Chewing Gum.

Things you must not do

Do not stop using QuitX Coated Chewing Gum suddenly.

You may get side effects similar to those you would get if you stopped smoking suddenly.

7. Side effects

Tell your pharmacist as soon as possible if you do not feel well while you are using QuitX Coated Chewing Gum.

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

If you get chest pain, irregular heartbeat or bad indigestion, do not smoke or use QuitX Coated Chewing Gum or any other nicotine medication. See your pharmacist or doctor as soon as possible.

Most of the undesirable effects reported by users of nicotine gums occur during the first few days or weeks and may be due to chewing incorrectly or to the effects of nicotine. Such effects include sore or irritated mouth or throat, jaw muscle ache, increased saliva, hiccups, indigestion or heartburn, nausea, vomiting, dizziness and headache.

Less common side effects are palpitations (feeling of fast or irregular heartbeat), tingling in the fingers or toes, skin redness or rash, hives (urticaria) and allergic reactions.

Some common withdrawal symptoms from giving up smoking are irritability, sleep disturbances, dizziness or headache.

Tell your pharmacist or doctor if these effects do not go away, or if you notice anything else that is making you feel unwell.

8. Overdosage

Overdose with QuitX Coated Chewing Gum could occur if many pieces are chewed at the same time or rapidly one after the other. The risk of overdose is small as nausea and vomiting usually occurs at an early stage with excessive nicotine intake.

The signs and symptoms of nicotine overdose include pallor, sweating, burning throat, nausea, salivation, vomiting, stomach upset or abdominal pain, diarrhoea, headache, dizziness, hearing and vision disturbances, tremor, confusion, weakness, seizures (fits), fast or irregular heartbeat, circulatory problems, fainting and breathing difficulties.

In the event of overdose or suspected overdose, seek immediate medical advice or contact a Poisons Information Centre (Telephone: 13 11 26).

9. Storage

It is very important to keep QuitX Coated Chewing Gum out of the reach of children, as doses of nicotine that are tolerated by adult smokers can cause severe poisoning in small children.

Store below 25°C.

10. Where to go for further information

This leaflet is only a summary of information about QuitX Coated Chewing Gum.

Ask your pharmacist or doctor if you have any questions, or if you experience any difficulties before, during or after using QuitX Coated Chewing Gum as they have more complete information.

QuitX Coated Chewing Gum is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298-3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

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