

Amcal Nicotine Chewing Gum 2 mg and 4 mg

Consumer Medicine Information

Please read this leaflet before you start using this medicine.

WHAT IS IN THIS LEAFLET?

This leaflet answers some common questions about Amcal Nicotine Chewing Gum.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor will be able to advise you about the risks and benefits of using Amcal Nicotine Chewing Gum.

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

Keep this leaflet with the medicine. You may need to read it again.

WHAT IS AMCAL NICOTINE CHEWING GUM USED FOR?

Amcal Nicotine Chewing Gum can help you stop smoking over a few months. You can also use it to help you stop smoking gradually over a longer period of time, if you cannot stop smoking immediately.

Whilst giving up isn't going to happen immediately, it is a habit you can break. But it's important to understand that there are two sides to quitting smoking.

Firstly, there is the psychological dependence on cigarettes. The smoking habit may have become an important part of your life, especially if you have smoked for many years.

Secondly, there is the physical addiction to nicotine to consider. Cigarettes contain nicotine and your body has become dependent on nicotine.

Amcal Nicotine Chewing Gum works on reducing your desire to smoke by providing some of the nicotine that you previously inhaled from cigarettes. This is what 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. Amcal Nicotine Chewing Gum does not act as quickly as smoking.

Amcal Nicotine Chewing Gum works most effectively when you have a strong personal commitment to stop smoking. You cannot rely on Amcal Nicotine Chewing Gum alone to break the habit. **You are more likely to quit smoking when using the product with help from your pharmacist, doctor, a trained counsellor or a support program.** Counselling is available from various groups and to get the best out of Amcal Nicotine Gum, we encourage you to enrol in a supportive group.

BEFORE YOU USE AMCAL NICOTINE CHEWING GUM

When you must not use it

Do not use Amcal Nicotine Chewing Gum if:

- Your mouth or throat is sore
- You are under 12 years old

- You are a non-smoker or an occasional smoker
- You are allergic or hypersensitive 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 Amcal Nicotine Chewing Gum can help. In general, any possible side effects associated with nicotine replacement therapy (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 start to use it

Talk to your doctor and ask for his/her advice before using Amcal Nicotine Chewing Gum if:

- you have had a recent heart attack or stroke
- you have angina (chest pain) that is not well controlled or is getting worse
- you have severe arrhythmia (irregular heartbeat)

Talk to your doctor or pharmacist and ask for his/her advice before using Amcal Nicotine Chewing Gum if:

- you have any type of heart disease, including angina
- you have had a stroke at any time in the past
- you have high blood pressure or any circulation disorder
- you have kidney or liver problems
- you have a stomach ulcer or persistent stomach upset
- you have hyperthyroidism (a disorder of the thyroid gland)
- you have diabetes, as you should monitor your blood sugar levels more often than usual when starting Amcal Nicotine Chewing Gum, you may find your insulin or other medication requirements alter
- you have pheochromocytoma (a tumour of the adrenal gland)
- you have an inability to tolerate fructose (as the gums contain sorbitol, which is a source of fructose)
- you are pregnant or breastfeeding
- you are aged 12 to 17 years
- you have a history of epilepsy (fits).

When taking this medicine there is a risk of dependence.

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.

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

As with other gums, Amcal Nicotine 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 Amcal Nicotine Chewing Gum

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

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.

If you are pregnant.

Ideally you should not use this program while you are pregnant, and you should stop smoking without using nicotine replacement therapy. Nicotine in any form may cause harm to your unborn baby. However, if you are unable to quit without the use of nicotine replacement therapy, seek advice from your pharmacist or doctor before starting a program. 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.

If you are breast-feeding.

Nicotine is excreted in breast milk in quantities that may affect the child even in therapeutic doses. Like smoking, nicotine replacement therapy should be avoided during breast-feeding. However, if you are unable to quit without the use of nicotine replacement therapy, seek advice from your pharmacist or doctor before starting a program. You are also recommended to use Amcal Nicotine Chewing Gum immediately after breast-feeding, to ensure that the baby gets the smallest amount of nicotine possible.

HOW TO USE AMCAL NICOTINE CHEWING GUM

How to get started

Amcal Nicotine 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 use Amcal Nicotine Chewing Gum

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

The appropriate dose will depend on your previous smoking habits.

Use 2 mg gum if:

- you were smoking less than 20 cigarettes a day

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.

Use 4 mg gum if:

- you were smoking more than 20 cigarettes a day
- you have previously failed to stop smoking with 2 mg gum

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

Follow these **4 easy steps**:

1. Chew one piece of gum slowly until the taste becomes strong.
2. Rest the piece of chewing gum between your gum and cheek.
3. Chew again when the taste has faded.
4. Repeat the chewing routine for about 30 minutes.

Chew only one piece of gum at a time.

Chew slowly.

The nicotine in Amcal Nicotine 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 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.

Usage Program for adults

There are two usage programs you can follow:

Program A. If you would like to stop smoking completely before starting the program:

- After about 3 months, gradually cut down the amount of gum you chew each day.
- When you are down to 1-2 pieces a day, you can stop using Amcal Nicotine Chewing Gum.
- You should be able to stop completely within 6 months from the start of the treatment.

Program B. If you cannot stop smoking completely before starting the program:

- Gradually increase gum use, while cutting down smoking.
- When you have cut down the number of cigarettes you smoke to a level you feel you can quit completely, follow Program A.

- If you have not cut down the number of cigarettes you smoke each day after 6 weeks, see your doctor or pharmacist.

Combination therapy

If you have relapsed in the past or if you experience cravings while using a single form of nicotine replacement therapy (NRT), you can combine the use of Amcal Nicotine Patch Step 1 with Amcal Nicotine Chewing Gum 2 mg.

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.

When using Amcal Nicotine Patch Step 1, chew one piece of Amcal Nicotine Chewing Gum 2 mg if you get a craving. Use at least 4 pieces of gum and not more than 12 pieces in a day. Continue for 12 weeks.

After 12 weeks, you can wean yourself off therapy by either of the following methods:

1. Stop use of Amcal Nicotine Patch and gradually reduce the number of Amcal Nicotine Chewing Gum 2 mg you use until you no longer need them.
2. a. Use Amcal Nicotine Patch Step 2 for 3-4 weeks, while using the same number of pieces of Amcal Nicotine Chewing Gum 2 mg in a day that you have routinely used.
b. Then use Amcal Nicotine Patch Step 3 for a further 3-4 weeks, while using the same number of pieces of Amcal Nicotine Chewing Gum 2 mg in a day that you have routinely used.
c. When patch use is no longer needed, gradually reduce the number of gums you use until you no longer need them.

Children 12 to 17 years old

Do not use for longer than 12 weeks. If you think you need to use for longer than 12 weeks, talk to your doctor or pharmacist.

Chew one piece of gum when you feel the urge to smoke. Follow the directions under 'How to use Amcal Nicotine Chewing Gum'. Use every 2 to 3 hours. Do not use more than 20 pieces of the 2 mg gum, or 10 pieces of the 4 mg gum in one day.

After about 8 weeks, gradually reduce to 1 to 2 pieces a day and then stop completely.

Do not use for children under 12 years.

WHILE YOU ARE USING AMCAL NICOTINE CHEWING GUM

Things you must do

Use Amcal Nicotine Chewing Gum as instructed.

If you follow these recommendations you should get the full benefit of the Amcal Nicotine Replacement Therapy Program.

Tell all of the doctors, dentists and pharmacists who are treating you that you are using Amcal Nicotine Chewing Gum.

Things you must not do

Do not stop using Amcal Nicotine Chewing Gum suddenly.

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

SIDE EFFECTS

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

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

Some effects, such as headache, irritability, sleep disturbances and light-headedness or dizziness, may be withdrawal symptoms due to low nicotine levels.

Most of the undesirable effects reported by users of nicotine gum occur during the first few weeks after beginning treatment and may be due to chewing incorrectly or to the effects of nicotine. Such effects include dizziness, headache, stomach trouble such as nausea, vomiting, indigestion or heartburn, increased saliva, hiccups, jaw muscle ache and a sore mouth or throat.

Some less common side effects of nicotine are rapid or irregular heartbeat, palpitations, tingling in the fingers or toes, redness or rash of the skin, hives (urticaria) and allergic reactions.

If you experience chest pain, seizures (fits), irregular heartbeat or bad indigestion, do not smoke or use Amcal Nicotine Chewing Gum or any other nicotine medication. See your pharmacist or doctor as soon as possible.

Other side effects not listed above may also occur in some people. Tell your pharmacist or doctor if these or any other side effects do not go away, or if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

IF YOU USE TOO MUCH (OVERDOSE)

If you smoke or use any other nicotine containing product while you are using Amcal Nicotine Chewing Gum, you may suffer an overdose of nicotine. However if used correctly, nicotine overdose is unlikely.

The general 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.

The risk of overdose is small as nausea and vomiting usually occurs at an early stage with excessive nicotine intake.

Children:

It is very important to keep Amcal Nicotine Chewing Gum out of the reach and sight of children, as doses of nicotine that are tolerated by adult smokers can cause severe poisoning in small children and can be fatal.

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

AFTER USE

Storage

Keep the gum in the blister pack inside the carton until you are ready to use it.

If you take the gum out of its blister pack, it may not keep well.

Store the gum in a cool dry place where the temperature stays below 25°C.

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

Do not leave it in the car or on windowsills.

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

If your pharmacist or doctor tells you to stop using the gum or you find that it has passed the expiry date, ask your pharmacist what to do with any gum that is left over.



This leaflet was prepared in July 2014

Date of amendment July 2019

ACC03714P:2

PRODUCT DESCRIPTION

Amcal Nicotine Chewing Gum is available in two nicotine dosage strengths - Amcal Nicotine 2 mg Gum and Amcal Nicotine 4 mg Gum.

You can choose from Fruit and Mint in 2 mg strength, and Mint in 4 mg strength.

All Amcal Nicotine Chewing Gums contain nicotine, chewing gum base (containing butylated hydroxytoluene), calcium carbonate, carnauba wax, gelatin, glycerol, mannitol, menthol, polacrillin, sodium bicarbonate, sodium carbonate anhydrous, sorbitol, talc, titanium dioxide, water - purified, xylitol.

Amcal Nicotine Chewing Gums contain saccharin, saccharin sodium, and acesulfamine potassium.

Flavours:

Fruit - fruit flavour. Mint - eucalyptus oil, peppermint oil.

All Amcal Nicotine Chewing Gums are sugar-free.

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

Each piece of gum also contains 11.5 mg (0.5 mmol) sodium which should be taken into account by those on a low sodium diet. For the 2 mg strength, this is equivalent to 230 mg (10 mmol) sodium per maximum dose of 20 pieces. For the 4 mg strength, this is equivalent to 115 mg (5 mmol) sodium per maximum dose of 10 pieces.

FOR MORE INFORMATION

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

Amcal Nicotine Chewing Gum is distributed by:

AVAILABLE ONLY FROM AMCAL

Allied Master Chemists of Australia Limited
3 Myer Place Rowville Vic 3178 Australia
www.amcal.com.au

AUSTRALIAN OWNED

Amcal Nicotine Chewing Gum is supplied by:

Perrigo Australia
25-29 Delawney Street, WA 6021 Australia
Consumer Service:
Australia: 1800 805 546