

Amcal Nicotine Chewing Gum

Active ingredient(s): Nicotine 2mg and 4mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amcal Nicotine Chewing Gum. **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 Amcal Nicotine Chewing Gum.**

Where to find information in this leaflet:

- [1. Why am I using Amcal Nicotine Chewing Gum?](#)
- [2. What should I know before I use Amcal Nicotine Chewing Gum?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Amcal Nicotine Chewing Gum?](#)
- [5. What should I know while using Amcal Nicotine Chewing Gum?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Amcal Nicotine Chewing Gum?

Amcal Nicotine Chewing Gum contains the active ingredient nicotine [2mg or 4mg]. 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 Chewing Gum, we encourage you to enroll in a supportive group.

2. What should I know before I use Amcal Nicotine Chewing Gum?

Warnings

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 gum
- 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 health 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.

Check with your doctor or pharmacist if you:

- have had a recent heart attack or stroke
- have angina (chest pain) that is not well controlled or is getting worse
- have severe arrhythmia (irregular heartbeat)
- have a type of heart disease, including angina
- have had a stroke anytime in the past
- have high blood pressure or any circulation disorder
- have kidney or liver problems
- have a stomach ulcer or persistent stomach upset
- have hyperthyroidism (a disorder of the thyroid gland)
- 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

- have phaeochromocytoma (a tumour of the adrenal gland)
- have an inability to tolerate fructose (as the gums contain sorbitol, which is a source of fructose)
- are pregnant or breastfeeding
- are aged 12 to 17 years
- have a history of epilepsy (fits)

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

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

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

Nicotine is excreted in breast milk in quantities that may affect the child even in therapeutic doses. Like smoking, NRT should be avoided during breastfeeding. However, if you are unable to quit without the use of NRT, seek advice from your pharmacist or doctor before starting a program.

You are also recommended to use Amcal Nicotine Chewing Gum immediately after breastfeeding, to ensure that the baby gets the smallest amount of nicotine possible from breast milk.

Take special care

- **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. Patients who wear dentures or have temporomandibular joint disease (difficulty chewing) may have trouble chewing Amcal Nicotine Chewing Gum.
- **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.
- **When taking this medicine there is a risk of dependence.**

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. They will be able to advise you if stopping smoking may affect the way these medicines work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Amcal Nicotine Chewing Gum.

4. How do I use Amcal Nicotine Chewing Gum?

How much to take / use

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

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.
- 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 2mg gum if:

- you were smoking less than 20 cigarettes a day

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

Use 4mg gum if:

- you were smoking 20 or more cigarettes a day
- you have previously failed to stop smoking with 2mg 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 2mg gum or 10 pieces of the 4mg gum in a day.

Most people use 8-12 pieces of the 2mg gum or 4-6 pieces of the 4mg 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 with Amcal Nicotine Chewing Gum 2mg.

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 Step 1 Nicotine Patch, chew one piece of Amcal Nicotine Chewing Gum 2mg 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 2mg you use until you no longer need them.
2. a. Use Amcal Step 2 Nicotine Patch for 3-4 weeks, while using the same number of pieces of Amcal

Nicotine Chewing Gum 2mg in a day that you have routinely used.

- b. Then use Amcal Step 3 Nicotine Patch for a further 3-4 weeks, while using the same number of pieces of Amcal Nicotine Chewing Gum 2mg 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 2mg gum, or 10 pieces of the 4mg 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.

If you use too much Amcal Nicotine Chewing Gum

If you think that you have used too much Amcal Nicotine Chewing Gum, 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.

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 overdosage 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.

5. What should I know while using Amcal Nicotine Chewing Gum?

Things you should do

- **Use Amcal Nicotine Chewing Gum exactly as instructed.**

- If you follow these recommendations, you should get the full benefit of the Amcal Nicotine Chewing Gum program.

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

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Amcal Nicotine Chewing Gum affects you.

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

Looking after your medicine

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 gums in a cool, dry place where the temperature stays below 25°C.

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

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 young children cannot reach it.

A locked cupboard at least 1.5 meters above the ground is a good place to store medicines.

Children: It is very important to keep Amcal Nicotine Chewing Gum out of 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.

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.

6. Are there any side effects?

Like all medicines Amcal Nicotine Chewing Gum 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.

Less serious /common side effects

Less serious side effects	What to do
<p>Gastrointestinal:</p> <ul style="list-style-type: none"> • Nausea • Vomiting • Diarrhoea • Constipation • Indigestion/Heartburn • Hiccups • Flatulence • Dry mouth • Excess saliva • Stomach upsets <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • Dizziness • Headache <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • Insomnia • Irritability <p>Respiratory system disorders:</p> <ul style="list-style-type: none"> • Cough <p>Other:</p> <ul style="list-style-type: none"> • Jaw muscle ache • Sore mouth or throat 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p> <p>These are mostly mild and short-lived. You may experience these side effects as you decrease the number of gums that you use.</p>

Serious/rare side effects

Serious side effects	What to do
<p>Cardiac disorders:</p> <ul style="list-style-type: none"> • Fast or very irregular heartbeat • Palpitations (feeling your heartbeat) <p>Immune System Disorders:</p> <ul style="list-style-type: none"> • Severe allergic reaction, symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint <p>Neurological disorders:</p> <ul style="list-style-type: none"> • Seizures (fits) • Tingling in fingers and toes <p>Gastrointestinal:</p> <ul style="list-style-type: none"> • Bad indigestion 	<p>Stop using Amcal Chewing Gum. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

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.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

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

What Amcal Nicotine Chewing Gum contains

Active ingredient (main ingredient)	Nicotine
Other ingredients (inactive ingredients)	Acesulfame potassium Chewing gum base (containing butylated hydroxytoluene) Calcium carbonate Carnauba wax Gelatin Glycerol Mannitol Menthol Polacrillin Saccharin Saccharin sodium Sodium bicarbonate Sodium carbonate Sorbitol Titanium dioxide Water purified Xylitol Mint flavour only: Eucalyptus oil Mint oil dementholised Peppermint oil Fruit flavour only: Fruit flavour

All Amcal Nicotine Chewing Gums are sugar-free.

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 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 (5mmol) sodium per maximum dose of 10 pieces.

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

What Amcal Nicotine Chewing Gum looks like

Amcal Nicotine Chewing Gum is a rectangular white chewing gum with polished surface.

- Amcal Nicotine Chewing Gum 2mg Mint (Aust R 229432)
- Amcal Nicotine Chewing Gum 4mg Mint (Aust R 229433)
- Amcal Nicotine Chewing Gum 2mg Fruit (Aust R 229431)

Who distributes Amcal Nicotine Chewing Gum



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 Patches are supplied in Australia by:

Perrigo Australia

Suite 7, Level 1,
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Belrose NSW 2085

Customer Service: 1800 805 546

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