

Amcal Nicotine Lozenges

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amcal Nicotine Lozenges. **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 Lozenges.**

Where to find information in this leaflet:

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1. Why am I using Amcal Nicotine Lozenges?

Amcal Nicotine Lozenges contains the active ingredient nicotine (either 2mg or 4mg).

Amcal Nicotine Lozenges are a stop smoking aid. They can help you stop smoking over a few months. You can also use them to help you stop smoking more gradually over a longer period of time.

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

They help you to give up smoking by replacing some of the nicotine you are used to getting from cigarettes. It is the nicotine in cigarettes that can make you physically addicted to them. This type of treatment is called Nicotine Replacement Therapy (NRT).

Amcal Nicotine Lozenges contain a nicotine resin and, when used, nicotine is released slowly from the resin and absorbed through the lining of the mouth. This medicine can reduce your urge to smoke by providing some of the nicotine previously inhaled from cigarettes and helps you resist cigarettes. You may feel the following withdrawal symptoms when you stop smoking: anger, irritability, frustration; anxiety; difficulty concentrating; restlessness; increased appetite and or weight gain; insomnia; depression. The nicotine in Amcal Nicotine Lozenges may help relieve some or many of these symptoms.

Amcal Nicotine Lozenges do not have the health dangers of tobacco because they do not contain the tar, carbon monoxide or other toxins present in cigarette smoke.

If possible, when giving up smoking, Amcal Nicotine Lozenges should be used with a stop smoking behavioural support programme.

Amcal Nicotine 2 mg Regular Strength lozenges are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up.

Amcal Nicotine 4 mg Extra Strength lozenges are suitable for smokers who have their first cigarette of the day within 30 minutes of waking up.

Your pharmacist or doctor may have given you this medicine for another reason. If you need more information ask your pharmacist or doctor.

2. What should I know before I use Amcal Nicotine Lozenges?

Warnings

Do not use Amcal Nicotine Lozenges if:

- You are allergic to nicotine or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You are a non-smoker.
- You are an occasional smoker.
- You suffer from phenylketonuria. The lozenge contains Phenylalanine.
- You are under 12 years of age.

Do not use the medicine after the expiry date (EXP) printed on the pack. If you take it after the expiry has passed, it may not work as well.

Do not use Amcal Nicotine Lozenges if the packaging is torn or shows signs of tampering.

If you are in hospital because of a heart attack, severe heart rhythm disturbances 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 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:

- If you have epilepsy. You should not use Amcal Nicotine Lozenges unless your doctor has told you to if you have epilepsy or are taking medicines for seizures.
- Have an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse.

- Have a stomach or duodenal ulcer or inflammation of the oesophagus. Swallowing nicotine can make your symptoms worse. Some people have reported getting mouth ulcers. If your symptoms do get worse you should talk to your doctor and you might want to use a non-oral type of NRT such as patches.
- Have heart or circulation problems including heart failure or stable angina or high blood pressure.
- Have had a stroke.
- Have any serious liver or kidney disease. You may be more prone to side effects.
- Are diabetic. You should monitor your blood sugar levels more often than usual when starting Amcal Nicotine Lozenges as you may find your insulin or other medication requirements alter.
- Have been diagnosed as having a tumour of the adrenal glands (phaeochromocytoma). Nicotine may make your symptoms worse.
- Have any allergies to any other medicines.
- Are pregnant or intend to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Take any medicines for any other condition.

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

If you are pregnant or breastfeeding then you should try to quit smoking without the use of Amcal Nicotine Lozenges if possible. However, it is better to stop smoking using NRT than to continue smoking.

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. Remember, the most important thing is to stop smoking.

Products that are taken intermittently, such as lozenges, 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.

If you are breastfeeding, tobacco smoke 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 secondhand smoke. You should use NRT products that are taken intermittently (e.g. lozenges rather than patches) and breastfeed just before you take the product. This allows as long a time as possible

between NRT use and feeding and will help your baby to get the smallest amount of nicotine possible.

Take special care:

- Each lozenge contains 15mg of sodium that should be taken into account by those who are on a low sodium diet.
- Lozenges can represent a choking hazard. Keep out of reach of children. Amcal Nicotine lozenges should be used with caution in patients with aspiration and swallowing problems.

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.

Stopping smoking, with or without nicotine replacement products such as Amcal Nicotine Lozenges, may alter the absorption of some medicines. The doses of the other medicines that you are using may need to be changed.

Some medicines may interfere with Amcal Nicotine Lozenges and affect how it works, including:

- Caffeine
- Theophylline
- Some medicines used to treat depression.
- Dextropropoxyphene and pentazocine - medicines that may be used for pain relief
- Insulin
- Some medicines used to treat mental disorders
- Frusemide (fluid tablet)
- Medicines used to treat ulcers
- Blood pressure medicines

These medicines may be affected by Amcal Nicotine Lozenges or affect how well Amcal Nicotine Lozenges 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 Lozenges. Your pharmacist or doctor can tell you what to do if you are taking any of these medicines.

If you have not told your pharmacist or doctor about any of these things, tell him/her before you take any Amcal Nicotine Lozenges.

4. How do I use Amcal Nicotine Lozenges?

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

During any attempt to give up smoking using Amcal Nicotine Lozenges, it is important that you make every effort to stop smoking completely. However, if you do smoke a cigarette while you are using NRT, you should continue your quit attempt. Talking to your pharmacist or doctor may help.

For some people, the use of more than one NRT product may help them to identify the combination most appropriate for their individual quit attempt.

Amcal Nicotine Lozenges Regular Strength are suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up

Amcal Nicotine Lozenges Extra Strength are suitable for smokers who have their first cigarette of the day within 30 minutes of waking up.

One lozenge should be placed in the mouth and be allowed to dissolve to be effective. From time to time the lozenge should be moved from one side of the mouth to the other. The lozenge should not be chewed, sucked or swallowed whole.

You should not eat or drink while a lozenge is in your mouth. Coffee, juices and fizzy drinks may reduce the absorption of nicotine and should not be taken while you are using a lozenge.

How much to take / use

For adults (and young people aged over 12 years) who want to stop in a few months:

Amcal Nicotine Lozenges should be used according to the following schedule:

Weeks 1 to 6: 1 lozenge every 1 to 2 hours

Weeks 7 to 9: 1 lozenge every 2 to 4 hours

Weeks 10 to 12: 1 lozenge every 4 to 8 hours

To help you stay smoke free over the next 12 weeks, take 1 lozenge in situations where you are strongly tempted to smoke.

During the initial treatment period (weeks 1 to 6) adults aged 18 years and over should use at least nine lozenges per day.

Do not use more than 1 lozenge at a time and do not use more than 15 lozenges per day.

For adult smokers who want to stop over several months:

Use a lozenge whenever you have a strong urge to smoke instead of smoking a cigarette. When you have reduced the number of cigarettes you smoke each day to a level from which you feel you can quit completely then use the schedule in the section above for smokers who want to quit in a few months. See your pharmacist or doctor if you have not reduced the number of cigarettes, you smoke each day after 6 weeks, or if you have not begun an attempt to quit completely after 6 months.

How long to use it

Lozenges should not be used after 9 months. If you find it difficult to give up Amcal Nicotine Lozenges or you are worried that you may start smoking again then speak to your pharmacist or doctor.

To give you the best chance for success, it is important you complete the step-down program in full. This is because the urge to smoke and withdrawal symptoms can occur for weeks after stopping smoking.

Adolescents aged 12 to 17 years old should only use Amcal Nicotine Lozenges for 12 weeks in total. If you think you

may need to use the lozenges for longer than 12 weeks, talk to your pharmacist or doctor.

NRT should only be used by those aged 12 to 17 years if a counselling program is used at the same time. NRT is not likely to work in this age group if there is no counselling with it.

Children under 12 years of age should not use Amcal Nicotine Lozenges. The levels of nicotine in NRT are suitable for people who are giving up smoking but not for children under 12. Children are more likely to be affected by nicotine and it could cause severe toxicity which can be fatal.

If you do start smoking again, you may want to talk to your pharmacist about how to get the best results from further courses of Amcal Nicotine Lozenges.

The directions given to you by your pharmacist or doctor may be different from the information in this leaflet. If you are unsure how to use this medicine, ask your pharmacist or doctor for advice.

If you use too much Amcal Nicotine Lozenges

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

Symptoms of nicotine over dosage include:

- Headache
- Dizziness
- Stomach upset
- Drooling
- Vomiting
- Diarrhoea
- Cold sweat
- Blurred vision
- Hearing distortion
- Confusion
- Weakness
- Fainting

If it is a large overdose, there may be collapse and breathing difficulty.

If you think that you or anyone has used too much Amcal Nicotine Lozenges, 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.

Keep telephone numbers of these places handy.

The lozenges are not suitable for children under 12 or for non-smokers. They may develop signs of nicotine overdose including headache, sickness, stomach pains and diarrhoea. Even small amounts of nicotine can be

dangerous to children. If you think a child has used any lozenges, you must contact a doctor immediately.

5. What should I know while using Amcal Nicotine Lozenges?

Things you should do

- Use Amcal Nicotine Lozenges exactly as your pharmacist or doctor has told you to.
- Remind any doctor, dentist or pharmacist you visit that you are using Amcal Nicotine Lozenges.
- Tell your doctor or pharmacist if you become pregnant while using Amcal Nicotine Lozenges.

Things you should not do

- Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe.
- Do not give this medicine to anyone else even if they have the same symptoms as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Amcal Nicotine Lozenges affects you. If used as recommended there are minimal risks associated with the use of Amcal Nicotine Lozenges in driving vehicles or operating machinery

Looking after your medicine

Keep your lozenges in the blister pack until it is time to use them. If you keep the lozenges out of the carton or the blister pack they will not keep well.

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

Keep Amcal Nicotine Lozenges in a cool dry place. Do not leave Amcal Nicotine Lozenges in the car on hot days.

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 windowsills.

Keep Amcal Nicotine Lozenges where young children and pets cannot reach them.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

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?

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.

Stopping smoking itself can cause some symptoms such as dizziness, headache, sleep disturbance, cough and cold-

like symptoms. Symptoms such as depression, irritability, anxiety and insomnia may also be related to withdrawal symptoms associated with giving up smoking.

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 • Difficulty swallowing • Mouth ulcer <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • Dizziness • Headache <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • Insomnia <p>Respiratory system disorders:</p> <ul style="list-style-type: none"> • Cough • Sore throat <p>Cardiac disorders:</p> <ul style="list-style-type: none"> • Palpitations (feeling your heartbeat) <p>Skin:</p> <ul style="list-style-type: none"> • Red or itchy skin 	<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 lozenges 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 • Changes from your normal heartbeat <p>Immune System Disorders:</p> <ul style="list-style-type: none"> • Severe allergic reaction, symptoms of which include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing <p>Neurological disorders:</p> <ul style="list-style-type: none"> • Seizures (fits) 	<p>Stop using Amcal Nicotine Lozenges.</p> <p>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.

Transferred dependence

Some people worry that they will quit smoking but become dependent on Amcal Nicotine Lozenges. This is very rare and, if it did happen, it is less harmful to you than continuing to smoke and an easier habit to break.

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.

Available only from Amcal

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

AUSTRALIAN OWNED

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7. Product details

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

What Amcal Nicotine Lozenges contains

Active ingredient (main ingredient)	Nicotine (2mg or 4mg) in the form of a resin complex (nicotine polacrilex)
Other ingredients (inactive ingredients)	Mannitol Sodium alginate Aspartame Sodium carbonate Magnesium stearate Xanthan gum Potassium bicarbonate Flavour – Peppermint (PI 106645)

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

What Amcal Nicotine Lozenges looks like

Amcal Nicotine Lozenges are cream/white embossed biconvex, round tablets with an odour of peppermint.

The 2mg lozenges (Aust R213239) are embossed with 'L344' and the 4mg lozenges (Aust R213240) with 'L873' on one face.

Who distributes Amcal Nicotine Lozenges

Manufactured in the United Kingdom for:

Perrigo Australia

Suite 7, Level 1, 13a Narabung Way
Belrose NSW 2085

Customer Service: 1800 805 546

Distributed by:

