

NICOTINELL® NICOTINE LOZENGES

Nicotine 2mg (as polacrilex) and Nicotine 4mg (as polacrilex)

Consumer Medicine Information

What is in this Leaflet?

This leaflet answers some common questions about Nicotinell Nicotine Lozenges.

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 doctor or pharmacist has weighed the risks of you using Nicotinell Nicotine Lozenges against the benefits this medicine is expected to have for you.

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

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

What are Nicotinell Nicotine Lozenges used for?

Nicotinell 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.

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). Nicotinell 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 Nicotinell Nicotine Lozenges may help relieve some or many of these symptoms.

Nicotinell 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, Nicotinell Nicotine Lozenges should be used with a stop smoking behavioural support programme.

Nicotinell 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.

Nicotinell 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.

Before you use Nicotinell Nicotine Lozenges

When you must not take it

You should not use Nicotinell Nicotine Lozenges if:

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

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.

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 diabetes you should monitor your blood sugar levels more often than usual when starting Nicotinell Nicotine Lozenges as you may find your insulin or other medication requirements alter.

If you have epilepsy, you should not use Nicotinell Nicotine Lozenges unless your doctor has told you to if you have epilepsy or are taking medicines for seizures.

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.

If you are pregnant or breastfeeding, it is best if you can give up smoking without the use of NRT. However, it is better to stop smoking using NRT than to continue smoking.

Do not use Nicotinell Nicotine Lozenges if you are under 12 years of age.

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. Make sure you keep nicotine containing products out of the reach and sight of children at all times.

Lozenges can represent a choking hazard.

Keep out of reach of children. Nicotinell Nicotine lozenges should be used with caution in patients with aspiration and swallowing problems.

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 Nicotinell Nicotine Lozenges if the packaging is torn or shows signs of tampering.

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.

Before you start to use it

You must tell your pharmacist or doctor if:

- You have an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse.
- You 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.
- You have heart or circulation problems including heart failure or stable angina or high blood pressure.
- You have had a stroke.
- You have any serious liver or kidney disease. You may be more prone to side effects.
- You are a diabetic.
- You have been diagnosed as having a tumour of the adrenal glands (phaeochromocytoma). Nicotine may make your symptoms worse.
- You have any allergies to any other medicines.
- You are pregnant or intend to become pregnant.
- You are breastfeeding or planning to breastfeed.

If you have not told your pharmacist or doctor about any of the above, tell them before you use Nicotinell Nicotine Lozenges.

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

If you are 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. 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.

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 second hand smoke. You should use NRT products that are taken intermittently (eg. 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.

Using other medicines

Tell your pharmacist or doctor if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Stopping smoking, with or without nicotine replacement products such

as Nicotinell Nicotine Lozenges, may alter the absorption of some medicines. The doses of the other medicines that you are using may need to be changed.

You should tell your pharmacist or doctor if you are using any other medicines including any of the following medicines:

- 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 Nicotinell Nicotine Lozenges or affect how well Nicotinell Nicotine Lozenges work.

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 Nicotinell Nicotine Lozenges.

Things to be careful of

Each lozenge contains 15mg of sodium that should be taken into account by those who are on a low sodium diet.

How to use Nicotinell Nicotine Lozenges

During any attempt to give up smoking using Nicotinell 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.

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

Nicotinell 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.

Dosage

For adults (and young people aged over 12 years) who want to stop in a few months, Nicotinell 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 Nicotinell 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 Nicotinell 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 Nicotinell Nicotine Lozenges.

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 Nicotinell 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 (Overdose)

If you smoke or use any other nicotine containing product while you are using Nicotinell 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.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too many Nicotinell Nicotine Lozenges.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

While you are using Nicotinell Nicotine Lozenges

Things you must do

Use Nicotinell Nicotine Lozenges exactly as your pharmacist or doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are using Nicotinell Nicotine Lozenges.

Tell your doctor or pharmacist if you become pregnant while using Nicotinell Nicotine Lozenges.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Nicotinell Nicotine Lozenges.

Nicotinell Nicotine Lozenges help most people but they may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- Sore throat, mouth irritation
- Nausea
- Hiccups
- Stomach upsets
- Vomiting
- Diarrhoea
- Excess saliva
- Dizziness
- Headache

These are the more common side effects of Nicotinell Nicotine Lozenges. Mostly these are mild and short lived. You may experience these side effects as you decrease the number of lozenges that you use.

Tell your doctor immediately if you notice any of the following:

- Changes from your normal heartbeat
- Mouth ulcer
- Red or itchy skin

These may be serious side effects of Nicotinell Nicotine Lozenges. These side effects are uncommon.

If any of the following happen, stop using Nicotinell Nicotine Lozenges and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- Fast or very irregular heartbeat
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. You may have a serious allergic reaction to the medicine.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some people. Tell your pharmacist or doctor 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.

Transferred dependence

Some people worry that they will quit smoking but become dependent on Nicotinell 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.

After using Nicotinell Nicotine Lozenges

Storage

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.

Keep Nicotinell Nicotine Lozenges in a cool dry place where the temperature stays below 25°C.

Heat and dampness can destroy some medicines. Do not leave Nicotinell Nicotine Lozenges in the car on hot days.

Do not store Nicotinell Nicotine Lozenges or any other medicine in the bathroom or near a sink.

Keep Nicotinell Nicotine Lozenges where 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.

Disposal

If your pharmacist or doctor tells you to stop using the lozenges, ask your pharmacist what to do with any lozenges that are left over.

If you have any more questions or are not sure about anything, ask your pharmacist or doctor.

Product Description

Active ingredient

Each lozenge contains either 2mg or 4mg nicotine in the form of a resin complex (nicotine polacrilex).

Other ingredients:

- Mannitol
- Magnesium stearate
- Sodium alginate
- Xanthan gum
- Potassium bicarbonate
- Sodium carbonate
- Aspartame
- Flavour – Peppermint (PI 106645)

Presentation

Nicotinell Nicotine Lozenges are cream/white embossed biconvex round tablets with an odour of peppermint. The 2mg lozenges are embossed with 'L344' and the 4mg lozenges with 'L873' on one face. They are available in packs of 36, 72, 96, 108, 120, 132, 144, 156 and 168 lozenges (not all pack sizes may be marketed).

2mg: AUST R 276925

4mg: AUST R 276926

Sponsor

Perrigo Australia
25 - 29 Delawney Street,
Balcatta, WA 6021

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