

Consumer Medicine Information (CMI) summary

[Full CMI](#) on next page has more details. If you are worried about this medicine, speak to your doctor or pharmacist.

1. Why am I using NicoZed®?

NicoZed® is a therapeutic nicotine vaping product system used to assist adult smokers in quitting smoking or managing nicotine intake as part of a structured smoking cessation plan under medical or pharmacy oversight.

NicoZed® PODs come in three strengths; two with active ingredients **at 20mg/mL or 35mg/mL nicotine (as benzoate and lactate) & one with 0 mg/mL nicotine**. The 0 mg/mL nicotine PODs are designed for Step 2 and Step 3 (see 3 Step-Step Down© protocol in Section 4) to help you maintain the behavioural habit while weaning off nicotine entirely.

For more information, see Section [1. Why am I using NicoZed®?](#) in the full CMI.

2. What should I know before I use NicoZed®?

Do not use if you have ever had an allergic reaction to nicotine (for the PODs containing nicotine), the salt component of the nicotine (benzoate and lactate), propylene glycol, glycerin, or any of the flavouring ingredients listed at the end of the CMI. Do not start NicoZed® if you do not already have a nicotine addiction.

Prior to using NicoZed®, your doctor or nurse practitioner or pharmacist should be advised if you:

- **Are pregnant or plan to become pregnant or are breastfeeding,**
- Have any other medical conditions or take any other medications;
- Have Cardiovascular conditions, (heart attack, angina, severe arrhythmia, or uncontrolled high blood pressure);
- Have severe liver or kidney disease;
- Have active stomach ulcer/s or diabetes;
- Have an overactive thyroid gland or a tumour of the adrenal glands;
- Have epilepsy or are medicated for controlling fits or seizures; or
- Are under 18 years of age.

For more information, see Section [2. What should I know before I use NicoZed®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NicoZed® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NicoZed®?

NicoZed® Vapes come in two parts...a NicoZed® rechargeable Device ("Device") and a NicoZed® POD ("POD"). Use NicoZed® when nicotine cravings occur as directed by your healthcare professional.

NicoZed 3 Step-Step Down© approach – Firstly stop smoking and use only NicoZed® for your cravings, then:

- Step 1. Start NicoZed® at the appropriate nicotine strength (20mg/mL or 35mg/mL);
- Step 2. When able to self-regulate, step down to 0mg/mL nicotine; and
- Step 3. Move beyond the NicoZed® Device to independence from both cigarettes and nicotine.

More instructions can be found in Section [4. How do I use NicoZed®?](#) in the full CMI.

5. What should I know while using NicoZed®?

Things you should do	Remind your doctor, nurse practitioner or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding before using NicoZed® or if you have any conditions noted in Section 2.
Things you should not do	Do not start using NicoZed® if you are not already a smoker or already have a nicotine addiction. Do not stop using NicoZed® suddenly to avoid withdrawal symptoms such as cravings. Do not smoke or use other nicotine-containing products. Do not supply NicoZed® to anyone else.
Driving or using machines	NicoZed® may in rare cases cause dizziness or nausea, particularly at first use or strength change. Do not drive or operate machinery if you experience these symptoms.
Drinking alcohol	Tell your doctor or nurse practitioner or pharmacist if you drink alcohol. Alcohol consumption can lower inhibitions & increase cigarette cravings, making it harder to succeed in quitting smoking
Looking after your medicine	Store below 25°C in a cool dry place out of direct sunlight. Keep PODs in blister pack until use. Keep NicoZed® out of reach of children & pets.

For more information, see Section [5. What should I know while using NicoZed®?](#) in the full CMI.

6. Are there any side effects?

Common side effects include cough, mouth or throat irritation, headache, nausea and dizziness. If you smoke or consume nicotine from other sources (eg. pouches) it could result in a nicotine overdose (only applicable to NicoZed® PODs containing nicotine (as benzoate and lactate) (20 mg/mL or 35 mg/mL PODs)).

Call 000 for an ambulance or go straight to the Emergency Department at your nearest hospital if you experience serious side effects such as signs of an allergic reaction (severe rash, swelling, difficulty breathing), rapid heartbeat, severe nausea or vomiting, low blood pressure or convulsions.

For more information, see Section [6. Are there any side effects?](#) in the full CMI



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

NicoZed®

Active ingredient(s): Nicotine (as Benzoate and Lactate) or 0mg/mL Nicotine.

Consumer Medicine Information (CMI)

This leaflet provides important information about using NicoZed®. **You should also speak to your doctor, nurse practitioner or pharmacist if you would like further information or if you have any concerns or questions about using NicoZed®.**

Where to find information in this leaflet:

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

1. Why am I using NicoZed®?

NicoZed® PODs contain the active ingredient nicotine (as benzoate and lactate) or 0 mg/mL nicotine.

NicoZed® is a therapeutic nicotine vaping product system. The eLiquid in the POD is vapourised during inhalation to help with your nicotine dependency.

NicoZed® PODs come in two strengths with Nicotine (as Benzoate and Lactate) & one with zero nicotine strength:

- 35mg/mL Nicotine (as Benzoate and Lactate)
- 20mg/mL Nicotine (as Benzoate and Lactate)
- 0mg/mL Nicotine.

NicoZed® is used to assist adult smokers in quitting smoking or managing nicotine intake as part of a structured smoking cessation plan under medical or pharmacy oversight. It works by delivering controlled amounts of nicotine vapour to help manage cravings and relieve physical withdrawal symptoms during smoking cessation. The 0 mg/mL PODs are designed for Step 2 and Step 3 (see 3 Step-Step Down© protocol in Section 4) of the transition plan to help you maintain the behavioural habit while weaning off nicotine entirely.

2. What should I know before I use NicoZed®?

Warnings

Do not use NicoZed® if:

- You are allergic to nicotine (for PODs containing nicotine), the salt component of nicotine (benzoate and lactate), propylene glycol, glycerin or any of the flavouring ingredients listed at the end of this leaflet.
- You do not already have a nicotine addiction or are not an established smoker.
- You are under 18 years of age, unless specifically directed by a doctor or nurse practitioner.

Check with your doctor, nurse practitioner or pharmacist if you have:

- Any other medical conditions or take any other medications;
- Cardiovascular or cerebrovascular conditions (such as heart attack, stroke, angina, severe arrhythmia, or uncontrolled high blood pressure).
- Severe liver or kidney disease.
- Active stomach ulcer/s or diabetes.
- An overactive thyroid gland or a tumour of the adrenal glands.
- Epilepsy or taking medication for controlling fits or seizures.

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 nurse practitioner before using NicoZed® if you are pregnant or intend to become pregnant. Nicotine passes to the foetus and can cause harm; stopping smoking or vaping without nicotine vaping therapy is preferred during pregnancy. Tell your doctor or nurse practitioner if you are unable to stop smoking during pregnancy.
- Check with your doctor or nurse practitioner before using NicoZed® if you are breastfeeding or intend to breastfeed. Nicotine passes into breast milk and may affect the infant. Tell your doctor or nurse practitioner if you are unable to stop smoking or vaping during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or nurse practitioner 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. When you stop smoking, your body's metabolism changes, which may affect how certain medicines are processed.

Stopping smoking and starting NicoZed®:

When you stop smoking tobacco cigarettes, your body processes certain medicines differently. Stopping smoking (with or without NicoZed®) may increase blood levels of some medicines, which means your doctor may need to lower your dose.

Medicines that may require dose adjustments when you stop smoking include:

- Theophylline (used to treat asthma and breathing conditions)
- Clozapine and olanzapine (used to treat mental health conditions)
- Insulin (used to manage diabetes)
- Warfarin (used to thin the blood)

- Tacrine or ropinirole (used for Parkinson's disease or Alzheimer's disease)

Other interactions:

- Adenosine (used for irregular heartbeats): Nicotine may increase the effect of adenosine on your heart rate and blood pressure.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NicoZed®.

4. How do I use NicoZed®?

How much to use

NicoZed® 3 Step-Step Down©

NicoZed® should be used as part of a structured 3-step transition plan. **Stop smoking cigarettes completely when you begin using NicoZed®:**

- **Step 1:** Start NicoZed® at the appropriate nicotine strength (20 mg/mL or 35 mg/mL) as prescribed by your doctor, nurse practitioner or recommended by your pharmacist to control initial cravings.
- **Step 2:** When you can self-regulate and manage cravings, step down to the 0 mg/mL nicotine POD to break chemical nicotine dependence while maintaining the physical routine. You may interchange POD strength (between 20mg/mL and the 0mg/mL POD) during this transition phase as you wean yourself off nicotine.
- **Step 3:** Gradually reduce usage of the NicoZed® Device until you achieve full independence from both cigarettes and vaping.

How to assemble and use the NicoZed® Device & POD System (two separate packs-purchased separately).

1. Remove all packaging from the NicoZed® POD, including the **two silicone rubber bungs** (one located at each end of the POD).
2. Insert the POD firmly into your rechargeable NicoZed® Device.
3. Power on the Device by **holding down the silver button for 5 seconds**. Confirm that the screen is on without the padlock symbol showing, which indicates the Device is unlocked for use.
4. Seal your lips around the chimney of the POD and gently inhale to ingest vapour into your mouth and airways when nicotine cravings occur.

Troubleshooting

- If NicoZed® does not generate vapour, repeat the powering on step above.
- If the NicoZed® Device screen under the silver button does not light up, recharge the battery via the USB port at the bottom of the Device.
- Confirm the POD contains eLiquid — the droplet icon on the Device screen should indicate eLiquid is remaining inside the POD.

NicoZed® has NFC built in-track your own use

At regular intervals you can tap your NicoZed® Device to the back of your compatible mobile phone and Near Field Communication (NFC) technology will provide usage insights to assist with your progress to ditching nicotine dependency fully. When you tap and use the NFC technology, a screen

should pop up on your compatible mobile phone showing your vaping puffs over time. Use this information to understand when you are triggered to need nicotine & seek ways to mitigate those triggers.

When to use NicoZed®

Use NicoZed® only when cravings occur, as instructed by your healthcare professional. Do not use it continuously or socially if cravings are absent.

If you forget to use NicoZed®

NicoZed® is used on demand when you experience nicotine cravings. If you forget to use it at a time you usually experience cravings, simply use a puff when the next craving occurs. **Do not inhale excessively or take extra puffs to make up for missed doses.**

If you use too much NicoZed® (Overdose)

If you smoke cigarettes or use other nicotine sources (e.g., nicotine pouches or patches) while using nicotine-containing NicoZed® PODs (20 mg/mL or 35 mg/mL), or if a child ingests the liquid contents, this can cause nicotine overdose or poisoning.

Signs of nicotine overdose include severe nausea, vomiting, dizziness, headache, excessive salivation, abdominal pain, cold sweats, confusion, rapid heartbeat, or fainting.

You should immediately:

- Phone the Poisons Information Centre (by calling **13 11 26**), or
- Contact your doctor or nurse practitioner, or
- **Call 000 for an ambulance or go straight to the Emergency Department at your nearest hospital.**

You should do this even if there are no immediate signs of discomfort or poisoning.

5. What should I know while using NicoZed®?

Things you should do

- Remind your doctor, nurse practitioner, dentist or pharmacist that you are using NicoZed®.
- Inform your healthcare provider straight away if you are pregnant or plan to become pregnant or are breastfeeding while using NicoZed®. Refer to Section 2 above for specific advice on using NicoZed® during these times.
- Monitor your progress along the 3-Step transition pathway to ensure you move toward complete independence from nicotine.

Things you should not do

- Do not start using NicoZed® if you are not already an established smoker or nicotine user.
- Do not stop using NicoZed® abruptly if doing so causes severe withdrawal symptoms or triggers a relapse to smoking cigarettes.
- Do not smoke tobacco cigarettes or use other nicotine-containing products concurrently with NicoZed®.
- Do not supply or sell NicoZed® PODs or Devices to anyone else.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NicoZed® affects you. NicoZed® may cause mild dizziness, light-headedness, or nausea in some people, particularly during initial use or when changing nicotine strengths. Do not drive or operate machinery if you experience these symptoms.

Drinking alcohol

Tell your doctor or nurse practitioner or pharmacist if you drink alcohol. Alcohol consumption can lower inhibitions and increase cigarette cravings, making it harder to succeed in quitting smoking.

Looking after your medicine

- Store the NicoZed® Device and PODs below 25°C in a cool, dry place out of direct sunlight.
- NicoZed® Device and PODs to be kept dry and must not be immersed in water or other liquids.
- Keep PODs inside their original blister packaging until immediately before use to protect them from moisture, heat, and light.
- Do not store NicoZed® in the bathroom, near a sink, in a hot car, or on windowsills.
- Keep NicoZed® PODs and Device strictly out of reach of children and pets. Concentrated nicotine liquid can be fatal if swallowed or absorbed through the skin.

Getting rid of any unwanted medicine

If you no longer need this medicine, if PODs are damaged or leaking, or if the expiry date has passed, take them to any local community pharmacy for safe disposal. Do not throw unused PODs into domestic rubbish bins or flush liquid into drains.

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.

See the information below and, if you need to, ask your doctor, nurse practitioner or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal & Respiratory: • Throat or mouth irritation • Cough or dry mouth • Nausea or indigestion • Changes in taste Neurological: • Mild headache • Light-headedness or dizziness • Hiccups	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction: • Swelling of the face, lips, mouth, tongue, or throat • Severe skin rash, itching, or hives • Difficulty breathing or swallowing Nicotine Toxicity / Cardiac: • Fast, slow, or irregular heartbeat • Chest pain or tightness • Severe nausea, vomiting, cold sweats, or faintness	Call 000 for an ambulance or go straight to the Emergency Department at your nearest hospital or call your doctor straight away if you notice any of these serious side effects.

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

Availability & Scheduling

- **NicoZed® 35 mg/mL PODs** are a **PRESCRIPTION ONLY MEDICINE (Schedule 4)** - require a prescription from a doctor or nurse practitioner.
- **NicoZed® 20 mg/mL and 0 mg/mL PODs** are a **PHARMACIST ONLY MEDICINE (Schedule 3)**. Available from a pharmacist without a prescription for adult smokers, or can be supplied on prescription.
- **NicoZed® Vape Device** is available separately from pharmacies for use with NicoZed® PODs.

What NicoZed® PODs contain

Active ingredient (main ingredient)	Nicotine (as Benzoate and Lactate) • 35mg/mL Nicotine (as Benzoate and Lactate) • 20mg/mL Nicotine (as Benzoate and Lactate) • 0mg/mL Nicotine (contains no addictive nicotine).
Other ingredients (inactive ingredients)	Propylene Glycol & Glycerin. Flavourings for mint, menthol or tobacco flavours

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

What NicoZed® looks like

NicoZed® Pods contain a clear to light amber liquid supplied in pre-filled sealed POD units designed exclusively for use with the NicoZed® Device system.

NicoZed® PODs come in three flavours:

- Menthol flavour
- Mint flavour
- Tobacco flavour

NicoZed® PODs come in three strengths:

- 35mg/mL Nicotine (as Benzoate and Lactate)
- 20mg/mL Nicotine (as Benzoate and Lactate)
- 0mg/mL Nicotine



Images above-not to actual size. Pen shown in image directly above is for size comparison to NicoZed® goods.

NicoZed® is not a registered medicine on the Australian Register of Therapeutic Goods (ARTG):

- As of July 2026, there are no therapeutic vapes that have been evaluated by the TGA and included in the Australian Register of Therapeutic Goods (ARTG) for smoking cessation or the management of nicotine dependence.
- Therapeutic goods not included in the ARTG are known as unregistered or unapproved goods.
- These products have not been assessed by the TGA for quality, safety and efficacy or performance.
- Therapeutic vapes are not a first line of treatment for smoking cessation, vaping cessation or the management of nicotine dependence.
- However, where clinically appropriate, there are access pathways for registered health care professionals to prescribe or supply therapeutic vapes for their patients where it is agreed that this is an appropriate course of treatment.

Anyone considering use of Vapes must know:

- Impacts on health from Vaping long term are unknown.
- Use NicoZed® only for smoking cessation or the management of nicotine dependence.
- Trial other pathways to give up smoking or vaping before using NicoZed® which may include:
 - Cold turkey. Willpower alone is hard, but it is advised as a preferential pathway. If 'cold turkey' pathway does not work for you then discuss treatment options with your trusted healthcare provider.
 - Nicotine Replacement Therapies (Products that contain nicotine in a smoke free format including gums, mists, patches, or other).
 - Varenicline (a prescription medication to reduce cravings and withdrawal symptoms).
 - Contacting Quitline (13 7848) for help. Quitline is staffed by qualified counsellors and provides confidential, professional, evidence-based counselling and information on how to quit smoking and/or vaping.
- For temporary use only.
- Cigarettes should not be smoked while using NicoZed®.

NicoZed® Product warnings:

- KEEP OUT OF REACH OF CHILDREN**
- Poisons Information Centre: Phone 131126**
- Avoid contact with eyes
- Avoid contact with skin
- Do not swallow
- Do not use if foil pack is broken or damaged.
- Seek Doctor's advice if pregnant or plan to become pregnant or are breastfeeding prior to use
- THIS PRODUCT CONTAINS NICOTINE, WHICH IS A HIGHLY ADDICTIVE SUBSTANCE.**
 - This applies to NicoZed® PODs in the strength of 20mg/mL and 35mg/mL Nicotine (as Benzoate and Lactate).
 - NicoZed® PODs with the strength of 0mg/mL Nicotine contain no addictive nicotine.
- NicoZed® Device to be kept dry and must not be immersed in water or other liquids.
- Only use NicoZed® PODs in a NicoZed® Device.

Who distributes NicoZed®

Arixl Pty Ltd
Unit 6/14 Commercial Drive, Pakenham Vic 3810
Australia

This leaflet was prepared in August 2026