

pBayPharma

***THERAPEUTIC VAPING PRODUCTS
INFORMATIONAL BOOKLET & CATALOGUE***

b About Bay Pharma

Bay Pharma, founded with a strong vision for the future of pharmaceutical innovation, is a pioneering supplier of therapeutic, pharmaceutical-grade vaporised nicotine products.

Our company operates at the intersection of cutting-edge research and rigorous safety standards, ensuring our offerings are always of the highest calibre.

Our product portfolio, robustly designed to meet the varied needs of our Australian customers, centres on therapeutic vaping products formulated to the highest pharmaceutical standards. Leveraging scientific knowledge and advanced technologies, we deliver products that meet the rigorous demands of the pharmaceutical industry.

Our Mission

Improve Australia's health with our innovative smoking and nicotine cessation therapies, empowering patients and healthcare providers nationwide

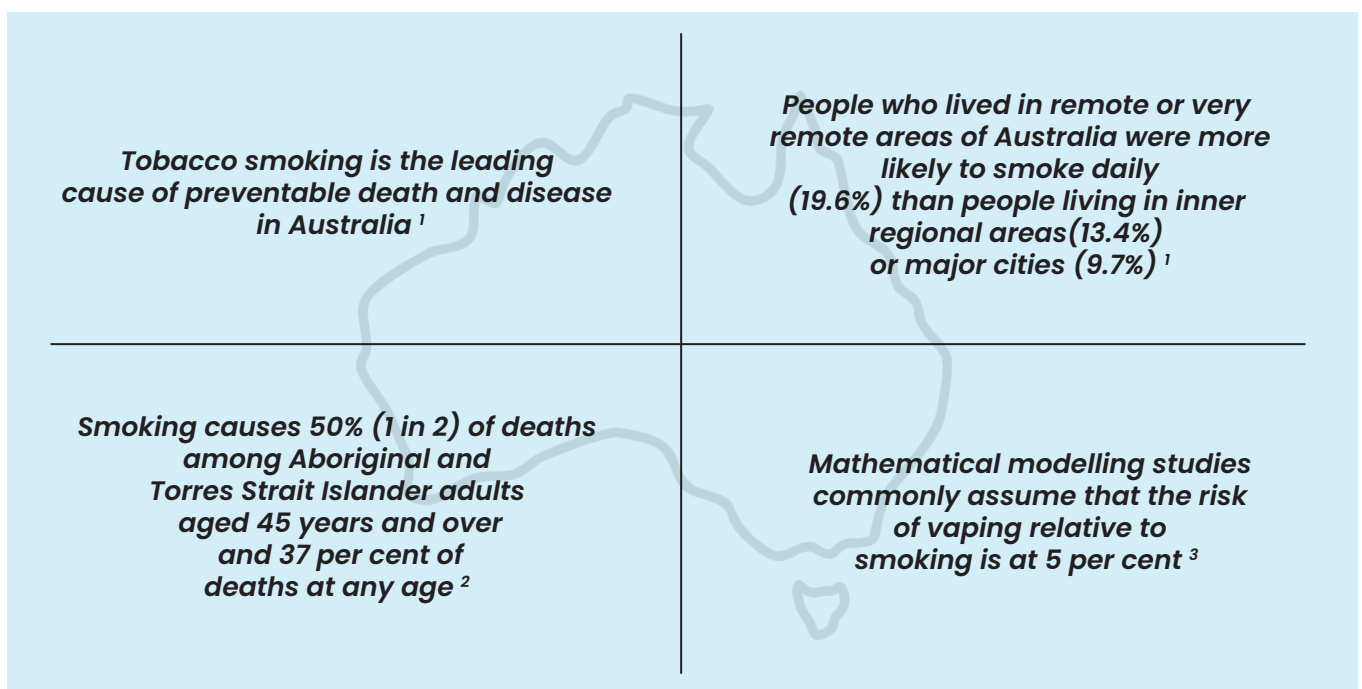
Our Vision

Be Australia's leader in therapeutic vaping, advancing health technology and promoting a smoke-free future for all Australians

Statement of Independence

Bay Pharma is wholly independent, Australian company. We stand independent from the tobacco industry and are committed to establishing a health-focused future that rises above traditional nicotine delivery systems.

Smoking Burden of disease



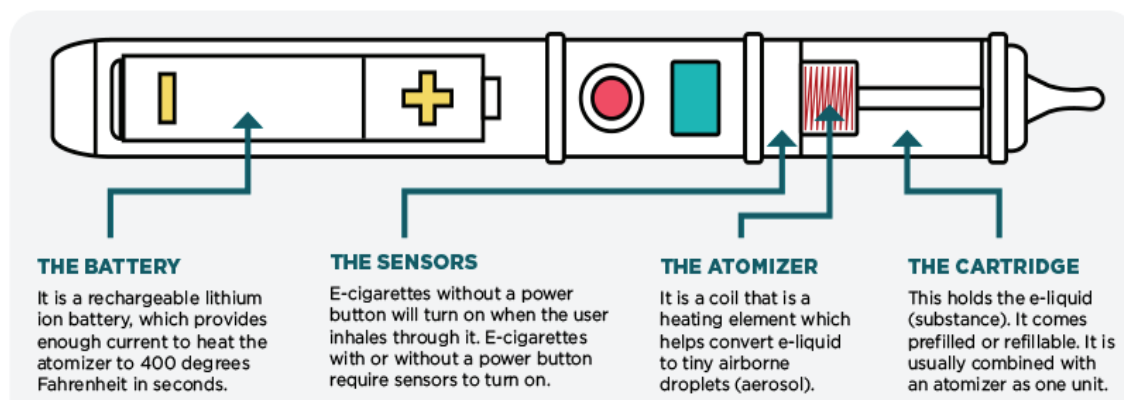
1. Australian Institute of Health and Welfare (2023) Alcohol, tobacco & other drugs in Australia, AIHW, Australian Government
2. <https://www.anu.edu.au/news/all-news/smoking-killing-one-in-three-first-nations-people>
3. <https://stories.uq.edu.au/contact-magazine/2022/ecigarettes-vaping-what-we-know-so-far/index.html>

What is a Therapeutic Vaping device?

Therapeutic vaping is the practice of inhaling a vapor containing nicotine produced by an electronic device. These devices heat a liquid solution which typically contains nicotine, propylene glycol, vegetable glycerin, and specified flavorings, transforming it into a breathable aerosol.

Therapeutic vaping devices are designed to mimic the physical sensation and ritual of smoking traditional cigarettes without burning tobacco. The key aspect of therapeutic vaping that replicates smoking is the "hand-to-mouth" action, providing a similar tactile experience to holding a cigarette. This action, combined with the inhalation and exhalation of vapor, aims to satisfy the behavioral and psychological aspects of smoking.

How does a therapeutic vaping device work?



Therapeutic Vaping Indications

Therapeutic vaping products can be prescribed for the following indications:

- To assist with smoking cessation
- Management of nicotine dependence

Is Therapeutic Vaping effective?

There is high-certainty evidence that therapeutic vaping with nicotine increase quit rates compared to NRT and moderate-certainty evidence that they increase quit rates compared to therapeutic vaping without nicotine¹

Patient Access to Therapeutic Vaping Products

From 1st October 2024, certain therapeutic NVPs will become available to patients as a pharmacy only medication.

- Therapeutic NVPs with 20mg/ml Nicotine or less available as Pharmacist Only Medicine
- Therapeutic NVPs with greater than 20mg/ml Nicotine available as Prescription Only Medicine

Requirements for Pharmacy Only Supply (20mg/ml Nicotine or less)

Pharmacist Must Ensure:

- Supply is to a persons aged 18 or over
- Professional advice is provided to the patient on alternative cessation supports and therapies, appropriate dose and frequency depending on age, weight and severity of condition, length of treatment, suitable titration, and interactions with other medicines
- Contact details about smoking cessation support services are provided to the patient
- The quantity of the goods does not exceed 1 month supply and is only supplied to the patient once in a month
- That the nicotine concentration does not exceed 20 mg/mL.
- Pharmacists need to complete a SAS-C application for new patients via TGA portal

Requirements for Prescription Only Supply (>20mg/ml Nicotine)

- Prescription from an Australian Healthcare professional (GP or Nurse Practitioner) required.
- Prescriber must be an Authorised prescriber OR complete SAS-C application.

Scheme	Scheme Notes
Authorised Prescriber Scheme	<ul style="list-style-type: none"> • Apply online (https://compliance.health.gov.au/sas/) for authority to prescribe NVPs for patients under your immediate care (without needing separate approval for each patient) • Valid for 5 years • Report number of patients for whom you have prescribed every 6 months
Special Access Scheme C	<ul style="list-style-type: none"> • A medical practitioner or nurse practitioner can use the online notification system to access the unapproved product immediately. • You must submit a form for each individual patient to notify the TGA within 28 days of use of the unapproved product. • A copy of the form must be kept with the patients medical record. No approval letter is required • A health practitioner such as a pharmacist can submit the form on behalf of the the prescriber

Pharmacy Ordering Information:

Available through CanView

www.canview.com.au



LULA



Medical Device Standard

Child Lock Feature

Quit Step Program

Quit Step 1

30mg/ml *Prescription Required

Take 3-5 puffs from the LULA pod device PRN when experience cravings to smoke. 1 pod per day (60mg/day).
Stop smoking by week 2. If patient is still smoking by week 4 refer to GP.
Additional counselling may include reducing usage 1 pod every 2 days

Week 1-8

Quit Step 2

20mg/ml

Take 3-5 puffs from the LULA pod device PRN when experience cravings to smoke. 1 pod per day (40mg/day).
If no prescription is available 20mg/ml can be used as step 1.
If patient is dual using or relapse to smoking refer to GP.

Week 8-16

Quit Step 3

0mg/ml

Take 3-5 puffs from the LULA pod device PRN when experience cravings to smoke. 1 pod per day (0mg/day).
Nicotine free placebo is designed to address psychological or habitual behaviour of smoking.
May be combined with NRT (Patch, gum). Aim to stop within 6 months when no risk of relapse to smoking

Week 16+

VARIANT	VOLUME	NICOTINE	RRP
LULA - Tobacco	2 x 2ml Pods	0 20 30mg/ml	\$22
LULA - Mint	2 x 2ml Pods	0 20 30mg/ml	\$22
LULA - Unflavoured	2 x 2ml Pods	0 20 30mg/ml	\$22
LULA Refillable Pods	2 x 2ml Pods	-	\$20
LULA Device - Black	580mAh	-	\$20

CHOSEN



Step Down Nicotine

CRP container

Salt & Freebase

VARIANT	VOLUME	NICOTINE	RRP	AVAILABLE FLAVOURS
Freebase Nicotine Vapouriser eliquid	60ml	0 3 6 12 mg/ml	\$28	Tobacco Mint Unflavoured
Salt Nicotine Vapouriser eliquid	30ml	20 30 mg/ml	\$28	Tobacco Mint Unflavoured

LULA LULA Refillable Pod Device

VARIANT	VOLUME	NICOTINE	RRP
LULA Refillable Pods	2 x 2ml Pods	-	\$20
LULA Device - Black	580mAh	-	\$20

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Introduction

This guide aims to assist prescribers in advising patients on the practical use of vaporized nicotine products to help quit smoking, quit nicotine use or manage nicotine dependence. Starting patients on a higher dose of nicotine is recommended to reduce the likelihood of dual use (smoking and vaping simultaneously) and to facilitate a gradual reduction of nicotine intake over time



Avoid Dual Use (Smoking and Vaping)

- **Importance of Exclusivity:** Emphasize that the health benefits of vaping is only realised if patients quit smoking completely
- **Support and Monitoring:** Encourage patients to keep a diary of their vaping and smoking habits to help identify triggers and manage cravings more effectively. **My QuitBuddy App** can assist with this.



Initial Experience and Expectations

- **Common Initial Reactions:** Patients may experience coughing, throat irritation, or dry mouth when they first use the device. These reactions typically subside after a few days.
- **Tips to Mitigate Discomfort:** Suggest patients drink water to stay hydrated and take breaks between puffs to reduce throat irritation. If coughing or throat irritation persists you may suggest trying an alternate flavouring or reduce the nicotine concentration.



Dosage and Frequency

- **Starting Dosage:** Suggest beginning with higher nicotine concentrations if available and gradually decrease overtime when there is no risk of relapse to smoking
- **LULA Quit Steps 30mg/ml > 20mg/ml > 0mg/ml**
- **Frequency of Use:** Advise patients to use the device when they feel cravings (ad libitum) but to gradually reduce the frequency of use over time.
- The goal is to first stop smoking and gradually wean off nicotine over time.

Proper Inhalation Technique

- **Taking a Puff:** Instruct patients to take slow, gentle puffs lasting 1-2 seconds each. Encourage them not to inhale too forcefully, as this can lead to coughing.
- **Puff Frequency:** Recommend starting with 3-5 puffs per session and adjusting based on their nicotine cravings and comfort level. Patients should avoid chain vaping to prevent excessive nicotine intake and potential irritation



For additional information on Bay Pharma products and access please contact Bay Pharma on **1300 938 651** or Email: **info@baypharma.com.au**

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Bay Pharma NVP products are not a registered medicine on the Australian Register of Therapeutic Goods (ARTG). NVPs have not been approved as smoking cessation aids in Australia. These products are considered to be 'unapproved' therapeutic goods and for use by those who are still motivated to quit smoking and have discussed NVP usage with their healthcare practitioner, NVPs may be a reasonable intervention to recommend. This needs to be preceded by an evidence-informed shared decision-making process

This communication is strictly for healthcare practitioners and patients as part of a consultation and should not be disseminated to the general public.

Bay Pharma Pty Ltd. (ABN 56 662 412 731), Level 4, 55 Clarence Street, Sydney 2000
Telephone: 1300 938 651 Email: info@baypharma.com.au
Date of Preparation January 2024