

Senator URQUHART: Can you tell me what therapeutic vaping products you all have currently on the market?

Hi Ayrton

Apologies for the late response to these questions on notice.

Please find attached our response and additional information:

- Bay Pharma Catalogue
- Product Information Sheet
- Example Certificate on Analysis
- Consumer Medical Information
- Example Toxicological Risk Assessment

Please let me know if any additional clarifications are required

Thanks

David

David Burns | Director Sales & Marketing

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LULA?

LULA pods contain nicotine as their active substance. These pods are designed to support individuals looking to quit smoking and manage nicotine addiction by supplying the nicotine typically obtained from smoking cigarettes. Additionally, they mimic the hand-to-mouth routine that smokers are accustomed to, aiding in the transition away from smoking.

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

2. What should I know before I use LULA?

Avoid using this product if you've previously experienced an allergic reaction to nicotine or any components listed in the Consumer Medicine Information (CMI) document.

Consult with your doctor regarding any existing medical conditions, current medications, or if you are pregnant, planning to become pregnant, or breastfeeding to ensure LULA is appropriate for your situation.

3. What if I am taking other medicines?

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 LULA?

LULA is designed for individuals aiming to quit smoking or manage nicotine dependency, serving as an alternative to cigarette smoking. It's crucial to use LULA under the guidance of a healthcare professional, such as a doctor or pharmacist, to ensure its proper application in smoking cessation or nicotine dependency management efforts.

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

5. What should I know while using LULA?

Things you should do	<ul style="list-style-type: none">• Inform any healthcare professional you consult, such as a doctor or pharmacist, if you have conditions like an overactive thyroid, high blood pressure, a history of stroke, significant liver or kidney disease, diabetes, adrenal gland tumors, or a history of epilepsy, including if you're on medication for seizure management.• Check with your doctor if you are pregnant or intend to become pregnant
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly – you may experience nicotine withdrawal symptoms.• Do not use this medicine if you are allergic to nicotine, or any of the ingredients listed at the end of this leaflet.• Do not use this medicine if you are a non-smoker or you are not currently nicotine dependent
Driving or using machines	<ul style="list-style-type: none">• Exercise caution when driving or operating machinery or tools after using LULA, as it may cause dizziness in some individuals. It's important to be aware of how it affects you personally before engaging in these activities.
Looking after your medicine	<ul style="list-style-type: none">• Ensure LULA pods remain in their sealed blister packaging until use, and keep them in a place that's cool and dry, where temperatures do not exceed 24°C. Also, make sure to store the pods away from any moisture, heat, or direct sunlight. Additionally, place LULA Pods out of the reach of young children and pets to ensure their safety.

6. Are there any side effects?

If you smoke or use any other nicotine containing product while you are using LULA, you may suffer an overdose of nicotine. However, if used correctly, nicotine overdose is unlikely. A large overdose may present symptoms such as exhaustion, convulsions or low blood pressure. In this event, 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.

LULA Pods

Active ingredient: *Nicotine Benzoate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using LULA.

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 LULA.

Where to find information in this leaflet:

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

1. Why am I using LULA?

LULA contains the active ingredient nicotine.

LULA is a nicotine vaping product designed to assist in quitting smoking. It works by supplying the nicotine traditionally obtained from cigarettes and mimicking the hand-to-mouth action of smoking, facilitating the transition away from cigarette use.

LULA may aid in smoking cessation.

LULA may aid in the management of nicotine dependence.

LULA pods are filled with a diluted nicotine solution that, when used with the LULA vaporizing device, is converted into vapor for inhalation. This process provides a substitute for the nicotine usually obtained from smoking cigarettes.

The combination of the device and pods, when used together, is known as the LULA System.

Utilizing the LULA System delivers nicotine to help alleviate withdrawal symptoms such as nausea or irritability, commonly experienced by individuals attempting to quit smoking. It also aids in reducing cigarette cravings and supports efforts to resist the urge to smoke.

2. What should I know before I use LULA?

Warnings

Do not use LULA 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 do not have an existing nicotine dependence.

Check with your doctor if you:

- have an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse.
- have heart or circulation problems including heart failure or stable angina or high blood pressure or have had a stroke. 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 LULA unless your doctor tells you to use it. Once you are discharged from hospital, you may use LULA in consultation with your doctor.

- have any serious liver or kidney disease. You may be more prone to side effects.
- are a diabetic. If you have diabetes you should monitor your blood sugar levels more often than usual when starting LULA 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 a history of epilepsy or are taking medicine to control any fits or seizures.

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

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

7. Are there any side effects?

Pregnancy and breastfeeding

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

Smoking during pregnancy can lead to complications such as inadequate fetal growth, premature delivery, or stillbirth. The most effective measure for enhancing your health and that of your unborn child is to quit smoking. The sooner you stop, the greater the benefits for both your well-being and your baby's development.

If you're pregnant, the ideal scenario is to quit smoking without relying on LULA. Should direct attempts to quit prove unsuccessful, your doctor might advise using LULA as a safer alternative for your baby compared to continuing smoking. It's recommended to make this decision early in pregnancy and to limit LULA use to 2-3 months. The primary goal is to quit smoking, and LULA should only be used upon medical advice.

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

Tobacco smoke causes breathing difficulties and other problems in babies and children. Ideally, if you are breastfeeding, you should try to stop smoking without using LULA.

LULA is not recommended for use during breastfeeding. Instead, nicotine replacement therapy (NRT) products that are used intermittently, such as gum or lozenges, are advised. To minimize nicotine exposure to the baby, it's best to breastfeed just before using these NRT products. This strategy ensures that the baby is exposed to the lowest possible amount of nicotine.

3. What if I am taking other medicines?

Inform your healthcare provider or pharmacist about any medications you are currently taking, including over-the-counter medicines, vitamins, and supplements purchased without a prescription from pharmacies, supermarkets, or health food stores.

Some medicines may interfere with LULA and affect how it works.

The effectiveness of LULA may be influenced by other medications you are taking, and likewise, LULA can affect how other medicines work. It's important to consult with your pharmacist or doctor regarding any potential interactions with medications you are using. They can provide specific guidance on how to manage these interactions.

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

4. How do I use LULA?

How much to take / use

1. Follow all directions given to you by your doctor or pharmacist carefully.
2. These directions may differ from the information contained in this leaflet.
3. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.
4. Use the LULA System when you feel the urge to smoke. It should be used as a direct alternative for smoking.
5. Follow the instructions provided and use LULA until your doctor tells you to stop.

When to take / use LULA

LULA should be used when you feel the urge to smoke. It should be used as a direct alternative for smoking.

How to use LULA

1. Remove pod from blister pack. Remove the silicone covers.
2. Insert the pods into the top of the LULA device. Firmly press the LULA pod into the LULA device.
3. For the best experience, prior to first using the LULA device, ensure the device is fully charged by using the USB-C charger provided.
4. The LED Indicator light on the front of the device will indicate your device's current charge level.
5. The LULA device is simple and familiar to use. The device can be activated by pressing the button on the front or drawing on the device.
6. LULA has a child lock feature, to deactivate the child lock feature press the button 5 times in quick succession. The LED will flash when the device is unlocked
7. To start, place the mouthpiece between your lips about halfway along the mouthpiece.
8. Draw firmly for 2 to 3 seconds. Aim to draw enough air through the device to fill your mouth. Then immediately inhale deeply and then exhale slowly. It's not unusual to cough when you first start, but this will

ease with continued use.

7. Wait at least 20 seconds before your next draw. This will allow the device to reset for the next puff and will enable you to see if your cravings have been satisfied.
8. Note – a flashing white light means there may be a connection error with your pod and device. Try removing the pods and re-inserting or replace with a new pod if it appears to be empty.

For further information about using the LULA device, please consult the User Guide provided with the device.

If you forget to use LULA

LULA is designed as a substitute for smoking cigarettes, aiding in the cessation process. It should be used strictly according to medical or pharmaceutical advice to ensure its effectiveness and safety.

If you stop using LULA suddenly, you may experience symptoms of nicotine withdrawal. Common symptoms of nicotine withdrawal include:

1. Feeling tense and irritable
2. Depression
3. Appetite changes
4. Constipation and gas
5. Insomnia
6. Difficulty concentrating
7. Cough and cold-like symptoms

If you use too much LULA

If you think that you have used too much LULA, you may need medical attention.

Using the LULA System while smoking or consuming any other nicotine-containing products could lead to nicotine overdose. Nevertheless, if LULA is utilized according to the instructions, the likelihood of experiencing a nicotine overdose is low. Always follow the recommended usage guidelines to minimize risks..

Symptoms of nicotine overdose include:

1. Headache
2. Dizziness
3. Stomach upset
4. Drooling
5. Vomiting
6. Diarrhoea
7. Cold sweat
8. Confusion
9. Fainting
10. Pale skin
11. Tremor

In cases of a significant overdose, symptoms may include extreme fatigue, seizures, low blood pressure, potential circulatory failure, and respiratory difficulties. It's critical to seek immediate medical attention if such symptoms are observed.

You should immediately:

4. phone the Poisons Information Centre (by calling 13 11 26), or
5. go to the Emergency Department at your nearest hospital.

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

WARNING – children are more likely to be affected by nicotine and it could cause severe toxicity which may be

fatal.

5. What should I know while using LULA?

Things you should not do

- Do not use LULA if you are allergic to nicotine or any of the ingredients listed at the end of this leaflet.
- Do not use LULA if you do not have an existing nicotine dependence.
- Do not use LULA to treat any other complaint unless your doctor or pharmacist says it is safe. This medicine is for the named patient for whom it is prescribed only.
- Do not give this medicine to anyone else even if they have the same symptoms as you.

It is discouraged to use LULA in conjunction with combustible cigarette smoking.

LULA is intended to support smoking cessation by replacing cigarettes. Dual-use is discouraged.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LULA affects you.

LULA may cause dizziness in some people. See: [if you use too much LULA?](#)

Looking after your medicine

Keep the LULA pods sealed in the blister pack until needed and store in a cool dry place where the temperature stays below 24°C.

Store 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 window sills.

Keep it where young children and pets cannot reach it. (new and used LULA pods contain nicotine, which can be harmful).

When to discard your medicine

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

Do not use if the packaging is torn, shows signs of tampering or if the blister pack is damaged.

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 disposal.

Do not use this medicine after the expiry date.

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.

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

What LULA looks like

LULA pods are available in five (5) flavours:

- Tobacco
- Mint
- Unflavoured
- Grape
- Strawberry

and,

LULA Pods are available in three (3) strengths:

- 0mg/ml (Nicotine Free)
- 20mg/ml Nicotine Salt
- 30mg/ml Nicotine Salt

LULA Pods are available in packs containing three (2ml) pods.

LULA is 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 the Therapeutic Goods and 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, whereby the patient is aware of the following:

- there are no NVPs approved for the ARTG
- the long-term health effects of vaping are unknown
- possession of nicotine-containing e-liquid without a prescription is illegal
- in order to maximise possible benefit and minimise risk of harms, only short-term use is recommended
- dual use (i.e., with continued tobacco smoking) should be avoided.

Who distributes LULA

Bay Pharma Pty Ltd.

Level 4, 55 Clarence Street

Sydney

2000

bBayPharma

For further information:

Email: info@baypharma.com.au

Telephone: 1300 938 651

Visit: www.baypharma.com.au

This leaflet was prepared in December 2023

LULA

Therapeutic Vaping System

The LULA therapeutic vaping system sets industry standards with its ISO 13485 medical device certification, combining simplicity with unparalleled quality. It features an innovative built-in Child Lock, ensuring safety and peace of mind for users seeking a reliable and superior vaping experience. LULA offer users flexibility with pre-filled pod options and refillable pod option.

Product Summary

LULA

Trade Name: LULA

Description: Pre-filled nicotine pod system (2x2ml pods)

Sponsor: Bay Pharma Pty Ltd.

Active Ingredient: Nicotine

Dose and Frequency: Recommend Max 1 pod per day. New users suggest 30mg/ml nicotine level to avoid dual use. Reduce over time when no risk of relapse to smoking.

Nicotine Levels: Nicotine Free | 20mg/ml | 30mg/ml

Flavours: Tobacco | Mint | Unflavoured | Grape | Strawberry

**LULA Device and Pods Sold Separately. Script not required for LULA device.*



Ordering LULA:

LULA is available to order from CanView
www.canview.com.au



How to write a script?

Patient's Medicare no.		Patient's Ref no.	
Patient's full name			
Patient's address			
	Postcode		
Entitlement no.			
PBS Safety Net entitlement cardholder	<input type="checkbox"/>		
Concessional or dependant, RPBS beneficiary or PBS Safety Net concession cardholder	<input type="checkbox"/>		
(Tick appropriate boxes)			
PBS	<input type="checkbox"/>	RPBS	<input type="checkbox"/>
Brand substitution not permitted	<input type="checkbox"/>		

Pharmacist/patient copy

LULA
30mg/ml Pods
30 Pods (1 Month Supply)
3 repeats

LULA Device

Please note: do not reuse

Doctor's signature _____ Date ____/____/____

Patient's or agent's signature _____ Date of supply ____/____/____

Agent's address _____

PHCS 1016

Example is equivalent to 3 months supply of therapeutic vaping product and includes corresponding device.
NB: PRESCRIBE BAY PHARMA PRODUCTS IN MULTIPLES OF 5 TO ASSIST WITH DISPENSING

LULA Instructional Video

Bay Pharma presents an instructional video on LULA therapeutic vaping system.



LULA Refillable Pod

LULA Refillable pod options is suitable for use with CHOSEN eLiquid products.



This information has been prepared for healthcare professionals providing patient access to therapeutic NVPs for the purposes of smoking cessation and the management of nicotine dependence. Bay Pharma products are included as a notified NVP product on TGA website.

BayPharma

Level 5, 55 Clarence Street, Sydney, NSW, 2000

Email: info@baypharma.com.au Tel: 1300 938 651 Website: www.baypharma.com.au

Date: 21/02/2024

Prepared by: Max F.

Certificate of Conformance

SAMPLE NAME	Batch
LULA – Tobacco – 30mg/ml	AU1227

Compositional Analysis

Reference: ZMYC-2022092602-4-30

NO	Name	CAS number	Weight % content
1	Propylene glycol	57-55-6	52.46%
2	Glycerol	56-81-5	40.00%
3	2-Isopropyl-N,2,3-trimethylbutanamide	51115-67-4	1.20%
4	Nicotine	54-11-5	2.68%
5	Benzoic acid	65-85-0	2.68%
6	Methylcyclopentenolone	80-71-7	0.29%
7	Furan ketone	3658-77-3	0.27%
8	2-acetylpyrazine	22047-25-2	0.26%
9	2,3, 5-trimethylpyrazine	14667-55-1	0.16%

Nicotine Quantitation Report

SAMPLE NAME	NICOTINE (mg/mL)	TGO Compliant	Report Reference
LULA – Tobacco – 30mg/ml	30.8mg/ml	Yes	ZMYC-2022092602-4-30

Microbiological Analysis

SAMPLE NAME	Test Item	Results	TGO Compliant	Report Reference
LULA – Tobacco – 30mg/ml	Aerobic Plate Count	<10CFU	Yes	TCT240201C002018
	Molds Yeast count	<10CFU	Yes	TCT240201C002018
	Gram Neg Bacteria resistant to bile salts	Not Detected	Yes	TCT240201C002018
	Escherichia Coli	Not Detected	Yes	TCT240201C002018
	Staphylococcus Aerus	Not Detected	Yes	TCT240201C002018
	Salmonella	Not Detected	Yes	TCT240201C002018

bBayPharma

Level 5, 55 Clarence Street, Sydney, NSW, 2000

Email: info@baypharma.com.au Tel: 1300 938 651 Website: www.baypharma.com.au

Prohibited Ingredients

Prohibited Ingredient	Results	TGO 110 Compliant	Report Reference
Acetoin	Not Present	Yes	ZMYC-2022092602-4-30
Benzaldehyde	Not Present	Yes	ZMYC-2022092602-4-30
Cinnamaldehyde	Not Present	Yes	ZMYC-2022092602-4-30
Diacetyl	Not Present	Yes	ZMYC-2022092602-4-30
Diethylene Glycol	Not Present	Yes	ZMYC-2022092602-4-30
Ethylene Glycol	Not Present	Yes	ZMYC-2022092602-4-30
Pentane-2,3-dione	Not Present	Yes	ZMYC-2022092602-4-30
Vitamin E Acetate	Not Present	Yes	ZMYC-2022092602-4-30

I hereby declare that this certificate of conformity has been produced with accurate and authentic information. Further, I hereby declare the product in the above batch/lot has been produced and manufactured in full compliance with the requirements of the Australian TGO 110, and any applicable legislation.

Authorised by:

Date: 21st February 2024



Max Fudakowski
Bay Pharma Pty Ltd.

pBayPharma

Level 5, 55 Clarence Street, Sydney, NSW, 2000

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Email: info@baypharma.com.au Tel: 1300 938 651 Website: www.baypharma.com.au

Date: 21/02/2024

Prepared by: Max F.

Certificate of Conformance

SAMPLE NAME	Batch
LULA – Unflavoured – Nicotine Free	AU1232

Compositional Analysis

Reference: 0830925C1-03C

NO	Name	CAS number	Weight % content
1	Glycerol	56-81-5	40.00%
2	Propylene glycol	57-55-6	60.00%

Nicotine Quantitation Report

SAMPLE NAME	NICOTINE (mg/mL)	TGO Compliant	Report Reference
LULA – Unflavoured – Nicotine Free	0mg/ml	Yes	0830925C1-03C

Microbiological Analysis

SAMPLE NAME	Test Item	Results	TGO Compliant	Report Reference
LULA – Unflavoured – Nicotine Free	Aerobic Plate Count	<10CFU	Yes	TCT240201C002005
	Molds Yeast count	<10CFU	Yes	TCT240201C002005
	Gram Neg Bacteria resistant to bile salts	Not Detected	Yes	TCT240201C002005
	Escherichia Coli	Not Detected	Yes	TCT240201C002005
	Staphylococcus Aerus	Not Detected	Yes	TCT240201C002005
	Salmonella	Not Detected	Yes	TCT240201C002005

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Level 5, 55 Clarence Street, Sydney, NSW, 2000

Email: info@baypharma.com.au Tel: 1300 938 651 Website: www.baypharma.com.au

Prohibited Ingredients

Prohibited Ingredient	Results	TGO 110 Compliant	Report Reference
Acetoin	Not Present	Yes	0830925C1-03C
Benzaldehyde	Not Present	Yes	0830925C1-03C
Cinnamaldehyde	Not Present	Yes	0830925C1-03C
Diacetyl	Not Present	Yes	0830925C1-03C
Diethylene Glycol	Not Present	Yes	0830925C1-03C
Ethylene Glycol	Not Present	Yes	0830925C1-03C
Pentane-2,3-dione	Not Present	Yes	0830925C1-03C
Vitamin E Acetate	Not Present	Yes	0830925C1-03C

I hereby declare that this certificate of conformity has been produced with accurate and authentic information. Further, I hereby declare the product in the above batch/lot has been produced and manufactured in full compliance with the requirements of the Australian TGO 110, and any applicable legislation.

Authorised by:

Date: 21st February 2024



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Email: info@baypharma.com.au Tel: 1300 938 651 Website: www.baypharma.com.au



Toxicological Risk Assessment

Tobacco 20mg

CHOSEN Vapouriser eLiquid

Strength
20mg/ml

SKU
ACHO30TOB20



EL-Science Toxicological Product Risk Assessment

Product Name	:	Tobacco 20mg
Brand Name	:	CHOSEN Vapouriser eLiquid
Supplier	:	EL Science
Product Version	:	V2
Assessment Performed By	:	Shaun Wedgewood
Assessment Date	:	17/01/2024

This assessment is designed to meet the requirements of GPSR 2005

Toxicological Product Risk Assessment - Summary

This product has been assessed against Health Criteria Values (HCVs) within a standard vaping model by EL-Science. The assessment shows that the eLiquid poses a non-substantial risk to human health over a prolonged period when used as intended as detailed in the product information leaflet.

Methodology

Health Criteria Value Thresholds (HCVs) are the concentration of specific flavour chemical ingredients at which the toxicology of the given chemical may cease to become non-significant when vaped over a prolonged period. EL-Science have commissioned the assessment of hundreds of flavour chemicals and hold full toxicological monographs as well as extended, toxicological assessment monographs for any chemical which is indicated as having a HCV. All toxicological monographs and any resulting toxicological models to produce the resulting HCVs have been performed by external qualified toxicologists.

EL-Science worked closely with one of the globally leading consultancies in respiratory toxicology to develop thresholds and models bespoke to the inhalation of flavour chemicals. The Product Risk Assessment (PRA) model is designed around the determination of thresholds for each chemical present within the product whilst considering cumulative toxicological pathways.

Using these thresholds, referred to as Health Criteria Values (HCVs) as core base data EL-Science then model the usage of a given product over a prolonged period using a standardised vaping model to determine the daily intake and potential impact of each product on specific toxicological pathways to produce the final assessment.

Sensitising compounds are identified in accordance with GHS/CLP. Sensitisers which do not exceed the GHS/CLP trigger are also presented to inform medical assistance being provided by medical professionals.

For further information or supporting evidence please contact EL-Science at contact@elscience.co.uk or call +44(0) 1733 352553

www.elscience.co.uk



Toxicological Risk Assessment Summary Information Table

Please see page 4 for the assessment key.

Toxicological Product Risk Assessment - EL-Science					
SKU	ACHO30TOB20	Assessment Performed By		SW	
Brand Name	CHOSEN Vapouriser eLiquid	Assessment Date		17/01/2024	
Product	Tobacco 20mg				
Supplier	EL Science	Product Version		V2.1	
Chemicals where assessment shows no HCV Required					
Chemicals with no HCV associated: 9					
Chemicals with HCV Assessment			Toxicity Assessment		
CAS Number	Chemical Name	Sensitiser	Local	Systemic	Overall
80-71-7	Corylone (Maple lactone)	S1		1	1
1122-62-9	2-Acetylpyridine			3	3
1124-11-4	2,3,5,6-Tetramethylpyrazine			1	1
22047-25-2	2-Acetylpyrazine			1	1
106-24-1	Geraniol	S0	1	1	1
106-22-9	Citronellol	S0			
14667-55-1	2,3,5-trimethylpyrazine			1	1
116-53-0	2-Methylbutyric acid		1		1
121-33-5	Vanillin			1	1
4940-11-8	Ethyl Maltol			1	1
107-92-6	Butyric acid		1		1



Assessment Summary

Each chemical associated with a HCV is indicated along with an assessment category. The overall PRA has then been reviewed and assigned a Consumption Factor by EL-Science. A flavour with HCV compounds at their maximum threshold would result in a Consumption Factor of 5 would indicate a recommended weekly intake of approximately 30ml per week.

Flavours containing HCV chemicals which are lower than the maximum threshold result in a lower Consumption Factor which effectively correlates to a higher acceptable weekly intake before the potential of increased risk begins to appear in the long term.

In addition, Sensitiser compounds have been highlighted. These are important compounds to communicate to the consumer via labelling and product information leaflets in order to allow susceptible consumers to avoid contact with these compounds.

Assessment Key

Health Criteria Values

There are three categories presented in this summary which are detailed as below;

- 1 - Chemical is significantly below the HCV threshold and poses negligible risk at this concentration.
- 2 - Chemical is below the HCV threshold and poses a non-substantial risk at this concentration so long as batch production is controlled. Further work to reduce this chemical could be undertaken.
- 3 – Chemical is above the HCV threshold (up to 3 x the HCV) and therefore potentially poses a non-negligible risk to the consumer if inhaled over a prolonged period. The product should be further developed to reduce the toxicological profile of the offending chemical(s).
- 4 – Chemical is more than 3 x the HCV level and therefore potentially poses a more substantial risk to the consumer if inhaled over a prolonged period. The product should be further developed to reduce the toxicological profile of the offending chemical(s).

Sensitiser Compounds

- S0 – This compound is classified as a sensitiser but is below the concentration level that would normally cause a concern and therefore poses a negligible risk.
- S1 – This compound is classified as a sensitiser but is below the GHS/CLP labelling trigger. This compound should be communicated to a doctor or medical professional as a precaution should a consumer have an adverse reaction to the product.
- S2 – This compound is classified as a sensitiser and is above the GHS/CLP labelling trigger. This compound should be presented clearly on the product packaging and information leaflet. This compound should be communicated to a doctor or medical professional as a **priority** should a consumer have an adverse reaction to the product.

EL-Science are happy to help you understand this risk assessment document or if you are a legislative body to provide any and all supporting evidence in accordance with the laws of England and Wales. EL-Science have invested approximately £2M in eliquid safety and Toxicology since 2014 and continue to lead the industry forward offering free and confidential advice and are keen to work closely with legislative bodies and steering groups.

You can reach us as contact@elscience.co.uk or call us directly on 01733 352553



Toxicological Product Risk Assessment – Certificate

Product Name	Tobacco 20mg
Brand Name	CHOSEN Vapouriser eLiquid
Supplier	EL Science
Assessment Date	17/01/2024

Assessment Outcome

EL-Science have invested over £2M in toxicology data and laboratories to develop our robust Product Risk Assessment (PRA) model to provide the consumer with full confidence and adequate information to make an informed choice when choosing an eLiquid flavour. Our model is backed up by over 20,000 pages of toxicological data investigating the inhalation pathways for each flavour chemical used to formulate an eLiquid and developed by over 20 chemists and toxicologists over a 4 year period.

EL-Science have designed the assessment model to be similar to that currently used in the food industry. With salt for example, if you exceed the recommended daily amount of salt intake you could potentially increase the risk of developing health complications in the long term.

This product has been assessed by EL-Science against Health Criteria Values (HCVs) associated with the Standard Vaping Model and summarised in the table below. To find the recommended weekly intake for this liquid read the appropriate Risk Factor row indicated and find the number 1.0 (or nearest to 1.0) and then read off the value at the bottom for the weekly amount in millilitres (mL).

The consumer should always read the label which may contain specific information on potential allergies. The product may also contain sensitisers which may adversely affect some consumers.

Consumption Factor	10	0.7	1.0	1.3	1.7	2.0	2.3	2.7	3.0	3.3
	9	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3.0
	8	0.5	0.8	1.1	1.3	1.6	1.9	2.1	2.4	2.7
	7	0.5	0.7	0.9	1.2	1.4	1.6	1.9	2.1	2.3
	6	0.4	0.6	0.8	1.0	1.2	1.4	1.6	1.8	2.0
	5	0.3	0.5	0.7	0.8	1.0	1.2	1.3	1.5	1.7
	4	0.3	0.4	0.5	0.7	0.8	0.9	1.1	1.2	1.3
	3	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0
	2	0.1	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.7
	CF=1	1	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3
		10	15	20	25	30	35	40	45	50
		ml per week								

Based on the above information the maximum recommended intake for this liquid is 50ml per week

Shaun Wedgewood

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For further information or supporting evidence please contact EL-Science at contact@elscience.co.uk or call +44(0) 1733 352553

pBayPharma

*THERAPEUTIC VAPING PRODUCTS
INFORMATIONAL BOOKLET*

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. With an unwavering commitment to health, safety, and quality, we are proudly compliant with the Therapeutic Goods Administration (TGO-110) Standards.

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

Our fundamental principles of integrity, transparency, and commitment govern every aspect of our operation. We aim to lead by example in demonstrating how a pharmaceutical company can revolutionize nicotine products while maintaining a resolute focus on health and safety.

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 methods. Our core objective is to provide alternatives for nicotine users while driving continuous improvement and innovation in the field.

Smoking Burden of disease



Tobacco smoking is the leading cause of preventable death and disease in Australia ¹

People who lived in remote or very remote areas of Australia were more likely to smoke daily (19.6%) than people living in inner regional areas (13.4%) or major cities (9.7%) ¹

Smoking causes 50% (1 in 2) of deaths among Aboriginal and Torres Strait Islander adults aged 45 years and over and 37 per cent of deaths at any age ²

Mathematical modelling studies commonly assume that the risk of vaping relative to smoking is at 5 per cent ³

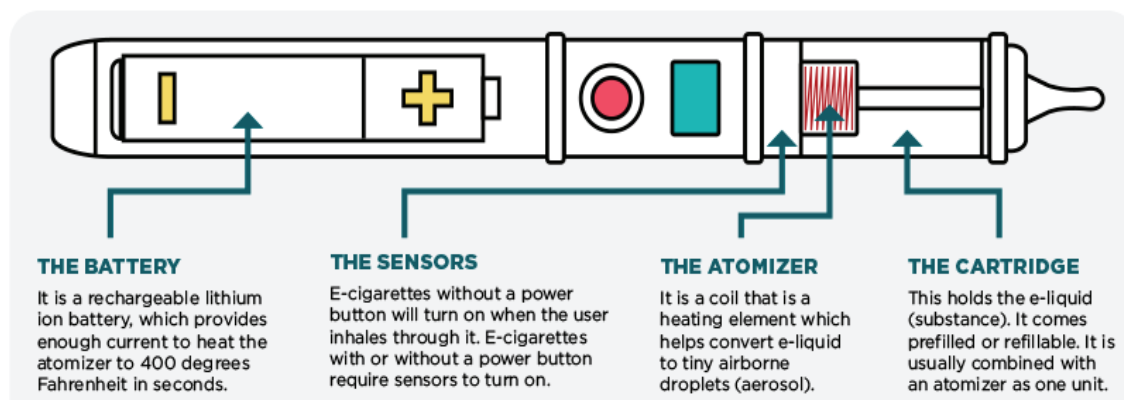
1. Australian Institute of Health and Welfare (2023) Alcohol, tobacco & other drugs in Australia, AIHW, Australian Government
2. <https://www.anu.edu.au/news/all-news/smoking-killing-one-in-three-first-nations-people>
3. <https://stories.uq.edu.au/contact-magazine/2022/ecigarettes-vaping-what-we-know-so-far/index.html>

i What is a Therapeutic Vaping device?

Vaping is the practice of inhaling a vapor produced by an electronic device known as an e-cigarette or vape. 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

How to prescribe therapeutic vaping products?

There are no therapeutic vaping products included in the ARTG and are therefore accessed as unapproved medicines.

There are 3 pathways a Medical Practitioner or Nurse Practitioner can prescribe therapeutic vaping products

Table 1. Prescribing Pathways

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 B	<ul style="list-style-type: none"> Apply online (https://compliance.health.gov.au/sas/) for authority to prescribe for a single patient Reapply for each patient
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

How to write a prescription

Below are example prescriptions for each of the Bay Pharma brands. Examples are equivalent to 3 months supply of therapeutic vaping product and include corresponding device.

NB: PRESCRIBE BAY PHARMA PRODUCTS AS PER BELOW EXAMPLES TO ASSIST WITH DISPENSING

Patient's Medicare no. - - Patient's Ref no.
 Patient's full name
 Patient's address
 Postcode
 Entitlement no.
 PBS Safety Net entitlement cardholder Concessional or dependant, RPBS beneficiary or PBS Safety Net concession cardholder
 (Tick appropriate boxes) PBS RPBS Brand substitution not permitted
ALLO Sync
30mg/ml Pods
30 Pods (1 Month Supply)
3 repeats
ALLO Sync Device
 Patient's or agent's signature _____ Date / /
 Agent's address _____
 I declare that I have received this medicine and the information relating to its use and that the information relating to its pharmaceutical benefit is correct. PMS1 1310

Patient's Medicare no. - - Patient's Ref no.
 Patient's full name
 Patient's address
 Postcode
 Entitlement no.
 PBS Safety Net entitlement cardholder Concessional or dependant, RPBS beneficiary or PBS Safety Net concession cardholder
 (Tick appropriate boxes) PBS RPBS Brand substitution not permitted
LULA
30mg/ml Pods
30 Pods (1 Month Supply)
3 repeats
LULA Device
 Patient's or agent's signature _____ Date / /
 Agent's address _____
 I declare that I have received this medicine and the information relating to its use and that the information relating to its pharmaceutical benefit is correct. PMS1 1310

Patient's Medicare no. - - Patient's Ref no.
 Patient's full name
 Patient's address
 Postcode
 Entitlement no.
 PBS Safety Net entitlement cardholder Concessional or dependant, RPBS beneficiary or PBS Safety Net concession cardholder
 (Tick appropriate boxes) PBS RPBS Brand substitution not permitted
CHOSEN eliquid
12mg/ml
60ml bottle X 5
(1 months supply)
3 repeats
LULA Device + Refill Pods
 Patient's or agent's signature _____ Date / /
 Agent's address _____
 I declare that I have received this medicine and the information relating to its use and that the information relating to its pharmaceutical benefit is correct. PMS1 1310

LULA



Medical Device Standard

Child Lock Feature

Step Down Nicotine

VARIANT	VOLUME	NICOTINE	RRP	\$/ml
LULA - Tobacco	2 x 2ml Pods	0, 20,30mg/ml	\$28	\$7
LULA - Mint	2 x 2ml Pods	0,20,30mg/ml	\$28	\$7
LULA - Unflavoured	2 x 2ml Pods	0,20,30mg/ml	\$28	\$7
LULA - Grape	2 x 2ml Pods	0,20,30mg/ml	\$28	\$7
LULA - Strawberry	2 x 2ml Pods	0,20,30mg/ml	\$28	\$7
LULA Refillable Pods	2 x 2ml Pods	-	\$20	-
LULA Device - Black	580mAh	-	\$20	-

1 POD PER DAY RECOMMENDED USAGE. NEW USERS RECOMMEND TO START ON 30MG/ML NICOTINE PODS
 SCHEDULE 4, UNREGISTERED MEDICINE. AP OR SAS APPROVAL REQUIRED
 DOSAGE: 1 LULA POD PER DAY.
 SCRIPT NOT REQUIRED FOR LULA DEVICE

Pharmacy Ordering Information:

Available through CanView

www.canview.com.au



ALLO

ALLO VAPOUR



Mesh Coil Design

Pod Activation

Step Down Nicotine

VARIANT	VOLUME	NICOTINE	RRP	\$/ml
ALLO Sync - Tobacco	3 x 2ml Pods	0,20,30mg/ml	\$28	\$4.66
ALLO Sync - Mint	3 x 2ml Pods	0,20,30mg/ml	\$28	\$4.66
ALLO Sync - Unflavoured	3 x 2ml Pods	0,20,30mg/ml	\$28	\$4.66
ALLO Sync - Grape	3 x 2ml Pods	0,20,30mg/ml	\$28	\$4.66
ALLO Sync - Strawberry	3 x 2ml Pods	0,20,30mg/ml	\$28	\$4.66
ALLO Sync Device - Black	350mAh	-	\$20	-

1 POD PER DAY RECOMMENDED USAGE. NEW USERS RECOMMEND TO START ON 30MG/ML NICOTINE PODS
 SCHEDULE 4, UNREGISTERED MEDICINE. AP OR SAS APPROVAL REQUIRED
 DOSAGE: 1 ALLO SYNC POD PER DAY.
 SCRIPT NOT REQUIRED FOR ALLO SYNC DEVICE

Pharmacy Ordering Information:

Available through CanView

www.canview.com.au



CHOSEN



Step Down Nicotine

CRP container

Salt & Freebase

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

DIRECTIONS: VAPOURISER ELIQUID FOR USE IN REFILLABLE VAPING DEVICES. SCHEDULE 4, UNREGISTERED MEDICINE. AP OR SAS-B OR SAS-C APPROVAL REQUIRED. REFILLABLE DEVICE REQUIRED. CHOSEN IS SUITABLE FOR USE WITH THE *LULA REFILLABLE VAPOURISER SYSTEM (*SOLD SEPERATELY)

LULA LULA Refillable Pod Device

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

Pharmacy Ordering Information:

Available through CanView

www.canview.com.au



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

pBayPharma

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 the Therapeutic Goods and 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.

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