WILD BY INSTINCT prefilled sealed pods

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.

▼ This medicine is new or being used differently. Please report side effects. See the <u>full CMI</u> for further details. [Include if applicable]

WARNING: Important safety information is provided in a boxed warning in the <u>full CMI</u>. Read before using this medicine. [Include if applicable]

1. Why am I using WILD BY INSTINCT prefilled sealed pods?

WILD BY INSTINCT PREFILLED SEALED PODS contains the active ingredient nicotine. WILD BY INSTINCT PREFILLED SEALED PODS are a nicotine vaping product (NVP) which may aid in smoking cessation or the process of reducing nicotine dependence For more information, see Section 1. Why am I using WILD BY INSTINCT prefilled sealed pods? in the full CMI.

2. What should I know before I use WILD BY INSTINCT prefilled sealed pods?

Do not use if you have ever had an allergic reaction to nicotine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use WILD BY INSTINCT prefilled sealed pods? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with WILD BY INSTINCT prefilled sealed pods 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 WILD BY INSTINCT prefilled sealed pods?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

More instructions can be found in Section 4. How do I use WILD BY INSTINCT prefilled sealed pods? in the full CMI.

5. What should I know while using WILD BY INSTINCT prefilled sealed pods?

Things you should do	 Notify your doctor or pharmacist you visit if you have an overactive thyroid gland; high blood pressure or have had a stroke; serious liver or kidney disease; are a diabetic; tumour of the adrenal glands; or you have a history of epilepsy or are taking medicine to control any fits or seizures. Check with your doctor if you are pregnant or intend to become pregnant. Remind any doctor, dentist, pharmacist or other health professional you visit that you are taking WILD BY INSTINCT prefilled sealed pods. Tell your doctor if your symptoms do not improve. 	
Things you should not do	 Do not stop taking this medicine suddenly. Do not take this medicine to treat any other complaint unless advised by your doctor. 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 do not have an existing nicotine dependence. 	
Driving or using machines	Be careful before you drive or use machinery or tools while taking WILD BY INSTINCT prefilled sealed pods. WILD BY INSTINCT prefilled sealed pods may cause dizziness in some people.	
Drinking alcohol	Take special care if you drink alcohol while taking this medicine.	
Looking after your medicine	 Store below 25 degrees Celsius in a cool dry place, away from sunlight. Keep this medicine out of sight or reach of children. 	

For more information, see Section 5. What should I know while using WILD BY INSTINCT prefilled sealed pods? in the full CMI.

6. Are there any side effects?

As with most therapies, taking nicotine may result in a person experiencing side effects. Tell your doctor if you notice any of the following: drowsiness, fatigue, dry mouth/eyes, changes in appetite, dizziness, headache, nausea, difficulty concentrating, memory impairment. Tell your doctor immediately if you notice any of the following: disorientation, loss of coordination or balance, chest pain, convulsions, strong abdominal pain, numbness, confusion, rapid heartbeat, low blood pressure/feeling faint, vomiting, fever, diarrhoea, burning sensation. If you smoke or use any other nicotine containing product while you are using WILD BY INSTINCT prefilled sealed pods, 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, low blood pressure, circulatory collapse and breathing difficulty. 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.

For more information, including what to do if you have any side effects, 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 affects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

WARNING: Do not take this medication if you are pregnant or breastfeeding

WILD BY INSTINCT PREFILLED SEALED PODS

Active ingredient(s): nicotine

Consumer Medicine Information (CMI)

This leaflet provides important information about using WILD BY INSTINCT prefilled sealed pods. 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 WILD BY INSTINCT prefilled sealed pods.

Where to find information in this leaflet:

- 1. Why am I using WILD BY INSTINCT prefilled sealed pods?
- 2. What should I know before I use WILD BY INSTINCT prefilled sealed pods?
- 3. What if I am taking other medicines?
- 4. How do I use WILD BY INSTINCT prefilled sealed pods?
- 5. What should I know while using WILD BY INSTINCT prefilled sealed pods?
- 6. Are there any side effects?
- Product details

1. Why am I using WILD BY INSTINCT prefilled sealed pods?

WILD BY INSTINCT prefilled sealed pods contain the active ingredient nicotine. WILD BY INSTINCT prefilled sealed pods are a nicotine vaping product (NVP) which may aid in smoking cessation by replacing the nicotine you are used to getting from cigarettes and by replicating the hand-to-mouth action associated with smoking.

WILD BY INSTINCT prefilled sealed pods may aid in smoking cessation

WILD BY INSTINCT prefilled sealed pods contain a dilute nicotine liquid. When used in conjunction with the WILD device the liquid is vaporised for inhalation which replaces the nicotine you would otherwise get from smoking.

Using the WILD BY INSTINCT prefilled sealed pods and WILD device provides nicotine to relieve some of the

unpleasant symptoms such as feeling ill or irritable that smokers or vapers often feel when they try to give up.

Nicotine can also reduce your cravings for a cigarette and help you to resist the urge to smoke or act as an aid in the process of reducing nicotine dependence.

This type of treatment is called Inhaled Nicotine Replacement Therapy (INRT).

2. What should I know before I use WILD BY INSTINCT prefilled sealed pods?

Warnings

Do not use WILD BY INSTINCT prefilled sealed pods 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 any other medical conditions such as an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse or 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 INRT unless your doctor tells you to use it. Once you are discharged from hospital, you may use INRT in consultation with your doctor.
- allergies to any other medicines, foods, dyes or
- preservatives.
- severe problems with your liver.
- severe problems with your kidneys.
- problems with your heart.
- any other medical conditions.
- any previous or current psychotic disorder.
- substance use disorder (abuse, dependence to alcohol, opioids, benzodiazepines, or illicit stimulants).
- are a diabetic (If you have diabetes you should monitor your blood sugar levels more often than usual when

starting WILD BY INSTINCT prefilled sealed pods as you may find your insulin or other medication requirements alter).

- have been diagnosed as having a tumor 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.
- take any medicines for any other condition
 - Oxybutinin for overactive bladder
 - Valium, Klonapin, Xanax, Halcion, Prosom, Voxam, Luvax – anti-depressants
 - warfarin used to prevent blood clots
 - oxymorphone a powerful painkiller
 - pentobarbital –for sedation and insomnia
 - methylphenidate, pemoline –to treat ADHD and narcolepsy
 - oxymetazoline, propylhexedrine, pseudoephedrine – used as decongestants
 - disulfiram -to treat chronic alcoholism
 - ketoconazole, fluconazole, itraconazole, amphotericin B –to treat fungal infections
 - ritonavir to treat HIV/AIDS
 - clarithromycin, rifampicin, erythromycin, ciprofloxacin, enoxacin – antibiotics to treat infections
 - fluoxetine –to treat major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, panic disorder, and premenstrual dysphoric disorder
 - carbamazepine –to treat epilepsy and nerve pain
 - St John's Wort a herbal remedy used to treat mood disorders
 - amiodarone –to treat irregular heartbeat
 - cyclosporine to treat rheumatoid arthritis, psoriasis, Crohn's disease, and in organ transplants to prevent rejection

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

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

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

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 INRT. However, if you have tried and this hasn't worked, your doctor may recommend you use INRT 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 INRT 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. You should only use INRT if your doctor has told you to.

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 INRT.

WILD BY INSTINCT prefilled sealed pods should not be used while breastfeeding. You should use NRT products that are taken intermittently (e.g. gum or lozenges) and breastfeed just before you take the product. This helps your baby to get the smallest amount of nicotine possible.

3. What if I am taking other medicines?

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

Some medicines may interfere with WILD BY INSTINCT prefilled sealed pods and affect how it works.

Medicines that may <u>increase</u> the effect of WILD BY INSTINCT prefilled sealed pods include:

- Any medication to treat depression and anxiety disorders
- Proton pump inhibitors (medications to treat gastrointestinal disorders including ulcers and reflux)
- Some anti-seizure medications, particularly valproate (e.g. Valprease, Valpro, Epilim)
- Some antibiotics and some anti-fungals
- Some medications to treat high cholesterol
- Some medications to treat blood clots, heart attacks, high blood pressure or angina
- Some medications to treat sleep apnoea
- Some medications to treat cancer
- Some medications to treat HIV/AIDS
- Some medications to treat inflammation and pain
- Some contraceptives and hormone replacement therapy (HRT) medications
- Loratadine (e.g. Claratyne) used to treat allergies
- Sildenafil (e.g. Viagra) used to treat erectile dysfunction
- Memantine (e.g. Ebixa, Memanxa) to treat symptoms of Alzheimer's Disease
- Safinamide (Xadago) to treat Parkinson's Disease
- Aprepitant (Apotex) to treat nausea and vomiting

Medicines that may <u>reduce</u> the effect of WILD BY INSTINCT prefilled sealed pods include:

- Some medicines to treat inflammation, including asthma (e.g. Prednisone, Pulmicort)
- Some medicines to treat seizures

- Some medicines to treat depression or anxiety disorders
- Some antibiotics
- Some contraceptives and HRT medication
- Dabrafenib (Tafinlar) to treat cancer
- Hydrocortisone
- Aspirin
- St John's Wort

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect WILD BY INSTINCT prefilled sealed pods.

4. How do I use WILD BY INSTINCT prefilled sealed pods?

How much to take / use

- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- Your doctor will provide you with a treatment schedule based on your needs. Always take WILD BY INSTINCT prefilled sealed pods as your doctor has told you.
- Only a doctor can start you on treatment with WILD BY INSTINCT prefilled sealed pods. Your doctor will assess you regularly to see if you should continue taking it.
- Use the WILD BY INSTINCT prefilled sealed pods when you feel the urge to smoke. It should be used as a direct alternative for smoking.
- Note that higher doses of WILD BY INSTINCT prefilled sealed pods are associated with an increased risk of experiencing side effects.
- Follow the instructions provided and use WILD BY INSTINCT prefilled sealed pods until your doctor tells you to stop.

When to take / use WILD BY INSTINCT prefilled sealed pods name

 WILD BY INSTINCT prefilled sealed pods should be used as indicated by your doctor.

How to use WILD BY INSTINCT prefilled sealed pods

Setting up your WILD BY INSTINCT system

- Before using the WILD BY INSTINCT device for the first time, ensure it is fully charged using the USB-C charger provided.
- Remove a new WILD BY INSTINCT prefilled sealed pod from its blister packaging and remove the top and bottom silicone plugs.
- Place your new WILD BY INSTINCT prefilled sealed pod on top of your WILD BY INSTINCT device, the magnets will automatically connect them.

The LED on your WILD BY INSTINCT Device will glow white, indicating that it has successfully paired with a WILD BY INSTINCT prefilled sealed pod.

The WILD BY INSTINCT device is simple and easy to use. It activates automatically when you draw through the mouthpiece and automatically enters standby mode when not in use.

Using your WILD BY INSTINCT system

- 1. To start, place the mouthpiece between your lips about halfway along the mouthpiece. Ensure that the device is angled downwards during use.
- Draw firmly for approximately two seconds. Aim to draw enough air through the device to fill your mouth.
- 3. Immediately inhale deeply and then exhale slowly. It's not unusual to cough when you first start, but this will ease with continued use
- Wait at least 20 seconds before your next draw. This will allow you see if your cravings have been satisfied.
- Note: a red LED light during use means your WILD BY INSTINCT prefilled sealed pod may be empty. Check the pod and replace it with a new one if it is empty.

For detailed information about using the WILD BY INSTINCT device, please consult the User Guide provided

If you forget to use WILD BY INSTINCT prefilled sealed pods

WILD BY INSTINCT prefilled sealed pods are intended for use as a replacement for cigarette smoking and for the purposes of smoking cessation or as an aid in the process to reduce nicotine dependence. Always use WILD BY INSTINCT prefilled sealed pods in line with the directions of your doctor or pharmacist.

If you stop using WILD BY INSTINCT prefilled sealed pods suddenly, you may experience symptoms of nicotine withdrawal. Common symptoms of nicotine withdrawal include:

- Feeling tense and irritable
- Depression
- Appetite changes
- Constipation and gas
- Insomnia
- Difficulty concentrating
- · Cough and cold-like symptoms

If you use too much WILD BY INSTINCT prefilled sealed pods

If you think that you have used too much WILD BY INSTINCT prefilled sealed pods name, you may need urgent medical attention.

If you smoke or use any other nicotine containing product while you are using the WILD BY INSTINCT prefilled sealed pods, you may suffer an overdose of nicotine. However, if used correctly, nicotine overdose is unlikely.

Symptoms of nicotine overdose include:

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

If it is a large overdose, there may be exhaustion, convulsions, low blood pressure, circulatory collapse and breathing difficulty.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- · contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while using WILD BY INSTINCT prefilled sealed pods?

Things you should do

- Take WILD BY INSTINCT prefilled sealed pods as prescribed by your doctor
- If you are about to start a new medicine, remind your doctor and pharmacist that you are taking WILD BY INSTINCT prefilled sealed pods
- Tell your doctor if you become pregnant while taking WILD BY INSTINCT prefilled sealed pods
- Tell your doctor if your symptoms do not improve.
- If you need to have any medical tests while you are taking WILD BY INSTINCT prefilled sealed pods, tell your doctor. It may affect the results of some tests.

Call your doctor straight away if you:

- Experience any of the side effects listed in Section 6.
 Are there any side effects?
- Tell your doctor if your condition worsens or does not improve.

Remind any doctor, dentist or pharmacist you visit that you are using WILD BY INSTINCT prefilled sealed pods.

Things you should not do

- Do not use WILD BY INSTINCT prefilled sealed pods if you are allergic to nicotine or any of the ingredients listed at the end of this leaflet.
- Do not use WILD BY INSTINCT prefilled sealed pods if you do not have an existing nicotine dependence.

- Do not use WILD BY INSTINCT prefilled sealed pods 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 WILD BY INSTINCT prefilled sealed pods in conjunction with combustible cigarette smoking. WILD BY INSTINCT prefilled sealed pods are 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 WILD BY INSTINCT prefilled sealed pods affects you.

WILD BY INSTINCT prefilled sealed pods may cause dizziness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effect of WILD BY INSTINCT prefilled sealed pods or this medicine may increase the effects of alcohol, such as loss of balance or the ability to respond quickly.

Looking after your medicine

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

Store it in a cool dry place away from moisture, heat or sunlight (under 25 degrees Celsius); 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 cannot reach it.

When to discard your medicine

Do not use WILD BY INSTINCT prefilled sealed pods beyond the expiry date printed on the package.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

NVPs have the potential to aid with smoking cessation efforts 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

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

Less serious side effects

Serious side effects

Serious side effects	What to do	
 Allergic reaction: Swelling of the face, lips, mouth, tongue or throat which may cause difficulty breathing Shortness of breath or difficulty breathing Skin reaction which may include 	Call your doctor straight away, or go straight to the Emergency Department at your nearest	
rash, itching, redness, blistering or peeling of the skin	hospital if you notice any of these serious	
Cardiovascular:	side effects.	
Rapid heartbeat	side effects.	
Irregular heartbeat		
Chest pain		
 Low blood pressure/feeling faint 		
Brain/Nervous system:		
 Convulsions 		
 Numbness 		
Burning sensation		
Vomiting		
Fever		
Loss of coordination or balance		
Disorientation or confusion		

- Depression
- Agitation
- Euphoria
- Hallucinations
- Psychosis
- Thoughts of suicide

Other

- Upper respiratory infection
- Strong abdominal pain
- Diarrhoea

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

This medicine is only available with a doctor's prescription.

What WILD BY INSTINCT PREFILLED SEALED PODS contain

Active ingredient (main ingredient)	Nicotine (as lactate) 20 mg/mL Nicotine (as lactate) 30 mg/mL Nicotine (as lactate) 50 mg/mL
Other ingredients (inactive ingredients)	Propylene glycol vegetable Glycerin Flavours
Potential allergens	

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

What WILD BY INSTINCT prefilled sealed pods looks like

WILD BY INSTINCT prefilled sealed pods come in 1 mL cartridges and are available in 3 flavours:

- Mint
- Menthol
- Tobacco

WILD BY INSTINCT prefilled sealed pods 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 Administration (TGA) has not evaluated them for quality, safety and effectiveness.

NVPs are not first-line treatments for smoking cessation. However, for people who have tried to achieve smoking cessation with approved pharmacotherapies but failed, 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.

Mandatory product warnings

- KEEP OUT OF REACH OF CHILDREN.
- Avoid contact with eyes.
- Avoid contact with skin.

Who distributes WILD BY INSTINCT prefilled sealed pods

from the fields pharmaceuticals Pty Ltd Lvl 15, 45 Pirie Street, Adelaide, SA 5000, Australia www.ftfpharmaceutical.com

This leaflet was prepared in November 2024.