



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Authorised Prescriber Scheme – NICOTINE only

Email completed form to:

Authorised.Prescribers@health.gov.au (preferred)

or fax to +61 2 6203 1105

HREC approval or specialist college endorsement is not required if the medicine, concentration (if any), dosage form, route of administration and indication match those listed on the **back of this form**. You will need to provide the relevant **item code** for the medicine you wish to apply for.

Privacy information

For general privacy information, go to <<https://www.tga.gov.au/privacy>>.

The TGA is collecting personal information in this form in order to:

- Assess the application; and
- Contact you, as the medical practitioner applying to supply the 'unapproved' therapeutic goods, to discuss the application where necessary.

The personal information of the medical practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or health practitioner registration.

PLEASE PRINT IN BLOCK LETTERS. Please complete the form clearly and in full. Forms cannot be processed if incomplete or illegible.

Product details

Item code

Code Number:

Active ingredient / device product description (including variant)

Nicotine in solution, salt or base form

Dosage form

Liquid or solid for vaporisation

Route of administration

Inhalation

Indication / reason for prescribing

Smoking cessation

Prescribing medical practitioner details

First name

Surname

AHPRA ID

Specialty

Email

Phone

Fax

Principal practice address

Consent for personal information to be displayed on the TGAs Nicotine Web Hub (optional)

I **consent** to the Therapeutic Goods Administration (TGA), being part of the Australian Government Department of Health, publishing on the TGA website:

- my name; and
- the name and address of the practice where I work,

for the purpose of identifying me as an authorised prescriber of nicotine in solution, salt or base form (solid or liquid), i.e., nicotine vaping products.

Exact information to be published on TGA website

I set out below exactly how I would like my personal information to appear on the TGA website.

My Name	
Practice name	
Practice address	

I understand that:

- the product is not approved for marketing in Australia and that the Therapeutic Goods Administration (TGA) is unable to vouch for the quality, safety or efficacy of this unapproved product, and that its use is regarded as experimental;
- the giving of an authority under subsection 19(5) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of, therapeutic goods by that person or another person;
- that in order to be given such an authority, the nicotine product matches the entry for nicotine in Regulation 12B(1B) of the *Therapeutic Goods Regulations 1990*.

I agree to:

- the collection of my personal information for the purposes set out above;
- obtain from each patient (or guardian) informed consent in relation to the proposed use of the unapproved product, and in this context, inform the patient that the product is not approved in Australia;
- the product only being prescribed for patients in my immediate care;
- the product only to being used in accordance with the treatment directions (being the protocol or product information or instructions for use);
- report any suspected adverse events to the TGA and the sponsor;
- comply with all relevant State/Territory legislation.

Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.

Medical practitioner's signature

Date

Please return form to authorised.prescribers@health.gov.au