

Guide on pseudoephedrine-containing products as restricted medicines

The Misuse of Drugs (Pseudoephedrine) Amendment Act 2024 reclassified pseudoephedrine to a restricted (pharmacist-only) medicine and from a Class B2 controlled drug to a Class C3 (partially exempt) controlled drug, eliminating the requirement for it to be recorded in a controlled drug register and stored in a controlled drug safe.

We recognise the concerns from members and their staff about the potential security risks of storing and selling pseudoephedrine-containing products. The below guidance includes safety and security measures, along with storage, sale, and recording requirements, and clinical considerations.

Note: It is not compulsory for community pharmacies to stock or sell pseudoephedrine-containing products.

Restricted medicine status

Pseudoephedrine is classified as prescription-only except when supplied as a restricted medicine by a pharmacist under the following conditions:

- Solid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 720 milligrams or less.
- Liquid-dose cough or decongestant medicines containing not more than 60 milligrams per recommended dose and not more than 240 milligrams per recommended daily dose, in a pack size of 800 milligrams or less.

Storage requirements

Under the Medicines Act 47(1)(b), as a restricted medicine, pseudoephedrine-containing products must legally be stored in a place in which young children or unauthorised persons do not have ready access. This is to prevent consumers buying a restricted medicine for the wrong purpose or without the proper advice. As such, restricted medicines are commonly stored behind a sales counter, in the dispensary or in a locked cupboard.

Restricted medicines that are prone to abuse, such as pseudoephedrine-containing products, are recommended to be stored away from the view of the public or in limited quantities on display to reduce a situation where there could be an argument if the pharmacist declines the sale and to decrease a potential break-in.

Dummy boxes and images of restricted medicines, such as behind a perplex screen or on a shelf wobbler, should not be displayed on the retail shelves in the pharmacy. This may be seen as going against the intent of the law in which the pharmacist must decide if the restricted medicine is clinically appropriate for the patient and be in control of the sale.

Sales requirements

As pseudoephedrine-containing products are restricted medicines, under the Medicines Act 18(1)(b), they must be sold by a qualified pharmacist to ensure that the medicine is clinically indicated for the person and their condition, and that its use will be safe and effective for the individual and they know how to use it correctly.

The pharmacist has control as to whether a restricted medicine is appropriate for a person or whether another product may be better in treating their symptoms or if the person should be referred for further investigation. Even if a consumer specifically requests a pseudoephedrine-containing product, the pharmacist may still choose not to sell it.

The pharmacist must use their clinical judgement as to the quantity of a restricted medicine to sell to a person and whether the restricted medicine can be sold in advance of symptoms. This must be done on an individual basis, taking into account the symptoms being treated, the medicine itself, how the product is used, if there is potential for abuse and if the consumer should be referred for further investigation if symptoms do not subside after using one pack.

Recording requirements

Under the Medicines Regulations 54A, the sale of a restricted medicine, including pseudoephedrine-containing products, must be recorded and the following details are required:

- Date of the sale.
- Name and address of the purchaser.
- Name and quantity of the medicine/product sold.
- Name of the pharmacist supplying the restricted medicine.

These records are essential to meet legal requirements, maintain accurate clinical records, and for safety purposes.

These records can be documented in the POS or through the dispensary system, depending on the pharmacy's procedures.

If a pharmacist suspects a person is drug-seeking a pseudoephedrine-containing product, they should:

- Request photo ID when recording the purchaser's details.
- If the purchaser is not the patient who will be taking the product, the pharmacist may want to also ask for the patient's details.
- Sell the smallest quantity possible and limit purchase to one pack per consumer.
- Decline the sale politely but firmly if they have concerns or if there are signs of excessive or repeated purchases of pseudoephedrine-containing products.

Clinical considerations

As pseudoephedrine-containing products are restricted medicines, the duty of care in the appropriate sale and use of these medicines lies with the pharmacist. It is imperative that the pharmacist conducts a comprehensive consultation to determine the clinical need for a pseudoephedrine-containing product for each individual consumer upon each occasion.

Contraindications, special warnings and precautions for use

The use of pseudoephedrine is contraindicated for children under 12 and individuals with the following conditions:

- Uncontrolled hypertension or severe coronary artery disease.
- Taking a monoamine oxidase inhibitor (MAOI) or have taken a MAOI within the previous 14 days.

Special precautions should be considered in people with the following conditions:

- Elderly people – no data available on its use in this age group.
- Hepatic impairment or severe hepatic dysfunction.
- Mild to moderate renal impairment or severe renal dysfunction.
- Hypertension.
- Hyperthyroidism.
- Diabetes mellitus.
- Coronary or ischemic heart disease.
- Glaucoma.
- Prostatic hypertrophy.
- Pregnancy – should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the foetus.
- Breastfeeding – not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

Interactions with other medicines and other forms of interactions

The following interactions with pseudoephedrine have been noted:

- Antidepressant medicines, e.g., tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis.
- Other sympathomimetic agents, such as decongestants, appetite suppressants, ADHD medicines, and amphetamine-like psychostimulants – may cause an increase in blood pressure and additive effects.
- Antihypertensives, e.g., beta-blockers, methyl dopa, alpha blockers – pseudoephedrine may antagonise the effect of certain classes of antihypertensives and cause an increase in blood pressure.
- Urinary alkalinisers, e.g., Ural, sodium bicarbonate – decrease the elimination of pseudoephedrine.
- Ergotamines and ergot alkaloids – increase vasoconstriction leading to an increase in blood pressure.
- Digoxin – can increase the risk of arrhythmias.

Adverse effects

Adverse effects experienced by people taking pseudoephedrine include:

- Nausea and vomiting.
- Cardiovascular stimulation – elevated blood pressure, palpitations.
- Tachycardia or arrhythmias.

- CNS stimulation – headache, restlessness, feeling jittery, insomnia, anxiety, euphoric mood, tremor and (rarely) hallucinations.
- Dysuria and urinary retention.

Children and the elderly are more likely to experience adverse effects than other age groups.

Pseudoephedrine can lead to rare but serious side effects such as ischaemic colitis, skin reactions (with or without pyrexia or erythema), posterior reversible encephalopathy, reversible cerebral vasoconstriction syndrome, and ischaemic optic neuropathy.

Safety and security measures

Pharmacy owners are legally responsible for ensuring the health and safety of their staff, contractors and the public accessing their premises and using their services. Pharmacy owners are also legally responsible for mitigating risks associated with the storage and sale of any medicines of potential misuse, such as pseudoephedrine-containing products.

Crime prevention is a priority and steps to protect against potential security risks include:

- Standard operating procedures (SOPs) – robust procedures should be in place and up to date on agreed processes when dealing with difficult people/people who pose a risk to security and in the event of an armed hold-up or robbery, and there should be regular evaluations of these procedures for ongoing continuous improvement.
- Staff training – all staff should be regularly trained in the pharmacy's SOPs on dealing with difficult people/people who pose a risk to security and in the event of a robbery and be aware of safety procedures.
- Regular audit of security measures – the pharmacy should be regularly inspected to ensure all security measures are in place, doors and windows have secure catches and deadlocks, there are no areas where intruders could gain entry, e.g. windows, roof, basement, etc. and the security company has an up-to-date list of key holders and names of who should be called out in event of the alarm going off.
- Security cameras – serve as a deterrent and provide useful information during break-ins.
- Panic buttons or duress alarms – once pressed, send a silent signal to the pharmacy's monitoring company or the Police to seek help.
- Fog cannons – emit dense fog to obstruct an intruder's vision, slowing them down.
- Roller doors – provide a physical barrier against ram raids and break-ins.
- Street furniture (planter boxes or benches) – deter ram raids and enhance aesthetics.
- Bollards – prevent vehicle access and deter ram raids.
- Ram raid beams – visual deterrents installed across storefronts.
- Building reinforcement – protects against break-ins with long-term structural solutions.

For detailed crime prevention strategies, consult the New Zealand Police Crime Prevention Checklist [here](#).

Pharmacies might also qualify for a fog cannon subsidy – further information found [here](#).

What to do in case of an incident that threatens the security and/or safety of your business or staff:

1. Notify the Police of the incident as soon as possible by calling the 105 line or report online [here](#).
2. If your staff feel threatened or unsafe call 111 immediately.
3. Do not escalate the issue/incident in store – stay calm and placate/appease offenders.
4. The public is allowed to film the incident however you have the right to ask them to leave.

5. Offenders can be trespassed (further information can be found [here](#)) but be careful that this does not escalate the situation.
6. Even as an essential service you can lock your doors if you feel you or staff are threatened or feel unsafe. If other customers are in store, make sure to communicate the reason for locking the door and wait for the Police to arrive.

Contact the Police National Retail Investigation Support Unit

The Police National Retail Investigation Support Unit could be of assistance if a pharmacy has any safety and or security concerns. Police liaison Matt Tierney heads up the National Retail Investigation Support Unit and can be contacted at matthew.tierney@police.govt.nz.

Set up a local business support group

Setting up a local business support group can protect your business, provide peace of mind and allow you and your neighbouring businesses to support one another and combine your local knowledge to reduce crime in your area.

It does not take a lot of time or involve a lot of work:

- Start small and discuss with a few nearby businesses and build your numbers slowly.
- Call a meeting to have a discussion.
- Invite your local Community Constable or local Neighbourhood Support representative along to provide information and answer your questions. They can give you information and training on:
 - reducing the opportunities for crime
 - preparing for and surviving civil disasters
 - dealing with a range of emergencies
 - solving community problems
 - networking.
- Share the work – your knowledge, skills, or time.

Useful resources

1. Medsafe Classification Database: <https://www.medsafe.govt.nz/profs/class/classintro.asp>
2. Medsafe pharmacist-only medicines FAQs: <https://www.medsafe.govt.nz/Consumers/PharmOnly.asp>
3. New Zealand Formulary, Pseudoephedrine: https://nzf.org.nz/nzf_1976
4. Sudafed Sinus and Nasal Decongestion Datasheet: <https://www.medsafe.govt.nz/profs/Datasheet/s/SudafedSinusAndNasalDecongestanttab.pdf>
5. New Zealand Legislation, Medicines Act 1981, Section 47, Storage and delivery of medicines: <https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55470.html#:~:text=No%20person%20who%20is%20in%20possession%20or%20charge,young%20children%20or%20unauthorised%20persons%20have%20ready%20access>
6. New Zealand Legislation, Medicines Act 1981, Section 18, Sale of medicines by retail: <https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55039.html>
7. New Zealand Legislation, Medicines Regulations 1984, Section 54A, Sale of medicines registers: <https://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM96826.html#:~:text=54A%20Sale%20of%20Medicines%20Registers%20%281%29%20This%20regulation,restricted%20medicine%2C%20or%20pharmacy-only%20medicine%2C%20sold%20by%20wholesale.>

8. New Zealand Pharmacy Council, Code of Ethics 2018: <https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Code-of-Ethics-2018-FINAL.pdf>
9. New Zealand Pharmacy Council, Protocol for the sale and supply of pharmacist only medicines: https://pharmacycouncil.org.nz/wp-content/uploads/2024/04/POMCC-Protocol_Updated-Nov2023-1.pdf
10. Auckland Transport, Protecting against ram raids: <https://at.govt.nz/driving-parking/protecting-against-ram-raids#:~:text=Well%2Dplaced%20planter%20boxes%20or,if%20the%20footpath%20is%20narrow>
11. Worksafe, Violence at work: <https://www.worksafe.govt.nz/topic-and-industry/work-related-health/violence-at-work/>
12. New Zealand Police, Protect your business: <https://www.police.govt.nz/advice-services/businesses-and-organisations/protect-your-business>
13. Ministry of Business, Innovation and Employment, Protect your retail shop with a fog cannon: <https://www.business.govt.nz/risks-and-operations/health-and-safety/fog-cannon-subsidy/>