

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking PLACIL?

PLACIL contains the active ingredient clomipramine hydrochloride. PLACIL is used to treat: depression that is longer-lasting and/or more severe than the typical "low moods" that everyone experiences from time to time due to the stress of everyday life; obsessive-compulsive disorders (OCD) and phobias in adults; and, muscle weakness in people with a sleep disorder called narcolepsy. For more information, see Section [1. Why am I taking PLACIL?](#) in the full CMI.

2. What should I know before I take PLACIL?

Do not take if you have ever had an allergic reaction to PLACIL 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 take PLACIL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PLACIL 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 take PLACIL?

- The dose, frequency and length of treatment will be determined by your doctor. Follow all directions given to you by your doctor or pharmacist carefully.
- Swallow the tablets with a full glass of water.

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

5. What should I know while taking PLACIL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using PLACIL. • Tell your doctor immediately if you become pregnant. Call your doctor straight away if you or someone you know: • has thoughts about or attempts to commit suicide. • develops new or worse depression/anxiety, panic attacks, difficulty sleeping, or other unusual changes in behaviour or mood, for example: being angry or violent, acting on dangerous impulses, extreme increase in activity and talking.
Things you should not do	• Do not stop using this medicine suddenly or lower the dose without checking with your doctor. • Do not let yourself run out of medicine over the weekend or on holidays.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how PLACIL affects you. • PLACIL may cause tiredness, dizziness, drowsiness or blurred vision in some people.
Drinking alcohol	• Tell your doctor if you drink alcohol. • PLACIL can increase the drowsiness caused by alcohol.
Looking after your medicine	• Keep your medicine in the original container until it is time to take a dose. • Store it in a cool dry place below 25°C.

For more information, see Section [5. What should I know while taking PLACIL?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PLACIL. All medicines have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. 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.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PLACIL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking PLACIL.**

Where to find information in this leaflet:

1. [Why am I taking PLACIL?](#)
2. [What should I know before I take PLACIL?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take PLACIL?](#)
5. [What should I know while taking PLACIL?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking PLACIL?

PLACIL contains the active ingredient **clomipramine hydrochloride**. PLACIL belongs to a group of medicines called tricyclic antidepressants. These medicines are thought to work by their action on brain chemicals called amines.

PLACIL is used to treat:

1. **depression that is longer-lasting and/or more severe than the typical "low moods" that everyone experiences from time to time due to the stress of everyday life.**
Depression is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive, lack of energy and feelings of guilt.
2. **obsessive-compulsive disorders and phobias in adults**
3. **muscle weakness in people with a sleep disorder called narcolepsy.**

The symptoms of these disorders vary from person to person. Your doctor can provide you with more information.

Ask your doctor if you have any questions about why PLACIL has been prescribed for you.

Your doctor may have prescribed PLACIL for another reason.

2. What should I know before I take PLACIL?

Warnings

Do not take PLACIL if:

- you are allergic to clomipramine, or any other tricyclic antidepressant, or any ingredients listed at the end of

this leaflet.

Symptoms of an allergic reaction may include:

- o rash, itching or hives on the skin
- o swelling of the face, lips, tongue or other parts of the body
- o difficulty in swallowing
- o wheezing or shortness of breath

Always check the ingredients to make sure you can take this medicine.

- PLACIL is not approved for use in children or adolescents below 18 years of age for the treatment of depression or other psychiatric disorders.

The safe use and effectiveness of PLACIL in treating the above conditions, for this age group, has not been established.

- **you are already taking another medicine called monoamineoxidase inhibitor (MAOI) or have been taking it within the past 2 weeks.**
 - o Taking PLACIL together with a MAOI or taking it too soon after stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and seizures (fits). Your doctor will tell you when it is safe to start taking PLACIL after stopping the MAOI.
- **you are recovering from a recent heart attack or you have congenital long QT syndrome - people with this inherited heart condition have electrical disturbances in the heart, which may cause sudden, extremely rapid heart rates.**

Taking PLACIL may make your condition worse.

- **the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.**

If you take this medicine after the expiry date has passed, it may not work as well.

In this case, return it to your pharmacist.

Check with your doctor if you have:

- heart or blood vessel problems including an irregular heart beat, coronary heart disease, angina (chest pain)
- an inherited heart problem called congenital long QT syndrome
- increased pressure in the eye from any cause (e.g. glaucoma)
- difficulty in passing urine (water), due to prostate problems or any other cause
- epilepsy or seizures (fits)
- liver or kidney problems
- a low level of potassium in your blood (called hypokalaemia)

- any mental disorder other than the one being treated (e.g. schizophrenia, mania, bipolar disorders)
- problems with blood pressure (either too high or too low)
- a blood disorder
- overactive thyroid
- chronic constipation
- Parkinson's disease
- a tumour of the adrenal gland
- lactose or galactose intolerance (PLACIL tablets contain sugars as lactose monohydrate)
- take any medicines for any other condition

If you have not told your doctor about any of the above, tell them before you start PLACIL.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

PLACIL should not be taken if you are pregnant unless your doctor has told you to do so. This medicine may affect your baby if you take it while you are pregnant, especially during the last 7 weeks of pregnancy. Your baby may have some side effects from the medicine during the first month after birth. Newborn infants whose mothers had taken this medicine up until delivery may show symptoms such as shortness of breath, abnormal bluish discoloration of the skin and mucous membranes, lethargy, feeding difficulties, colic, irritability, convulsions, tremor, overactive muscle tone, poor muscle tone or spasms, during the first hours or days of life. If there is a need to take PLACIL when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby. Your doctor may also recommend gradually stopping PLACIL in the 7 weeks before giving birth.

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

Breastfeeding is not recommended while you are taking PLACIL. The active ingredient passes into breast milk and may affect your baby.

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 PLACIL and affect how it works. These include:

- other medicines for depression, such as:
 - MAOIs, such as phenelzine (e.g. Nardil), tranylcypromine (e.g. Parnate) and moclobemide (e.g. Aurorix, Arima). You must not take PLACIL together with a MAOI (see Section [2. What should I know before I take PLACIL?](#))

- SSRIs and SNRIs, such as fluoxetine (e.g. Prozac, Lovan), paroxetine (e.g. Aropax, Paxtine), sertraline (e.g. Zoloft), fluvoxamine (e.g. Luvox, Movox), and nefazodone (Serzone)

- medicines for high blood pressure or heart problems
- medicines to help you sleep or calm you down
- some medicines for anxiety
- medicines for other mental disorders
- medicines for seizures (fits) or epilepsy, such as carbamazepine (Teril, Tegretol) or phenytoin (Dilantin)
- medicines to prevent blood clots such as warfarin (Coumadin, Marevan)
- diuretic medicines, also called fluid or water tablets
- some medicines for colds or allergies, including antihistamines and some nose drops, hayfever or travel sickness
- anticholinergic medicines, which are used to relieve stomach cramps, spasms and travel sickness, e.g. hyoscine (Buscopan), mebeverine (Colofac)
- medicines for thyroid problems
- cimetidine (Tagamet, Magicul), a medicine used to treat reflux and stomach ulcers
- certain medicines for Parkinson's disease such as biperiden (Akineton), benztropine (Cogentin)
- oestrogens (e.g. birth control pills, hormone replacement therapy)
- nicotine in medicines used to help you quit smoking such as nicotine gum, patches lozenges or inhalers
- methylphenidate (Ritalin®, Attenta) a medicine used to treat attention deficit hyperactivity disorder (ADHD) and narcolepsy
- disulfiram, a medicine for alcoholism
- rifampicin, an antibiotic
- terbinafine, a medicine used to treat skin, hair or nail infections due to fungus
- medicines used to reduce fat in blood
- grapefruit/grapefruit juice or cranberry juice.

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

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

4. How do I take PLACIL?

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

Take PLACIL exactly as described by your doctor.

Your doctor will tell you how many tablets you need to take each day and when to take them. The dose may

depend on your age, your condition and whether or not you are taking any other medicines.

PLACIL is usually started using low doses. Your doctor may gradually increase this dose depending on how you respond to this medicine.

- For depression, obsessive compulsive disorders and phobias, treatment is usually started with a low dose of 2 or 3 tablets (50 to 75 mg) each day. The dose can be increased slowly up to 4 to 6 tablets (100 to 150 mg) each day. Some people will need higher doses than others because each person's body chemistry is different. Once you are feeling better, your doctor may be able to slowly reduce the dose. The usual adult maintenance dose is between 2 to 4 tablets (50 to 100 mg) each day.
- For muscle weakness accompanying narcolepsy, the dose is usually from 1 to 3 tablets (25 to 75 mg) each day.
- If you are older than 65 years old, your doctor will probably start with a low dose (e.g. 1 tablet a day (25 mg)) to help avoid side effects. The dose is gradually increased over about ten days to 2 to 3 tablets (50 to 75 mg) each day and kept at that dose for the rest of your treatment.

When to take PLACIL

- Take the tablets in 2 or 3 doses spaced throughout the day, unless your doctor advises you otherwise.
- If you have narcolepsy and you have trouble sleeping at night, take the last dose before the evening to avoid making your insomnia worse.
- Take your medicine about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take PLACIL

- Swallow the tablets with a glass of water.
- PLACIL can be taken with or without food.
- If your stomach is upset after taking the tablets, take them with a meal or after a snack.

How long to take PLACIL for

Take this medicine until you doctor tells you to stop treatment.

The length of treatment will depend on your condition and how you respond to PLACIL.

Most medicines of this type take time to work, so do not be discouraged if you do not feel better right away.

Some of your symptoms may improve in 1 or 2 weeks, but it can take up to 4 or 6 weeks to feel the full benefit of PLACIL. Even when you feel well, you will usually have to take PLACIL for several months or longer, to make sure that the benefits last.

Do not stop taking PLACIL suddenly as you could suffer possible withdrawal symptoms.

If you forget to take PLACIL

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the dose as soon as you remember, and then go back to taking the tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much PLACIL

If you think that you or anyone else has taken too much PLACIL, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

If you take too much PLACIL, you may feel sleepy, restless or agitated. You may have stiffness or unusual muscle movements, fever, sweating, vomiting, difficulty breathing, a drop in blood pressure, fast or irregular heartbeat, fits or other symptoms. You may lose consciousness.

Children are much more sensitive than adults to tricyclic antidepressants. An accidental overdose is especially dangerous.

5. What should I know while taking PLACIL?

Things you should do

If you become pregnant while taking PLACIL, tell your doctor immediately.

Do not stop taking your tablets until you have spoken to your doctor. Your doctor can discuss with you the risks of taking it while you are pregnant.

Call your doctor or a mental health professional straight away or go to the nearest hospital for treatment if you or someone you know develop any of the following:

- thoughts or talk about suicide or dying
- thoughts or talk of self-harm or harm to others
- attempts of self-harm or to commit suicide
- new or worsening depression
- new or worsening anxiety
- feeling very agitated or restless
- panic attacks
- new or worsening irritability
- difficulty sleeping (insomnia)
- acting on dangerous impulses

- an extreme increase in activity and talking
- acting aggressive, being angry, or violent
- other unusual changes in behaviour or mood

Symptoms such as these may be associated with an increased risk of suicidal thinking and behaviour and must be taken seriously.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults under 25 years of age.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to take some blood tests and check your heart and blood pressure from time to time.

This helps to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PLACIL.

Remind any doctor, dentist or pharmacist you visit that you are taking PLACIL.

Before having any surgery or emergency treatment, even a minor procedure, tell the doctor or dentist in charge that you are taking PLACIL or have been taking it within the last two weeks or so.

Your doctor may ask you to stop taking PLACIL a few days before elective surgery to avoid unnecessary side effects.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If this medicine causes your mouth to feel dry and this problem doesn't go away after 2 weeks, tell your doctor or dentist. Be sure to have regular dental checkups.

Continuing dryness of the mouth may increase the chance of gum disease or cavities. You can relieve dry mouth by frequent sips of water, sucking sugarless lollies or chewing sugarless gum.

If you wear contact lenses and find that your eyes are dry, sticky or irritated, tell your doctor.

These side effects could damage your eyes.

Things you should not do

- Do not stop taking this medicine suddenly.
- Do not stop taking PLACIL or lower the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use it to treat any other complaints unless your doctor tells you to.

If you stop taking this medicine suddenly, your condition may worsen or you may have unwanted side effects such as headache, nausea (feeling sick), vomiting, diarrhoea and nervousness. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Taking pain relievers, sleeping tablets or antihistamines

- **Be careful when taking pain relievers, sleeping tablets or antihistamines (medicines for colds or allergies such as hay fever) while you are taking PLACIL.**
- PLACIL can increase the drowsiness caused by medicines that affect your nervous system.

Lightheadedness

If this medicine makes you feel lightheaded, be careful when getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

You can usually prevent these symptoms by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Exposure to sunlight or sunlamps

Be careful to stay out of direct sunlight as much as possible until you find out if your skin is more sensitive than usual. Wear protective clothing and use sunscreen. Do not use a sunlamp.

PLACIL makes some people more sensitive than usual to sunlight. Wear protective clothing and use SPF 30+ sunscreen.

Smoking

Tell your doctor if you smoke.

Nicotine can affect the amount of PLACIL that is in your body. Changes in your usual smoking habits can also change the effects of PLACIL.

Lactose intolerance

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

Allergies

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Elderly

Families and carers should be aware that special care might be needed when elderly patients take PLACIL.

They may become confused and are more likely to experience side effects when taking PLACIL.

Driving or using machines

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

PLACIL may cause tiredness, dizziness, drowsiness, lightheadedness or blurred vision in some people.

If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining alcohol with PLACIL can make you more drowsy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while being treated with PLACIL..

After you have stopped taking PLACIL, you should still be careful for 1 or 2 weeks since some of the effects of the medicine will still be in your body.

Looking after your medicine

- Keep your medicine in the original container until it is time to take a dose.
- Store below 25°C.

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

Store it in a cool dry place 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PLACIL.

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.

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

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

PLACIL can cause confusion or disorientation, especially in older people or those with Parkinson's disease. Your family or carer should be aware of this. Special care may be needed.

Patients aged 50 years or older and taking a medicine from this group are more likely to experience bone fractures.

Patients with pre-existing heart conditions and the elderly should be monitored for heart health, as they are at an increased risk of heart attack, stroke and sudden death.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal-related: • constipation • increased appetite and weight gain • decreased appetite • nausea (feeling sick), vomiting, diarrhoea • poor appetite or weight loss Reproductive system-related: • reduced sexual desire or difficulty in reaching orgasm • swelling of the breasts or discharge of milk • swelling of the testicles • delayed or no ejaculation of semen if you are a male Psychological: • tired feeling and mental dullness • feeling of unrest or anxiety • disturbed sleep or nightmares • change in sense of taste • confusion, hallucinations • loss of memory or reduced concentration • Nervous system-related:	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• drowsiness, dizziness, blurred vision or difficulty focusing your eyes, especially when treatment is started or the dose is increased. • lightheadedness, especially when you get up too quickly from a sitting or lying position. • a compelling need to be in constant motion • repetitive, involuntary, purposeless movements • shakiness or trembling • muscle spasms • headache • sweating or hot flushes Kidney-related: • difficulty urinating (passing water) or frequently passing of large amounts of urine Other: • dry mouth • dry or sticky eyes if you wear contact lenses • sores in the mouth or on the tongue • increased sensitivity to the sun • ringing in the ears • hair loss	

Serious side effects

Serious side effects	What to do
Psychological: • any numbness, weakness or tingling of the arms or legs • unsteadiness when walking or difficulty coordinating your movements • weakness or loss of balance • difficulty in speaking or slurred speech	Call your doctor straight away. The above list includes serious side effects that require medical attention.

Serious side effects	What to do
• severe drowsiness or dizziness • confusion or hallucinations (seeing, hearing or feeling things that are not there) • unusually high energy, irritability or outbursts of anger • mood swings alternating from one of excitement, overactivity and uninhibited behaviour to a depressed mood. Infection-related: • constant flu-like symptoms (fever, chills, sore throat or swollen glands, tiredness or lack of energy) • eye pain Liver-related: • signs of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine Gastrointestinal-related: • pain in the stomach or abdomen that is severe or doesn't go away Blood-related: • bruising or bleeding more easily than usual	

Very serious side effects

Very serious side effects	What to do
• signs of allergic reaction such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; difficulty swallowing; shortness	See your doctor immediately or go to the Emergency at your nearest hospital if you notice any of the following. These are very serious side effects. You may need

Very serious side effects	What to do
- of breath, wheezing or troubled breathing - fast or irregular heart beat (pounding, racing, skipping beats) or chest pain - fainting spells or seizures (fits) - a sudden increase in body temperature, extremely high blood pressure and severe convulsions especially in conjunction with fast heart rate and sweating. This may be due to a very rare condition called neuroleptic malignant syndrome, which has been reported with various antipsychotic medicines - symptoms like agitation, confusion, diarrhoea, high temperature, increased blood pressure, excessive sweating and rapid heartbeat (a syndrome due to an increase in naturally occurring messenger, serotonin)	urgent medical attention or hospitalisation.

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 PLACIL contains

Active ingredient (main ingredient)	clomipramine hydrochloride 25 mg
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Other ingredients (inactive ingredients)	lactose monohydrate maize starch povidone sodium starch glycollate magnesium stearate purified talc Instacoat Universal White (A05G15138) ARTG PI No: 144681
Potential allergens	sugar as lactose sulfites

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

What PLACIL looks like

PLACIL 25 mg is a white, biconvex tablet, marked "CI 25" on one side and "G" on the other; supplied in packs of 50 tablets (AUST R 143879).

Who distributes PLACIL

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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