#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 Neulactil?

Neulactil contains the active ingredient periciazine. Neulactil is used to treat patients who feel very anxious and/or tense. It is used in patients to control symptoms such as impulsiveness and aggression. It is also used in patients with severe mental conditions when a person loses contact with reality and is unable to think and judge clearly. Your doctor may have prescribed Neulactil for another reason. For more information, see Section <u>1</u>. <u>Why am I using Neulactil?</u> in the full CMI.

# 2. What should I know before I use Neulactil?

Do not use if you have ever had an allergic reaction to Neulactil 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 Neulactil? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with Neulactil 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 Neulactil?

• Swallow the tablets with a glass of water. Take Neulactil at about the same time each day.

More instructions can be found in Section <u>4. How do I</u> <u>use Neulactil?</u> in the full CMI.

# 5. What should I know while using Neulactil?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using Neulactil.</li> <li>Tell your doctor if you are pregnant, breastfeeding, or trying to become pregnant.</li> </ul>
Things you should not do	<ul> <li>Do not take Neulactil to treat any other</li> </ul>

	<ul> <li>complaints unless your doctor tells you to.</li> <li>Do not stop taking Neulactil, or lower or raise the dosage, without checking with your doctor.</li> </ul>
Driving or using machines	<ul> <li>Be careful driving or operating machinery until you know how Neulactil affects you.</li> <li>As with other medicines of this kind, Neulactil may cause dizziness, light-headedness, and drowsiness in some people.</li> </ul>
Drinking alcohol	<ul> <li>Alcohol should be avoided while on treatment with Neulactil.</li> <li>If you drink alcohol, dizziness or light- headedness may be worse.</li> </ul>
Looking after your medicine	<ul> <li>Keep your tablets in a cool dry place protected from light where the temperature stays below 25°C.</li> </ul>

For more information, see Section <u>5. What should I know</u> while using Neulactil? in the full CMI.

# 6. Are there any side effects?

The most common and serious side effects are allergic reaction (see the full CMI for details), fever, altered consciousness, severe confusion, distortion of the body, restlessness, stiffness or tightness in the arms or legs, lack of normal muscle movement, uncontrollable twitching, jerking or writhing movements, skin rash, yellowing of the skin and eyes, darkening of the urine, aggravation of glaucoma, abnormal pigmentation on certain areas of the eye, blurred vision, changes in heartbeat, severe pain in the stomach with bloating, gut cramps and vomiting, high fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucinations, or if you are sweating a lot, low white blood cells in a blood test result, which can cause frequent infections such as fever, severe chills, sore throat or mouth ulcers, blood cells and platelet count changes in blood test results, increased bleeding and bruising. Tell your doctor or pharmacist immediately if you notice these as you may need urgent medical attention. 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.

# **Neulactil**®

#### Active ingredient: periciazine

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Neulactil. 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 Neulactil.

#### Where to find information in this leaflet:

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

# 1. Why am I using Neulactil?

# Neulactil contains the active ingredient periciazine.

This active ingredient belongs to a group of medicines called phenothiazines.

# Neulactil is used to treat patients who feel very anxious and/or tense.

It is used in patients to control symptoms such as impulsiveness and aggression.

It is also used in patients with severe mental conditions when a person loses contact with reality and is unable to think and judge clearly.

Your doctor may have prescribed Neulactil for another reason.

Ask your doctor or pharmacist if you have any questions about why Neulactil has been prescribed for you.

# 2. What should I know before I use Neulactil?

# Warnings

## Do not use Neulactil if:

- you are allergic to periciazine or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
  - asthma, wheezing or shortness of breath
  - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
  - hives, itching or skin rash
  - fainting

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

- you have circulatory disorders
- you have blood or bone marrow disorders
- you have a history of high blood pressure in the eyes (certain types of glaucoma)
- you are receiving local anaesthetics around the spinal cord
- you have uncontrolled fitting disorders
- you have liver problems
- you have phaeochromocytoma (rare tumour of the adrenal gland)
- you have difficulty passing urine or prostate problems
- you are taking medicines used to treat Parkinson's disease (disease of the brain that affects movement)

# Check with your doctor if you:

- take any medicines for any other condition
- take any other substances, such as foods, preservatives or dyes
- have or have had any medical conditions, especially the following:
  - kidney problems
  - epilepsy fits
  - Parkinson's disease
  - decreased thyroid activity
  - heart failure, other problems with the heart or blood vessels
  - blood clots or a history of blood clots in your family
  - bowel problems

- dementia
- diabetes
- tumour of the adrenal gland
- muscle weakness (myasthenia gravis)
- certain types of glaucoma- high pressure in the eyes
- prostate problems
- low potassium levels
- brain damage

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. Are there any side effects</u>?

# Pregnancy and breastfeeding

Neulactil is not recommended during pregnancy.

Talk to your doctor before taking this medicine if:

- you are a woman of childbearing age and not using effective contraception, or
- you are pregnant, might become pregnant, or think you may be pregnant.

Neulactil is not recommended during breastfeeding.

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

Babies exposed to antipsychotic medicines including Neulactil during the third trimester of pregnancy are at risk of experiencing breathing problems, difficulty in feeding, spasms, restlessness, involuntary movements and/or withdrawal symptoms following delivery.

# **Children and adolescents**

Do not use in children less than 1 year of age.

Neulactil is not recommended in children aged below 3. In children aged between 3-6 it should only be used in exceptional circumstances.

Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.

# 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 Neulactil and affect how it works.

These include:

- sedatives, medicines to help you sleep or to calm you down.
- sedative antihistamines (medicines used to prevent or relieve the symptoms of allergy).
- medicines used to treat high blood pressure.
- medicines used to treat mental illness e.g. antidepressants, antipsychotics.

- medicines used to treat a fast or irregular heart beat (antiarrhythmics) e.g. amiodarone, quinidine, disopyramide.
- medicines that can slow your heart beat e.g. diltiazem, verapamil.
- medicines that can reduce potassium levels in the blood e.g. diuretics, laxatives.
- other medicines that can affect your heart rate e.g. methadone, pentamidine.
- adrenaline (epinephrine) (sends more oxygen to brain and muscles).
- desferrioxamine (a medicine used to remove excess iron from the body).
- lithium (a medicine used to treat mood swings and some types of depression).
- medicines metabolised by CYP2D6 enzymes such as amitriptyline.
- anticholinergics, medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease.
- medicines for the treatment of infections (antimicrobials)
- medicines for the treatment of diabetes.
- medicines for the treatment of epilepsy or seizures.

These medicines may be affected by Neulactil or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Neulactil.

# 4. How do I use Neulactil?

## How much to take

- Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.
- Follow all directions given to you by your doctor and pharmacist carefully.
- These directions may differ from the information contained in this leaflet.
- If you do not understand the instructions given to you, ask your doctor or pharmacist for help.

#### How to take Neulactil

• Swallow the tablets with a glass of water.

## When to take Neulactil

• Take Neulactil at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

It does not matter if you take Neulactil before or after food.

# How long to take Neulactil

Neulactil helps control your condition, but does not cure it. Therefore you must take Neulactil every day. Continue taking the tablets for as long as your doctor or pharmacist tells you.

Do not stop using it unless your doctor or pharmacist tells you to, even if you feel better.

## If you forget to use Neulactil

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

## If you use too much Neulactil

If you take too much Neulactil you are more likely to experience side effects.

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

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), 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.

You may need urgent medical attention. If you take too much Neulactil, you may experience:

- drowsiness
- low body temperature
- low blood pressure
- shaking of your limbs
- stiffness
- shaking
- unusual heart beats
- muscle twitching
- difficulty in swallowing and breathing
- convulsions
- loss of consciousness leading to coma

# 5. What should I know while using Neulactil?

### Things you should do

If you experience an allergic reaction (see <u>Are there any</u> <u>side effects?</u>), seek medical help right away.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Neulactil.

If you become pregnant while taking Neulactil, tell your doctor.

### Things you should not do

- Do not stop using taking Neulactil, or lower or raise the dosage, without checking with your doctor.
- Do not give Neulactil to anyone else, even if they have the same condition as you.
- Do not take Neulactil to treat any other complaints unless your doctor tells you to.

#### Things to be careful of

Neulactil may cause you to become extra sensitive to sunlight. Make sure you avoid exposure and protect your eyes from strong sunlight.

Take care when standing up too quickly from sitting down to avoid becoming dizzy.

Neulactil may put you at risk of hyperthermia or hypothermia particularly during hot or very cold weather if you are over the age of 65 years.

# Driving or using machines

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

As with other medicines of this kind, Neulactil can cause dizziness, blurred vision, and drowsiness in some people. Make sure you know how you react to Neulactil before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

# **Drinking alcohol**

#### Tell your doctor if you drink alcohol.

Alcohol should be avoided while on treatment with Neulactil. If you drink alcohol, dizziness or lightheadedness may be worse.

# Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they will not keep as well.
- Keep your tablets in a cool dry place protected from light where the temperature stays 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.

#### Keep it where young children cannot reach it.

#### 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.

If you are over 65 years of age you may have an increased chance of getting 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

Less serious side effects	What to do
<ul> <li>General</li> <li>changes in body temperature</li> <li>drowsiness</li> <li>dizziness, especially on standing up from a sit down or lying position</li> <li>nasal stuffiness</li> <li>dry mouth (sometimes with mouth infections)</li> <li>swelling of hands, ankles, feet</li> <li>increased appetite and weight gain</li> <li>unusual secretion of breast milk</li> <li>growth of breasts in males</li> <li>Nervous System related</li> <li>insomnia</li> <li>agitation or aggressiveness</li> <li>mood changes or feeling anxious</li> </ul>	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
Gut related	
<ul> <li>constipation</li> </ul>	
• diarrhoea	
• vomiting	
• nausea	
Skin related	
<ul> <li>sweating</li> <li>symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal</li> <li>changes in the colour of the skin</li> <li>Genito-urinary related</li> </ul>	
<ul> <li>difficulty passing urine</li> <li>absence or irregular menstrual periods</li> <li>impotence</li> <li>false positive pregnancy tests</li> <li>changes in libido</li> <li>inability to ejaculate</li> </ul>	

### **Serious side effects**

Serious side effects	What to do
<ul> <li>General</li> <li>fever</li> <li>high blood sugar (glucose) levels</li> <li>low blood salt (sodium) levels</li> <li>low white blood cells in a blood test result, which can cause frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>an increase in the number of white blood cells found in a blood test result</li> <li>a decrease in the number of platelets found in a blood test result, which can lead to bleeding and bruising</li> <li>Skin related</li> <li>skin rash</li> <li>Nervous System related</li> <li>severe confusion</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul> <li>distortion of the body</li> <li>uncontrollable twitching, jerking or writhing movements</li> <li>seizures, fits or convulsions</li> <li>restlessness</li> <li>lack of normal muscle</li> </ul>	
<ul> <li>movement</li> <li>stiffness or tightness in the arms or legs</li> <li>altered consciousness</li> <li>high fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucinations, or if you are sweating a lot (symptoms relating</li> </ul>	
<ul> <li>to Neuroleptic malignant syndrome)</li> <li>involuntary movement of tongue, face, mouth or jaw (symptoms of Tardive Dyskinesia)</li> <li>Heart related</li> </ul>	

Serious side effects	What to do
<ul> <li>changes in the way the heart beats</li> </ul>	
<ul> <li>very fast, uneven or forceful heartbeat (palpitations), weakness, fainting (symptoms relating to QT prolongation)</li> </ul>	
Gut related	
<ul> <li>severe pain in the stomach with bloating, gut cramps and vomiting</li> </ul>	
Liver related	
<ul> <li>yellowing of the skin and or the eyes</li> <li>darkening of the urine</li> </ul>	
Eye related	
<ul> <li>abnormal pigmentation on certain areas of the eye</li> </ul>	
<ul> <li>blurred vision</li> </ul>	
• aggravation of glaucoma	
Allergic reaction	
<ul> <li>cold, clammy skin, palpitations, dizziness, weakness or fainting, rash, itching, swelling</li> </ul>	

Serious side effects	What to do
of the face, lips, mouth, tongue or throat which may cause shortness of breath, difficulty breathing or swallowing	

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.

Neulactil tablets should not be frequently handled. Care should be taken to minimise contact of Neulactil tablets with the skin.

## **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 <u>www.tga.gov.au/reporting-problems</u> or in New Zealand at <u>https://nzphvc.otago.ac.nz/reporting</u>. 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 Neulactil contains

Active ingredient (main ingredient)	periciazine 2.5 or 10 mg
Other ingredients	cellulose microcrystalline
(inactive ingredients)	lactose monohydrate
	wheat starch
	colloidal anhydrous silica
	magnesium stearate
Potential allergens	contains lactose
	contains gluten (within wheat starch)

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

#### What Neulactil looks like

Neulactil 2.5mg tablets are yellow, scored, and marked 'NEULACTIL'. They are available in packs of 100 tablets. (AUST R 27524)

Neulactil 10mg tablets are yellow, scored, and marked '10'. They are available in packs of 100. (AUST R 27523)

## Who distributes Neulactil

Distributed in Australia by:

Clinect Pty Ltd 120 – 132 Atlantic Drive Keysborough VIC 3173 Australia Free Call Australia: 1800 899 005

Distributed in New Zealand by:

Clinect NZ Pty Limited C/- Ebos Group Limited 108 Wrights Road Christchurch 8024 New Zealand Free Call New Zealand: 0800 138 803

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