

**PACKAGE LEAFLET:
INFORMATION FOR THE PATIENT**

Neulactil® 2.5mg Tablets
(pericyazine)

Read all of this leaflet carefully before you start taking this medicine because it contains information important for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Neulactil 2.5mg Tablets but will be referred to as Neulactil throughout this leaflet.

What is in this leaflet:

1. What Neulactil is and what it is used for
2. What you need to know before you take Neulactil
3. How to take Neulactil
4. Possible side effects
5. How to store Neulactil
6. Contents of the pack and other information

1. What Neulactil is and what it is used for



Neulactil belongs to a group of medicines called 'phenothiazines'. It works by blocking the effect of a chemical in the brain. It can be used for:

- Schizophrenia
- The short term treatment of anxiety, agitation and violent or dangerously impulsive behaviour when used with other medicines

2. What you need to know before you take Neulactil



Do not take this medicine and tell your doctor if:

- × You are allergic (hypersensitive) to pericyazine or any of the other ingredients in this medicine (listed in Section 6)
- × Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- × You are pregnant, might become pregnant or think you may be pregnant (see Section below: 'Pregnancy and breast-feeding')

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Neulactil.



Warnings and Precautions

Talk to your doctor or pharmacist before you take this medicine if:

- ▲ You have heart problems or a family history of heart problems
- ▲ You have ever had a stroke
- ▲ You have liver or kidney problems
- ▲ You have thyroid problems
- ▲ You have Parkinson's disease
- ▲ You have dementia
- ▲ You have epilepsy or have had fits (seizures)
- ▲ You have depression
- ▲ You have ever had alcohol problems
- ▲ You have an enlarged prostate gland
- ▲ You have had glaucoma (painful eyes with blurred vision)
- ▲ You have a tumour on the adrenal gland called 'phaeochromocytoma'
- ▲ You have a form of muscle weakness called 'myasthenia gravis'
- ▲ You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual. Your doctor may do blood tests to check this
- ▲ You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- ▲ You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- ▲ You are not eating properly
- ▲ You are allergic to other phenothiazine medicines such as prochlorperazine
- ▲ You are elderly, this is because elderly people are more likely to get certain side effects particularly during very hot or very cold weather. In these conditions, you could be at risk of hyperthermia or hypothermia
- ▲ You are elderly and also have dementia, tell your doctor if this is the case
- ▲ You are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before you take Neulactil.



Other medicines and Neulactil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Neulactil can affect the way some other medicines work. Also some medicines can affect the way Neulactil works. In particular, check with your doctor if you are taking any of the following:

- Medicines to control your heart beat such as amiodarone, disopyramide or quinidine
- Medicines for high blood pressure such as doxazosin, terazosin, guanethidine, clonidine or propranolol
- Medicines for indigestion and heartburn (antacids)
- Medicines for diabetes
- Medicines for Parkinson's disease such as levodopa or selegiline
- Medicines for fits (epilepsy) such as carbamazepine or phenobarbital
- Medicines to help you sleep or lower your anxiety
- Other medicines used to calm emotional and mental problems
- Medicines for depression including amitriptyline and amitriptylinoxide
- Some medicines used for infections (antibiotics) such as moxifloxacin
- Some medicines used for cancer (cytotoxics)
- Amphetamines - used for Attention Deficit Hyperactivity Disorder (ADHD)
- Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or incontinence
- Adrenaline - used for life threatening allergic reactions
- Desferrioxamine - used when you have too much iron in your blood
- Lithium - used for some types of mental illness

Neulactil with alcohol

Do not drink alcohol while being treated with Neulactil. This is because alcohol can add to the effects of Neulactil and cause serious breathing problems.

Pregnancy and breast-feeding

Do not take this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant

Do not breast-feed if you are being given Neulactil. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed talk to your doctor or pharmacist before taking any medicine.

The following symptoms may occur in newborn babies of mothers that have used Neulactil in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.



Driving and using machines

You may feel sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

Neulactil contain lactose and methylparahydroxybenzoate (E218)

- **Lactose.** This medicine contains lactose, a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Neulactil
- **Methylparahydroxybenzoate (E218).** This medicine contains methylparahydroxybenzoate (E218), a type of preservative. This may cause allergic reactions which may not happen straight away. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

3. How to take Neulactil

Always take Neulactil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Do not touch the tablets for any longer than is necessary as you may get skin redness, swelling and itching (contact skin sensitisation)
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

Recommended dose

Adults

Schizophrenia

- The starting dose is 75mg daily in divided doses
- The dose may be increased by 25mg per day at weekly intervals depending on your illness

- The highest dose is usually not more than 300mg per day

Anxiety, agitation and violent or dangerously impulsive behaviour

- The starting dose is 15mg to 30mg daily, divided into two doses. The larger dose should be taken in the evening

Elderly

Schizophrenia

- The starting dose is 15mg to 30mg daily, in divided doses
- The dose may then be increased depending on your illness

Anxiety, agitation and violent or dangerously impulsive behaviour

- The starting dose is 5mg to 10mg daily, divided into two doses. The larger dose should be taken in the evening

Use in children

Neulactil is not recommended for children.

Exposure to sunlight

Neulactil can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

Tests

Before and during treatment your doctor may want to carry out some tests. These might include blood tests and an ECG to check your heart is working properly.

If you take more Neulactil than you should

If you take more Neulactil than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

This is so the doctor knows what you have taken. The following effects may happen: feeling drowsy, loss of consciousness, increased or rapid heart beat, changes in heart beat, uneven heart beats and feeling very cold. You may also experience dizziness, light-headedness, fainting (due to low blood pressure) and movements that you cannot control (for example of the eyes, neck, arms and legs).

If you forget to take Neulactil

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Neulactil

Keep taking Neulactil until your doctor tells you to stop. Do not stop taking Neulactil just because you feel better. If you stop taking Neulactil suddenly, your illness may come back and you may have other effects such as feeling or being sick and difficulty sleeping. In some cases you may also get symptoms such as feeling restless or movements that you cannot control (for example of the eyes, neck, arms and legs).

Your doctor will gradually stop your medicine to prevent these effects happening.



If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Neulactil and see a doctor or go to a hospital straight away if:

- You have swelling, pain or redness in your legs as this could be a sign of a blood clot (deep vein thrombosis)
- You have chest pain or difficulty in breathing as this could be a sign of a blood clot which has travelled through blood vessels to the lungs (pulmonary embolism)
- You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- You have yellowing of the skin or eyes (jaundice). These could be signs of liver damage
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia'
- You may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- You have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs
- You have a high temperature, sweating, stiff muscles, fast heart beat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious but rare side effect called 'neuroleptic malignant syndrome'
- You have a very fast, uneven or forceful heart beat (palpitations). You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain
- You have a long lasting, painful erection of the penis

Tell a pharmacist or doctor as soon as possible if you have any of the following side effects:

- You are breathing more slowly or less deeply than normal

- Feeling restless and not being able to keep still (akathisia)
- Feeling dizzy, light-headed or faint when you stand or sit up quickly (due to low blood pressure)
- Rigid or stiff muscles, trembling or shaking, difficulty moving
- Passing large amounts of urine, excessive thirst and having a dry mouth or skin. You may also be more likely to get infections, such as thrush. This could be due to too much sugar in your blood (hyperglycaemia).

Talk to your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- Abnormal production of breast milk in men and women
- Breast enlargement in men
- Loss of menstrual periods
- Difficulty in getting or keeping an erection (impotence)
- Difficulty sleeping (insomnia)
- Feeling agitated
- Dry mouth
- Being more sensitive to the sun than usual
- Stuffy nose
- Skin rashes
- Skin redness, swelling and itching (contact skin sensitisation)

As with other phenothiazine medicines, there have been very rare reports of sudden death with Neulactil. These are possibly caused by heart problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Neulactil

- Keep out of the sight and reach of children.
- Do not take the tablets after the expiry date which is stated on the carton and blister label after 'Exp'. The expiry date refers to the last day of that month.
- Store in original package in order to protect from light.
- If the tablets become discoloured or show any other signs of deterioration, seek the advice of your pharmacist.
- Remember if your doctor tells you to stop taking this medicine, return an unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Neulactil contains

Each tablet contains 2.5mg of the active substance pericyazine.

The other ingredients are anhydrous lactose, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, colloidal anhydrous silica and methylparahydroxybenzoate (E218).

What Neulactil looks like and contents of the pack

Neulactil is a very pale lime-yellow colour tablet with, 'NEULACTIL' embossed on one face and a breakline on the other.

Neulactil is available in pack of 100 tablets

Manufactured by: Famar Health Care Services Madrid S.A.U., Avda. Leganés, 62, Alcorcón 28923 (Madrid), Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK. **POM**

Neulactil® 2.5mg Tablets; PL 18799/2523

Leaflet date: 22.03.2017

Blind or partially sighted?

Is this leaflet hard to see or read?

Call 0208 515 3763 to obtain the leaflet in a format suitable for you.

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The name of your medicine is Pericyazine 2.5mg Tablets but will be referred to as Pericyazine throughout this leaflet.

What is in this leaflet:

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1. What Pericyazine is and what it is used for



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- × Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- × You are pregnant, might become pregnant or think you may be pregnant (see Section below: 'Pregnancy and breast-feeding')

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Pericyazine.



Warnings and Precautions

Talk to your doctor or pharmacist before you take this medicine if:

- ▲ You have heart problems or a family history of heart problems
- ▲ You have ever had a stroke
- ▲ You have liver or kidney problems
- ▲ You have thyroid problems
- ▲ You have Parkinson's disease
- ▲ You have dementia
- ▲ You have epilepsy or have had fits (seizures)
- ▲ You have depression
- ▲ You have ever had alcohol problems
- ▲ You have an enlarged prostate gland
- ▲ You have had glaucoma (painful eyes with blurred vision)
- ▲ You have a tumour on the adrenal gland called 'phaeochromocytoma'
- ▲ You have a form of muscle weakness called 'myasthenia gravis'
- ▲ You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual. Your doctor may do blood tests to check this
- ▲ You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- ▲ You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- ▲ You are not eating properly
- ▲ You are allergic to other phenothiazine medicines such as prochlorperazine
- ▲ You are elderly, this is because elderly people are more likely to get certain side effects particularly during very hot or very cold weather. In these conditions, you could be at risk of hyperthermia or hypothermia
- ▲ You are elderly and also have dementia, tell your doctor if this is the case
- ▲ You are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely.

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- Amphetamines - used for Attention Deficit Hyperactivity Disorder (ADHD)
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- Adrenaline - used for life threatening allergic reactions
- Desferrioxamine - used when you have too much iron in your blood
- Lithium - used for some types of mental illness

Pericyazine with alcohol

Do not drink alcohol while being treated with Pericyazine. This is because alcohol can add to the effects of Pericyazine and cause serious breathing problems.

Pregnancy and breast-feeding

Do not take this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant

Do not breast-feed if you are being given Pericyazine. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed talk to your doctor or pharmacist before taking any medicine.

The following symptoms may occur in newborn babies of mothers that have used Pericyazine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.



Driving and using machines

You may feel sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

Pericyazine contain lactose and methylparahydroxybenzoate (E218)

- **Lactose.** This medicine contains lactose, a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Pericyazine
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3. How to take Pericyazine

Always take Pericyazine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Do not touch the tablets for any longer than is necessary as you may get skin redness, swelling and itching (contact skin sensitisation)
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

Recommended dose

Adults

Schizophrenia

- The starting dose is 75mg daily in divided doses

- The dose may be increased by 25mg per day at weekly intervals depending on your illness
- The highest dose is usually not more than 300mg per day

Anxiety, agitation and violent or dangerously impulsive behaviour

- The starting dose is 15mg to 30mg daily, divided into two doses. The larger dose should be taken in the evening

Elderly

Schizophrenia

- The starting dose is 15mg to 30mg daily, in divided doses
- The dose may then be increased depending on your illness

Anxiety, agitation and violent or dangerously impulsive behaviour

- The starting dose is 5mg to 10mg daily, divided into two doses. The larger dose should be taken in the evening

Use in children

Pericyazine is not recommended for children.

Exposure to sunlight

Pericyazine can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

Tests

Before and during treatment your doctor may want to carry out some tests. These might include blood tests and an ECG to check your heart is working properly.

If you take more Pericyazine than you should

If you take more Pericyazine than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

This is so the doctor knows what you have taken. The following effects may happen: feeling drowsy, loss of consciousness, increased or rapid heart beat, changes in heart beat, uneven heart beats and feeling very cold. You may also experience dizziness, light-headedness, fainting (due to low blood pressure) and movements that you cannot control (for example of the eyes, neck, arms and legs).

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If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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- You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- You have yellowing of the skin or eyes (jaundice). These could be signs of liver damage
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia'
- You may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
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- Feeling dizzy, light-headed or faint when you stand or sit up quickly (due to low blood pressure)
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