

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Pericyazine 10 mg/ 5 ml
Syrup**

Read all of this leaflet carefully before you take this medicine because it contains important information 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 only. Do not pass it on to others. It may harm them, even if their symptoms 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.

What is in this leaflet:

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

1. What pericyazine is and what it is used for

The name of your medicine is Pericyazine 10 mg/ 5 ml Syrup (referred to as pericyazine throughout this leaflet). This 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:

Adults

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

Children

- Schizophrenia
- Other behavioural problems

2. What you need to know before you take pericyazine

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 have urine retention due to a prostate disorder
- You are taking a dopaminergic antiparkinsonism drug

- You have increased pressure in the eye (glaucoma)
- You have a history of a low white blood cell count
- It is intended for a child younger than 1 year.

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.

**Take special care with pericyazine
Check with your doctor or pharmacist before you take this medicine if you:**

- have liver or kidney problems
- have thyroid problems
- have heart problems or a family history of heart problems
- have ever had a stroke
- have Parkinson's disease
- have dementia
- have epilepsy or have had fits (seizures)
- have depression
- have ever had alcohol problems
- have an enlarged prostate gland
- have had glaucoma (painful eyes with blurred vision)
- have a tumour on the adrenal gland called 'phaeochromocytoma'
- have a form of muscle weakness called 'myasthenia gravis'
- 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
- have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- are not eating properly
- are allergic to other phenothiazine medicines such as prochlorperazine
- 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
- are elderly and also have dementia, tell your doctor if this is the case
- are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely
- are intolerant to fructose, or have glucose and galactose malabsorption syndrome or sucrose-isomaltase deficiency.

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

Pericyazine is not recommended in children under 3 years of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal

medicines. This is because pericyazine can affect the way some other medicines work. Also some medicines can affect the way pericyazine works.

In particular, check with your doctor if you are taking any of the following:

- Medicines to control your heartbeat 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)
- Medicines which can alter electrolytes (salt levels) in your blood
- 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

Taking pericyazine with food and drink

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

Talk to your doctor or pharmacist before taking 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.

Important information about some of the ingredients of pericyazine

Sucrose. This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking pericyazine.

Contains 3.39g of sucrose per 5ml. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

Sodium. This syrup contains 28 mg sodium per 5ml dose. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult.

Small amounts of sulphites. These may rarely cause severe allergic reactions (hypersensitivity) and difficulty in breathing (bronchospasm).

This is more likely to happen if you have a history of asthma or allergies. The chances of this happening are rare. Tell a doctor or nurse straight away if you get a rash, swallowing or breathing problems and swelling of your lips, face, throat or tongue.

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
- Take care when taking the syrup and avoid skin contact as you may get skin redness, swelling and itching (contact skin sensitisation)
- Take the medicine as directed by your doctor and pharmacist.
- If you are not sure how much to take, check with them first.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults:

Schizophrenia and other behavioural problems

- The starting dose is 37.5ml (75mg) daily in divided doses
- The dose may be increased by 12.5ml (25mg) per day at weekly intervals depending on your illness
- The highest dose is usually not more than 150ml (300mg) per day

Anxiety, agitation and violent or dangerously impulsive behaviour

- The starting dose is 7.5ml to 15ml (15-30mg) daily in two divided doses. The larger dose should be taken in the evening

Elderly:

Schizophrenia and other behavioural problems

- The starting dose is 7.5ml to 15ml (15-30mg) daily in divided doses

Anxiety, agitation and violent or dangerously impulsive behaviour

The starting dose is 2.5ml to 5ml (5-10mg) daily in two divided doses. The larger dose should be taken in the evening

Children (over 1 year of age):

Schizophrenia and other behavioural problems

- Your doctor will decide on the dose according to the child's weight
- The initial dose for a child weighing 10kg is 0.25ml (0.5mg)
- The dose should be increased by 0.5ml (1mg) for each additional 5kg of bodyweight up to a total dose of 5ml (10mg) daily
- The highest dose that should be prescribed to keep the illness under control is twice that of the first dose given
- Pericyazine is not recommended for infants under 1 year of age.

Anxiety, agitation and violent or dangerously impulsive behaviour

- Pericyazine is not recommended for use in children with these conditions.

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 heartbeat, changes in heart beat, uneven heart beats and feeling very cold. You may also experience dizziness, lightheadedness, 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 pericyazine

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.

If you stop taking pericyazine

Keep taking pericyazine until your doctor tells you to stop. Do not stop taking pericyazine just because you feel better. If you stop taking pericyazine 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 lower your dose until you 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, pericyazine can cause side effects, although not everybody gets them.

Stop taking pericyazine 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)
- 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)
- have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling
- have yellowing of the skin or eyes (jaundice). These could be signs of liver damage
- have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia'
- get infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs
- have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious but rare side effect called 'neuroleptic malignant syndrome'
- get a bloated feeling and cramping pain in the abdomen (stomach) be sick (vomit) have indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. This could be caused by an obstruction or blockage of the intestine
- have a very fast, uneven or forceful heartbeat (palpitations). You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain
- 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, lightheaded 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)
- Problems with eyesight
- You have difficulty in passing water (urine)
- Changes in eye colour.

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)
- Reduced sexual desire in women
- Feeling drowsy or sleepy
- 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)
- Putting on weight
- Body temperature changes
- Feeling anxious
- Mood changes.

Blood tests

- The results of some blood tests may show higher levels of liver enzymes than normal.

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

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

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 side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store pericyazine

Keep this medicine out of the sight and reach of children.

Do not use pericyazine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Discard any medicine remaining 1 month after opening the bottle. Keep the bottle in the outer carton in order to protect from light.

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 Pericyazine 10 mg/5 ml Syrup contains

- Each 1 ml of syrup contains 2 mg of the active substance, pericyazine.
- The other ingredients are sucrose, caramel, spearmint oil, peppermint oil, fruit cup 868, Polysorbate 20, citric acid anhydrous, sodium citrate, sodium sulphite anhydrous (E221), sodium metabisulphite (E223), ascorbic acid, sodium benzoate (E211) and purified water.

What pericyazine looks like and contents of the pack

Pericyazine is a clear orange brown syrupy liquid.

Supplied in 100ml and 1 litre amber glass bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK.

Manufacturer:

Unither Liquid Manufacturing, 1-3 Allee de la Neste, Z.I. d'en Signal, 31770 Colomiers, France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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