

PACKAGE LEAFLET: INFORMATION FOR THE USER

NEULEPTIL® 10 mg hard capsules

pericyazine

SANOFI 

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions, or you are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In this leaflet:

1. What Neuleptil 10 mg hard capsules are and what they are used for
2. What you need to know before you take Neuleptil 10 mg hard capsules
3. How to take Neuleptil 10 mg hard capsules
4. Possible side effects
5. How to store Neuleptil 10 mg hard capsules
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1. WHAT Neuleptil 10 mg hard capsules ARE AND WHAT THEY ARE USED FOR

Pharmacotherapeutic group

Neuleptil belongs to a group of medicines known as antipsychotics. It acts on the brain.

Therapeutic indications

It is used to treat a disease characterized by symptoms such as hearing, seeing or feeling things that do not exist, being unusually suspicious, having misguided beliefs, speaking and behaving incoherently and being emotionally and socially distant. People with this disease can also feel depressed, guilty, worried or tense.

This medicine is for use in adults only.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Neuleptil 10 mg hard capsules

Contraindications

Do not take Neuleptil 10 mg hard capsules in the following situations:

- if you are allergic to the active ingredient (pericyazine) or to any of the other ingredients of this medicine. See section 6 for a list of ingredients;
- if you have difficulty urinating;
- if you have or are at risk for glaucoma (a disease of the eye where pressure of the liquid inside the eye is increased and can affect your vision);
- if you have previously experienced a major drop in the number of certain white blood cells (agranulocytosis);

- if you are taking a medicine containing cabergoline or quinagolide (medicines used to treat abnormal secretion of breast milk).

Precautions for use and special warnings

Take special care with Neuleptil 10 mg hard capsules
Talk to your doctor before taking Neuleptil 10 mg hard capsules:

- if you have heart disease;
- if you are at risk, e.g. you smoke or have high blood pressure, too much sugar, cholesterol or fat in your blood, this medicine should be used with caution because the risk of stroke (cerebrovascular accident) may be increased;
- if you have liver or kidney disease;
- if you have ever had seizures (in the past, or recently) or epilepsy;
- if your prostate (gland that produces sperm) has increased in size;
- if you are constipated.

This medicine must be used with caution:

- in elderly people with dementia;
- if you or a family member have a history of blood clots, since taking antipsychotics has been associated with the formation of blood clots.

During treatment

- You must tell your doctor immediately if the following occur:
 - if you experience muscle stiffness, consciousness disorders and fever. If this happens, you must stop your treatment immediately and also tell your doctor;
 - if you experience fever, paleness, heavy sweating or any other sign of infection. This is because in exceptional cases, this medicine can cause your white blood cells to decrease, which can promote infection;
 - if you are constipated for a long time, you feel bloated and have stomach pain. This is because in very rare cases, this medicine can cause your bowel movements to stop (intestinal obstruction).
- To detect any potential heart disorders, your doctor may have the electrical activity of your heart examined (electrocardiogram). This is because some medicines in the same group as Neuleptil (antipsychotics) can, in very rare cases, cause heart rate disorders (see Section 4).
- If you are diabetic or are at risk for diabetes, you will have to monitor your blood sugar levels carefully during treatment.

Taking or using other medicines

Do not take Neuleptil with medicine containing cabergoline or quinagolide (medicines used to treat excessive or abnormal secretion of breast milk).

You must avoid taking Neuleptil if you are already taking:

- a medicine used to treat Parkinson's disease;
- a medicine that contains alcohol and/or ethanol.

If you are taking or have recently taken any other medicine, even an over-the-counter medicine, tell your doctor or pharmacist.

Food and drink

You must avoid drinking alcoholic beverages during treatment.

Pregnancy

This medicine may only be used during pregnancy on your doctor's advice.

The following symptoms may appear in newborn babies whose mothers have taken Neuleptil during the last trimester of pregnancy (last 3 months): tremors, muscle

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stiffness and/or weakness, drowsiness, agitation, trouble breathing, difficulty feeding. If your baby develops one of these symptoms, contact your doctor.

If you discover that you are pregnant, contact your doctor. Only he/she can decide whether it is necessary to pursue treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Breast-feeding is not recommended during treatment with this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine can cause drowsiness; if you feel drowsy, you must ask your doctor's advice before driving.

3. HOW TO TAKE Neuleptil 10 mg hard capsules

Dosage

This medicine is for use in adults only.

The doses can vary. Your doctor will adjust the dose for you personally.

Always take the dose prescribed by your doctor. If you are unsure of anything, ask your doctor or pharmacist.

Method and route of administration

This medicine is taken orally.

Swallow the capsules with a large glass of water.

If you take more Neuleptil 10 mg hard capsules than you should:

If you take more of this medicine than you should, immediately inform your doctor or go to the emergency medical service of the nearest hospital, as this medicine can cause serious heart disorders.

4. POSSIBLE SIDE EFFECTS

As with all medicines, Neuleptil can cause side effects, although not all patients have them:

- feeling of dizziness when standing up suddenly from a lying down or seated position,
- dry mouth, difficulty urinating, constipation or even intestinal blockage (occlusion),
- visual disturbances, including problems relating to the ability of the eye to adjust to different distances (accommodation disorders),
- drowsiness, anxiety, mood disorders,
- shaking, rigidity and/or abnormal movements,
- impotence, frigidity,
- weight gain,
- absence of menstrual period, enlarged breasts, abnormal discharge of breast milk,
- change in blood sugar levels,
- change in body temperature,
- blood clots in the veins, particularly in the legs (symptoms include swelling, pain and redness of the legs) can travel via the blood vessels to the lungs, causing pain in the chest and difficulty breathing. If you feel any of these symptoms, consult a doctor immediately.

The following side effects may occur more rarely:

- heart rate disorders (possibly life-threatening in exceptional cases),
- abnormal results for certain laboratory tests (testing positive for certain antinuclear antibodies),

- allergic skin reaction, excessive reaction of the skin to sun or ultraviolet rays,
- liver disease with yellowing of the skin and eyes, inflammation of the liver (hepatitis).

The following side effects may occur exceptionally:

- major drop in the number of certain white blood cells that could lead to serious infection (agranulocytosis),
- fever, heavy sweating, paleness, muscle stiffness, consciousness disorders: if these symptoms occur, you must stop treatment immediately and contact a doctor or emergency department,
- painful and prolonged erection,
- brownish deposits in the eyes, which generally have no effect on vision.

Unknown incidence:

Neonatal abstinence syndrome in newborns whose mothers have taken Neuleptil during the last trimester of pregnancy (last 3 months) – (see "Pregnancy").

If any side effects become serious, or if you notice any side effects not mentioned in this package leaflet, inform your doctor or pharmacist.

5. HOW TO STORE Neuleptil 10 mg hard capsules

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use Neuleptil after the expiry date indicated on the box.

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. FURTHER INFORMATION

What Neuleptil 10 mg hard capsules contain

The active substance is:

Pericyazine 10.00 mg for one hard capsule.

The other ingredients are:

Calcium hydrogen phosphate, magnesium stearate.

Composition of the hard capsule shell: gelatin, titanium dioxide (E 171).

What Neuleptil 10 mg hard capsules look like and contents of the pack

This medicine is a hard capsule (box of 50).

Marketing Authorization Holder and Operating Company

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Manufacturer

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