PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Neuleptil 10 mg Capsules,

Neuleptil Drops 4%

SANOFI

Active ingredient:

Neuleptil 10 mg Capsules

Each capsule contains: Periciazine 10 mg

Neuleptil Drops 4%

Each drop contains: Periciazine 1 mg,

each ml contains 40 drops.

Inactive ingredients: See section 6.

Read this leaflet carefully in its entirety before using the medicine. Keep this leaflet, you may need to read it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for infants and children under 3 years of age.

If a side effect worsens or if a side effect that is not mentioned in this leaflet occurs, please refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for treatment of psychotic disorders.

Therapeutic group: an antipsychotic-neuroleptic agent from the phenothiazine group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

you are breastfeeding;

you are sensitive to periciazine or any of the medicine's ingredients (see section 6);

you are at risk of suffering from glaucoma (abnormally increased pressure in the eye);

you have difficulty urinating as a result of prostate problems;

there is a known history of agranulocytosis (a significant decrease in granulocytes - a type of white blood cells);

in combination with dopamine preparations (cabergoline and quinagolide) that are not given for the treatment of Parkinson's disease.

Special warnings regarding use of the medicine

Before treatment with Neuleptil, tell the doctor if:

- you are pregnant (Neuleptil Drops contains alcohol);
- you are also taking the following medicines: medicines containing alcohol, levodopa (a medicine given in conditions of dopamine deficiency, such as Parkinson's disease).
- you are suffering, or have suffered in the past, from impaired function of: the digestive system such as chronic constipation (risk of intestinal obstruction), the heart and/or blood vessels, the liver, the kidneys, from seizures, from epilepsy, from prostate enlargement.

This medicine may cause special sensitivity if you are exposed to the sun. Therefore, avoid exposure to the sun and take appropriate precautions (long clothing, a hat, protective creams, etc.).

Do not use this medicine frequently or for a prolonged period without consulting the doctor.

If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.

Caution should be exercised in patients with risk factors for stroke and in elderly patients suffering from dementia, if you or any of your family members suffered from blood clotting and this since taking antipsychotic preparations can cause formation of blood clots.

You must inform the doctor if you are about to undergo surgery (including dental surgery) during treatment.

Avoid sudden transition from a lying/sitting position to standing.

Neuleptil Drops: Do not let the preparation come into contact with the skin.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

You should especially inform the doctor or pharmacist if you are taking:

medicines affecting the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's disease, epilepsy), medicines containing alcohol, levodopa (a medicine given for conditions of dopamine deficiency, such as Parkinson's disease), antiallergics, surgical anesthetics, narcotic analgesics, medicines for Parkinson's disease, lithium, antidepressants, phenylbutazone, thiouracil (for thyroid), other phenothiazines, epinephrine, medicines for lowering blood pressure, nitrates or nitrites or preparations containing these ingredients, atropine or atropine derivatives.

Topical gastrointestinal medicines - adsorbing medicines (e.g., charcoal) and antacids, medicines for heartburn containing magnesium oxide or hydroxide, aluminum oxide or hydroxide, calcium oxide or hydroxide - wait at least two hours between taking these medicines and taking Neuleptil.

Use of the medicine and food

The medicine can be taken with a meal or between meals.

Use of the medicine and consumption of alcohol

Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

Pregnancy and breastfeeding

Do not use the medicine if you are breastfeeding.

Before treatment with Neuleptil, tell the doctor if you are pregnant.

Driving and using machines

Use of this medicine may impair alertness. Caution should therefore be exercised when driving a car, operating dangerous machines and in any activity requiring alertness. Children should be cautioned about riding bicycles or playing near the road, and the like.

Important information about some of the medicine's ingredients

The alcohol content in Neuleptil Drops is 12% v/v, i.e., 96.9 mg alcohol per 40 drops (1 ml). Because of this, administration of the drops is recommended for those suffering from liver diseases, alcoholism, epilepsy, cerebral function problems and for pregnant women.

Neuleptil Drops contains sucrose and therefore not recommended for use if you suffer from fructose intolerance, galactosemia, glucose or galactose malabsorption or sucrase-isomaltase deficiency.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

This medicine is not usually intended for infants and children under 3 years of age.

Use in children under 6 years of age will be done only in special cases according to the decision of a specialist.

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember, but never take two doses together!

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by the doctor.

Sometimes the benefit of the treatment will be felt only after several weeks.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting a doctor and even then, gradually.

Wait at least two hours between taking this medicine and taking antacids, topical gastrointestinal medicines.

Neuleptil Capsules: Do not chew! Swallow the medicine with water.

Tests and follow-up

Before starting treatment with Neuleptil it is recommended that an ECG test be performed (this test is recommended before administration of neuroleptic medicines such as Neuleptil).

In patients with diabetes or with risk factors for diabetes glycemic monitoring should be carried out during the course of treatment with the medicine.

For women who received the medicine in the third trimester of pregnancy the newborn must be monitored and treated if necessary.

In children receiving drops - an annual medical examination should be carried out and the dosage should be adjusted regularly in accordance with the medical condition of the child.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine consult the doctor of pharmacist.

This medicine has been prescribed for the treatment of your ailment. In another patient it may cause harm. Do not give this medicine to your relatives, neighbors or acquaintances.

4. SIDE EFFECTS

As with any medicine, use of Neuleptil may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

A feeling of dizziness when suddenly changing from a lying/sitting position to standing, dryness of the mouth, difficulty passing urine, constipation and even intestinal obstruction, drowsiness (especially at the beginning of treatment), anxiety, mood changes, stiff or abnormal movements, loss of motility, cessation of menstrual periods, discharge of breast milk, breast tissue enlargement in men, impotence, frigidity, weight gain, hyperglycemia, diabetes, changes in sugar tolerance, QT interval prolongation, skin allergy, sensitivity to light, vision problems, jaundice, long lasting erection of the penis.

Respiratory system-related problems, effects related to the atropinic effect of the preparation and neurological problems were observed in newborns of women who took the preparation in the third trimester of pregnancy (see section 3. How Should You Use the Medicine? - Tests and follow-up).

Effects requiring special attention:

Dizziness, weakness, skin rash, changes in quality of vision, involuntary movements, fainting, shortness of breath or difficulty breathing - rare: refer to the doctor immediately.

Muscle rigidity or consciousness problems accompanied by unexplained fever - stop treatment and refer to the doctor immediately.

Fever, pallor or excessive sweating (with or without signs of inflammation such as sore throat and the like): refer to the doctor immediately.

Sore throat or throat inflammation or any other inflammation: refer to the doctor immediately.

Prolonged constipation or flatulence and severe abdominal pain: refer to the doctor immediately.

Disturbance in heart rate or changes in blood pressure: refer to the doctor immediately.

Formation of blood clots in the veins, especially of the legs (symptoms can include swelling, pain and redness of the legs). The blood clot can reach the lungs, which will cause chest pain and breathing difficulties - if you experience these symptoms refer to the doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult with the doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning!

This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you took an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

This medicine has been prescribed for the treatment of your ailment. In another patient it may cause harm. Do not give this medicine to your relatives, neighbors or acquaintances.

Store the medicine at a temperature below 25°C and protect from light.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Neuleptil Drops:

shelf life after opening: 6 months.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Neuleptil 10 mg Capsules

Calcium hydrogen phosphate dihydrate, Magnesium stearate, Titanium dioxide, Gelatin.

Neuleptil Drops

Sucrose (each drop contains 6.25 mg), Glycerol, Ethyl alcohol 96%, Tartaric acid, Ascorbic acid, Caramel (E150), Peppermint oil, Purified water.

What the medicine looks like and the contents of the package:

Neuleptil 10 mg Capsules - each package contains 50 white capsules.

Neuleptil Drops - each package contains a 30 ml bottle that contains a brown-yellowish liquid.

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

Manufacturer: Neuleptil 10 mg Capsules: Haupt Pharma Livron, France or Famar Health Care Services Madrid S.A.U., Spain.

Neuleptil Drops: A. Nattermann & Cie GmbH, Germany.

License holder: sanofi-aventis Israel ltd., Address: P.O. Box 8090, Netanya 4250499.

This leaflet was checked and approved by the Ministry of Health in March 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

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Neuleptil Drops: 062 81 22128 21