Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Willentine 250 mg

capsules

Active ingredient and its quantity
Each capsule contains:
trientine hydrochloride 250 mg

Inactive ingredients and allergens in the medicine - see section 6 **"Additional information".**

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

The medicine is intended for the treatment of Wilson's disease in adults, adolescents and children aged 5 years or older intolerant to D-Penicillamine therapy.

Therapeutic group: Various gastrointestinal and metabolic products.

Wilson's disease is an inherited disorder resulting from accumulation of copper in body tissues. Excessive copper accumulation may be caused by impairment of the liver mechanism of excreting free copper into the bile.
Liver cells called hepatocytes store excess copper, but when their capacity is exceeded, copper is released into the blood and accumulates in extrahepatic tissues. This disease is treated with a low copper diet and the use of copper chelating agents to facilitate its excretion from the body.
The active ingredient, trientine hydrochloride, is a chelating compound assisting in removal of excess copper from the body.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (trientine hydrochloride) or to any of the other ingredients in this medicine (see section 6 "Additional information").

Special warnings about using this medicine

- Regular medical supervision is required throughout the entire period of medicine administration. Iron deficiency anemia may occur, especially in women, pregnant women and children.
- Contact dermatitis may occur, therefore any area exposed to the capsule contents should be washed with water immediately.
- For the first month of treatment, you should measure your temperature nightly and report any symptom such as fever or rash to your doctor.
- Pay attention to signs of hypersensitivity and inform your attending doctor.

Children
There is no information about the safety and efficacy of using this medicine in children below the age of 5.

Tests and follow up
Prior to starting treatment and during the period of treatment with the medicine, your doctor will refer you to blood and urine tests.

Drug interactions:
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.
Avoid taking the medicine with mineral supplements since they may interfere with absorption of the medicine. Iron deficiency may develop, especially in children and pregnant or menstruating women, or as a result of the low copper diet recommended for Wilson's disease. If necessary, iron supplements may be given for short periods, but since iron and the active ingredient of this medicine may inhibit each other's absorption, you should wait at least two hours between administration of this medicine and the iron supplement.

Pregnancy and breastfeeding:
Pregnancy
There is no sufficient information regarding use of the medicine in pregnant women. The medicine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Breastfeeding
It is not known whether this medicine is excreted in breast milk. Since many medicines are excreted in breast milk, caution should be exercised when the medicine is administered to a breastfeeding woman.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dose is usually:
500-750 mg/day for children and 750-1250 mg/day for adults given in divided doses; two, three or four times daily.
This may be increased to a maximal dose of 2000 mg/day for adults or 1500 mg/day for children aged 12 and under.

Do not exceed the recommended dose.

Mode of administration
- Take the medicine on an empty stomach, at least one hour before a meal or two hours after a meal and at least one hour apart from any other medicine, food, or milk. This will enable maximal absorption and reduce the likelihood of medicine inactivation by metal binding in the gastrointestinal tract.
- The capsules should be swallowed whole with water and should not be opened or chewed.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine.
Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Iron deficiency; Systemic lupus erythematosus; Muscle tone disorder (dystonia); Muscle spasm; Severe muscle weakness (myasthenia gravis); Heartburn; Epigastric pain and tenderness; Thickening, fissuring and peeling of the skin; Hypochromic microcytic anemia; Acute gastritis; Oral sores (aphthoid ulcers); Abdominal pain; Black stool (melena); Anorexia; Malaise; Cramps; Muscle pain; Weakness; Rhabdomyolysis

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
  Storage conditions: Store in a refrigerator (2°C-8°C). Close the bottle well.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
gelatin, water, stearic acid, titanium dioxide, FD&C Yellow 6, imprinting black ink (contains shellac, propylene glycol, black iron oxide, dehydrated alcohol, isopropyl alcohol, butyl alcohol, strong ammonia solution, and potassium hydroxide)

What the medicine looks like and contents of the pack:
Capsules with white opaque body imprinted with "101" and orange opaque cap imprinted with "NAV" in black ink.
The medicine is marketed in a plastic bottle containing 100 capsules. The bottle contains a dessicant.

Registration holder's name and address: TrustPharm Ltd., 50 Hakishon Street, Tel Aviv.

Manufacturer's name and address:
Apothecon Pharmaceuticals Pvt. Limited, Pin – 391440, District – Vadodara, State – Gujarat, India.

Revised in May 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
169-34-36612-99