

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

The medicine is dispensed with
a doctor's prescription only.

Pride 100 Pride 400

Film-Coated Tablets

The active ingredient and its quantity:
Pride 100: Each tablet contains
Amisulpride 100 mg
Pride 400: Each tablet contains
Amisulpride 400 mg
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 to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. Do not use in children and adolescents under 18 years of age.

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

1. WHAT IS THE MEDICINE INTENDED FOR?
The medicine is intended to treat schizophrenia.
Therapeutic group: **Pride** belongs to the substituted benzamides group of antipsychotics.

2. BEFORE USING THE MEDICINE

- ❗ Do not use the medicine if:**
- You are sensitive (allergic) to amisulpride or to any of the ingredients of the medicine (see section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
 - You are breastfeeding (see "Pregnancy and breastfeeding" section).
 - You are suffering from breast cancer or a prolactin-dependent tumor.
 - You are suffering from a tumor on the adrenal gland (called pheochromocytoma).
 - You are taking levodopa, a medicine for treatment of Parkinson's disease, and dopaminergic agonists such as bromocriptine, ropinirole (see section "Do not take **Pride** if you are taking the following medicines").
 - You are under 18 years of age.
 - You have been diagnosed with a tumor in the pituitary gland.

If any of the above applies to you (or in the case of doubt), consult with your doctor before taking **Pride**.

Special warnings regarding use of the medicine

- Before treatment with **Pride**, tell the doctor if:
- You suffer from impaired kidney function.
 - You suffer from Parkinson's disease.
 - You have ever had epileptic fits.
 - You have a disturbance/irregularity in your heart rate.
 - You suffer from a heart disease or there is a family history of heart problems.
 - You have risk factors for a stroke.
 - You, or someone in your family, have, or have had in the past, blood clots, since a correlation has been found between antipsychotic medicines and formation of blood clots.
 - You suffer from diabetes or risk factors for diabetes.
 - You suffer from a slow pulse (less than 55 beats per minute).
 - You have been told that your blood potassium levels are low.
 - You are elderly, as there is a greater chance of developing low blood pressure or impaired alertness in the elderly. In elderly people suffering from dementia and who are taking antipsychotics, a small increase in the number of deaths compared to those who were not taking antipsychotic medicines, has been reported.
 - You are suffering from a decrease in the number of white blood cells (agranulocytosis). This could cause you to get infections more easily than usual.
 - You, or someone in your family, has a history of breast cancer.
 - You have high levels of prolactin.
- If any of the above apply to you (or in case of doubt), consult with the doctor before taking **Pride**.
- ❗ If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**
- Do not take Pride if you are taking the following medicines:**
- Levodopa – to treat Parkinson's disease.
 - Medicines of the "dopaminergic agonist" group, such as ropinirole and bromocriptine.
- Consult the doctor if you are taking any of the following medicines:**
- Medicines to treat irregular heart rhythm, such as quinidine, disopyramide, amiodarone, sotalol.
 - Other antipsychotics that are used to treat mental disorders.
 - Medicines from the opiate group to treat severe pain, such as morphine or pethidine.
 - Medicines for high blood pressure and heart problems, such as diltiazem, verapamil, guanfacine and digitalis.
 - Clonidine used for treatment of migraines, flushing or high blood pressure.
 - Mefloquine for treatment of malaria.

- Sedatives and hypnotics, such as barbiturates and benzodiazepines.
- Analgesics such as tramadol and indomethacin.
- Anesthetics.
- Medicines from the antihistamine group such as promethazine, which may make you sleepy.

If any of the above apply to you (or in case of doubt), consult with the doctor before taking **Pride**.

❗ Use of the medicine and food and alcohol consumption
Swallow the medicine with water before a meal. Do not drink alcoholic beverages during the course of treatment with the medicine. This is because alcohol may impair the medicine's activity.

❗ Pregnancy and breastfeeding
Do not take the medicine if you are breastfeeding or are planning to breastfeed. Consult the doctor before taking the medicine if you are pregnant, might become pregnant or think you may be pregnant.
The following symptoms may occur in babies of mothers who took **Pride** in the last three months of their pregnancy: tremor, muscle stiffness and/or weakness, sleepiness, agitation, breathing and feeding problems. If you notice that your baby develops any of these symptoms, refer to the doctor.

❗ Driving and operating machinery
You may feel less alert, drowsy or sleepy and have blurred vision while taking the medicine. If this happens, do not drive or operate machinery.

❗ Important information about some of the ingredients of the medicine
This medicine contains lactose, a type of sugar (see section 6 - "Further information"). If you have been told by your doctor that you are sensitive to certain sugars, consult him before taking the medicine.

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.

- Taking the medicine**
- Take the medicine by mouth.
 - Swallow the medicine whole with water. If necessary, the tablet may be halved for immediate use. There is no information regarding crushing or chewing the tablet.
 - Take the medicine before a meal.
 - If you feel that the effect of the medicine is too weak or too strong, do not change the dose on your own, consult your doctor.

How much to take
The dose of **Pride** you need to take depends on your illness. Be sure to strictly follow the doctor's instructions.

Adults
In general, if the daily dose is up to 400 mg, take the medicine once a day. If the daily dose is greater than 400 mg, the daily dose should be divided into twice daily.

Elderly
Use with caution in the elderly, due to risk of decreased blood pressure and impaired alertness.

Patients with kidney problems
Your doctor may need to prescribe a lower dosage for you.

Children
Do not use this medicine in children and adolescents under 18 years of age.

Do not exceed the recommended dose.

Tests and follow-up
Taking **Pride** may alter the results of some blood tests; these include tests that measure the "prolactin" hormone and liver enzymes. If you are planning to undergo blood tests, it is important to tell the doctor you are taking **Pride**. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you, so that the doctor knows what you have taken. You may suffer from the following effects: feeling restless or shaky, muscle stiffness, reduced alertness or sleepiness, which could lead to loss of consciousness.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.
Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine. Keep taking **Pride** until the doctor instructs you to stop. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If you stop, your illness may return or get worse. Do not stop taking **Pride** suddenly, unless you received an explicit instruction from a doctor. Stopping treatment suddenly may cause withdrawal effects, such as: nausea or vomiting; sweating; difficulty falling asleep or feeling restless; muscle stiffness or involuntary body movements; recurrence of psychotic symptoms.

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 or pharmacist.

4. SIDE EFFECTS
As with any medicine, use of **Pride** 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.

Stop use and refer immediately to a doctor or hospital if:

- You suffer from a high fever, sweating, stiff muscles, fast heartbeat, fast breathing and a feeling of confusion, drowsiness or agitation. These could be the symptoms of a serious but rare side effect called "neuroleptic malignant syndrome".
- You have a different pulse than normal, a very fast pulse or chest pain, which can result in a heart attack or a life-threatening heart disorder.
- You have blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs and cause chest pain and breathing difficulties. If you notice these symptoms, seek medical help immediately.
- You have infections more frequently than usual. This could be because of a blood disorder called agranulocytosis, or a decrease in the number of white blood cells (neutropenia).

Uncommon (effects that occur in 1-10 users in 1,000)

- You are suffering from an allergic reaction. Symptoms may include: an itchy, lumpy rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You are having an epileptic fit.

Refer to your doctor as soon as possible if you suffer from any of the following side effects:

Very common side effects - effects that occur in more than one user in ten: Tremor, muscle stiffness or spasm, slow movement, secretion of more saliva than usual or feeling restless.

Common side effects - effects that occur in 1-10 users in 100: Involuntary movements, mainly of the arms and legs (these symptoms can be reduced if the doctor lowers the dose of **Pride** or prescribes additional medicines).

Uncommon side effects - effects that occur in 1-10 users in 1,000: Involuntary movements, mainly of the tongue or face.

Additional side effects:

Common side effects - effects that occur in 1-10 users in 100: Insomnia, anxiety, nervousness; feeling drowsy and sleepy; constipation, nausea, vomiting, dry mouth; weight gain; unusual production of breast milk in men and women, breast pain; menstrual period stops; breast enlargement in men; erectile or ejaculation disturbances; feeling dizzy (which can be due to low blood pressure).

Uncommon side effects - effects that occur in 1-10 users in 1,000: Excess blood sugar (hyperglycemia); slowing of the heartbeat.

Side effects of unknown frequency (effects whose frequency has not yet been determined): Feeling confused; increased levels of fat (triglycerides) or cholesterol in the blood; tiredness, weakness, confusion, muscle pain or dysfunction. This may be as a result of low blood sodium levels; malaise, confusion or weakness, nausea, loss of appetite, nervousness. This may be as a result of a condition called Syndrome of inappropriate antidiuretic

hormone secretion (SIADH); benign tumor (such as prolactinoma); blurred vision; a condition called "osteoporosis", when your bones are more fragile; nasal congestion.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "[Reporting Side Effects of Drug Treatment](#)" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects. Alternatively, a report can be made to "[Unipharm Ltd.](#)".

5. HOW SHOULD THE MEDICINE BE STORED? Avoid poisoning! This medicine and any other medicine should be stored in a safe place out of the reach of children and/or infants in order to avoid poisoning. **Do not induce vomiting** without explicit instruction from the doctor!

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

Store at a temperature below 25°C and in a place protected from light.

6. FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains the following ingredients: Microcrystalline cellulose, Lactose monohydrate, Sodium starch glycolate, Hydroxypropyl methylcellulose, Magnesium stearate, Coating blend (white).
Each **Pride 100** tablet contains 22.7 mg lactose monohydrate.
Each **Pride 400** tablet contains 90.8 mg lactose monohydrate.

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

Pride 100 are round, biconvex, white, film-coated tablets, with a score line on one side.

Pride 400 are oval, biconvex, white, film-coated tablets, with a score line on one side.

Pride is packed in trays (blisters), inserted into a carton box.

Pride is available in packs of 5, 7, 10, 14, 15, 20 and 30 tablets.

Not all package sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

This leaflet was checked and approved by the Ministry of Health in February 2016 and was updated in accordance with the Ministry of Health guidelines in July 2018.

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

Pride 100: 155 40 34398 01
Pride 400: 155 41 34416 01