

**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 film-coated tablet contains

Amisulpride 100 mg

**Pride 400:** each film-coated tablet contains

Amisulpride 400 mg

**Inactive and allergenic ingredients in the preparation** – see section 6 “Further information”. See also in section 2 under “Important information about some of the ingredients of the medicine”.

**Read the 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.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat schizophrenia.

**Therapeutic group:** **Pride** belongs to the substituted benzamide group of antipsychotics.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6 “Further information”). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You have breast cancer or a prolactin-dependent tumor.
- You have 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 2 under “Drug interactions”).
- You have been diagnosed with a tumor in the pituitary gland.
- The patient is under 18 years of age.

Do not take the medicine if any of the above conditions apply to you. If you are not sure, consult with your doctor or pharmacist before taking **Pride**.

### Special warnings regarding use of the medicine

#### Before treatment with **Pride**, tell the doctor if:

- You have kidney problems.
- You have Parkinson's disease.
- You have ever had seizures (epileptic fits).
- You have an irregular heart rate.
- You have heart disease or you have a family history of heart problems.

- Your doctor has told you that you might have had a stroke.
- You or someone else in your family has a history of blood clots, since a correlation has been found between medicines such as **Pride** and formation of blood clots.
- You are diabetic or have been told you have an increased risk of having diabetes.
- You have a slow heartbeat (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 feeling sleepy in the elderly. A small increase in the number of cases of death of elderly people with dementia has been reported for patients taking antipsychotics, compared to those not taking antipsychotics.
- You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual.

- You frequently have infections which manifest themselves as a fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leukopenia – a reduced number of white blood cells.
- You or someone else in your family has a history of breast cancer.
- You have high levels of prolactin.

Severe liver problems have been reported with **Pride**. Refer to your doctor immediately if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pain or you notice yellow discoloration of the eyes or skin.

If you are not sure if any of the conditions above apply to you, consult with your doctor or pharmacist before taking **Pride**.

### Children and adolescents

The medicine is not intended for children and adolescents under the age of 18, as the efficacy and safety of use of the preparation at these ages have not been proven.

### Tests and follow-up

Taking **Pride** may affect the results of some blood tests; these include tests to measure the hormone called prolactin and liver tests. If you are about to undergo blood tests, it is important to tell your doctor that you are taking **Pride**.

### Drug interactions

**If you are taking, have recently taken, or you may take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** This is because **Pride** can affect the way some other medicines work. Likewise, some medicines can affect the way **Pride** works.

**In particular, do not take **Pride** and tell the doctor if you are taking any of the following medicines:**

- Levodopa – a medicine 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 used to control your heart rate, such as quinidine, disopyramide, amiodarone and sotalol.
- Clozapine, used to treat schizophrenia.
- Additional antipsychotic medicines used to treat mental problems.
- Medicines to treat severe pain called opiates, such as morphine or pethidine.
- Medicines to treat hypertension and heart problems, such as diltiazem, verapamil, guanfacine and digitalis.

- Clonidine, used to treat migraines, hot flushes or high blood pressure.
- Mefloquine to treat malaria.
- Medicines which help you sleep, such as barbiturates and benzodiazepines.
- Pain-killers, such as tramadol and indomethacin.
- Anesthetics.
- Antihistamines such as promethazine, which may cause sleepiness.

If you are not sure if any of the conditions above apply to you, consult with your doctor or pharmacist before taking **Pride**.

### Use of the medicine and food

Swallow the medicine with plenty of water before a meal.

### Use of the medicine and alcohol consumption

Do not drink alcohol during the course of treatment with the medicine. This is because alcohol may harm the way the medicine works.

### Pregnancy, breast-feeding and fertility

Consult the doctor before taking the medicine if you are pregnant or breast-feeding, think you are pregnant or are planning to become pregnant.

#### Pregnancy

**Pride** tablets are not recommended during pregnancy and in women of child-bearing age not using proper contraception. If you use **Pride** tablets during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, uncontrollable trembling of the body, sleepiness, breathing problems, or difficulty in feeding. Consult with your doctor if your baby develops any of these symptoms.

#### Breast-feeding

You should not breast-feed during treatment with **Pride** tablets. Talk to your doctor about the best way to feed your baby if you are taking **Pride** tablets.

### 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 use any tools or machines.

### 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 have an intolerance to certain sugars, consult with him before taking the medicine.

**Pride** contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, it is essentially “sodium-free”.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor’s instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

### The recommended dosage

The dose of **Pride** that you take will depend on your illness. Be sure to follow the doctor’s instructions exactly.

#### 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

Your doctor will need to monitor your condition carefully as you are at greater risk for low blood pressure or sleepiness due to taking this medicine.

### People with kidney problems

The doctor may need to prescribe you a lower dosage.

### Children and adolescents

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

### Do not exceed the recommended dose.

#### Taking the medicine

- Take the medicine by mouth.
- Swallow the medicine with water. If needed, the tablet can 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 yourself; consult the doctor.

#### If you accidentally took a higher dosage

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 package of the medicine with you, so that the doctor knows what you have taken. The following effects may occur: feeling restless or shaky, rigid muscles, feeling drowsy or sleepy, which could lead to a loss of consciousness.

#### If you forgot to take the medicine

If you forgot to take a dose of the medicine, take it as soon as you remember. However, if it is almost time for your next dose, skip the forgotten dose. Do not take a double dose to make up for the forgotten dose. Adhere to the treatment regimen as recommended by the doctor.

#### If you stop taking the medicine

Keep taking **Pride** until the doctor tells 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 your doctor. Suddenly stopping use may cause withdrawal effects, such as:

- Nausea or vomiting.
- Sweating.
- Sleeping difficulties or feeling restless.
- Muscle stiffness or unusual body movements.
- Symptoms of your illness may return.

**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:** Uncommon side effects (effects that may affect up to 1 in 100 users):

- You have an allergic reaction. The signs may include: an itchy, lumpy rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You experienced a seizure (epileptic fit).

- You get infections more frequently than usual. This can happen because of a blood disorder called agranulocytosis or a decrease in the number of white blood cells (leukopenia or neutropenia).

Rare side effects (effects that may affect up to 1 in 1,000 users):

- You are suffering from a high temperature, sweating, stiff muscles, rapid heartbeat, rapid 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 very rapid or unusual heart rate or chest pain, which could result in a heart attack or 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 any of these symptoms, seek medical help immediately. **Refer to the doctor as soon as possible if you suffer from any of the following effects:**

*Very common side effects (may affect more than 1 in 10 users):*

- Tremor, muscle stiffness or spasm, slow movement, secretion of more saliva than usual or feeling restless.

*Common side effects (may affect up to 1 in 10 users):*

- Involuntary movements, mainly of the arms and legs (these symptoms can be reduced if the doctor reduces the dose of **Pride** or prescribes additional medicine for you).

*Uncommon side effects (may affect up to 1 in 100 users):*

- Involuntary movements, mainly of the tongue or face.

#### Additional side effects include:

- Common side effects (may affect up to 1 in 10 users):
- Sleeping difficulties (insomnia), or anxiety or nervousness.
  - Feeling drowsy or sleepy.
  - Constipation, nausea or vomiting, dry mouth.
  - Weight gain.
  - Unusual production of breast milk in men and women, breast pain.
  - Menstrual period stops.
  - Breast enlargement in men.
  - Difficulty in getting or maintaining an erection, or in ejaculating.
  - Feeling dizzy (can be due to low blood pressure).
  - Blurred vision.

Uncommon side effects (may affect up to 1 in 100 users):

- Slowing of the heart rate.
- High blood sugar (hyperglycemia).
- Feeling confused.
- Nasal congestion.
- A condition called “osteoporosis” when your bones are more fragile.
- High levels of fats (triglycerides) or cholesterol in the blood.
- Accidental inhalation of food with risk of pneumonia (lung infection).

Increase in blood pressure.

- Difficulty urinating.
- Liver tissue damage.

Rare side effects (may affect up to 1 in 1,000 users):

- Benign tumor (such as prolactinoma).

- Malaise, confusion or weakness, nausea, loss of appetite, feeling nervous. This may be as a result of a disease called syndrome of inappropriate antidiuretic hormone secretion (SIADH).

- Tiredness, weakness, confusion, achiness of muscles that are not in motion or dysfunctional. This may be due to low sodium levels in your blood.
- Side effects of unknown frequency (effects whose frequency has not been determined):
- Restless legs syndrome (uncomfortable feeling in legs temporarily relieved by movement and whose symptoms worsen at the end of the day).
  - Increased sensitivity of your skin to sun and ultraviolet light.
  - Falls due to reduced balance, which can lead to fractures.

**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.**

### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to “Unipharm Ltd.”.

### 5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!

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.

**Storage conditions:** 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** is packaged in trays (blisters), inserted into a carton box.

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

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

The package contains 5, 7, 10, 14, 15, 20 or 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.

Revised in July 2022 according to MOH guidelines.

Registration number 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