

**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:

Each **Pride 100** film-coated tablet contains: Amisulpride 100 mg

Each **Pride 400** film-coated tablet contains: Amisulpride 400 mg

For a list of the inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine.

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 (Amisulpride) 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 are pregnant or might become pregnant (see in section 2 "Pregnancy, breastfeeding and fertility").
- You have breast cancer or a prolactin-dependent tumor.
- You have a tumor in the adrenal gland (called pheochromocytoma).
- You are taking medicines that might change the heart rhythm, such as medicines used to control your heartbeat (see in section 2 "Drug interactions").
- You are taking levodopa, a medicine for treatment of Parkinson's disease (see in section 2 "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 applies to you. If you are uncertain, consult 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 a slow heart rate (under 55 beats per minute).
- The potassium levels in your blood are low.
- 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 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 are diabetic or have been told you have an increased risk of developing diabetes.
- You are elderly, as the elderly have a greater chance of developing low blood pressure or to feel sleepy.
- You are elderly and have dementia.
- You or someone else in your family has a history of breast cancer.
- You have high levels of prolactin, a hormone that is produced in the pituitary gland.

Severe liver problems have been reported when taking **Pride**. **Refer to your doctor immediately** if you experience fatigue, loss of appetite, nausea, vomiting, abdominal pains or you notice yellowing of the eyes or the skin.

During treatment, if you develop muscle stiffness or muscle loss associated with muscle pain (rhabdomyolysis), fast breathing, sweating, impaired consciousness (drowsiness/sleepiness) and unexplained fever – **stop the treatment immediately and consult a doctor urgently** as these symptoms are signs of a rare syndrome called neuroleptic malignant syndrome which can have a fatal outcome (see section 4 "Side effects").

If you are not sure if any of the above conditions applies to you, consult 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 certain blood tests, including tests that measure the hormone called prolactin and liver tests. If you are due to undergo blood tests, it is important to tell your doctor that you are taking **Pride**. If you have additional questions regarding use of this medicine, ask your doctor or pharmacist.

Drug interactions

If you are taking, or have recently taken, 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:

- Medicines used to control your heartbeat, such as quinidine, disopyramide, procainamide, amiodarone and sotalol.
- Bepiridil, used to treat heart diseases.
- Cisapride, used to treat heartburn.
- Thioridazine or sultopride, used to treat mental illnesses.
- Methadone, used to treat pain and opiate addiction.
- Antibiotics such as erythromycin (given by injection) or sparfloxacin.
- Vincamine (given by injection), used to treat brain circulation problems.
- Halofantrine, used to treat malaria.
- Pentamidine, used to treat pneumonia.
- Levodopa, used to treat Parkinson's disease.
- Clozapine, used to treat schizophrenia.

Tell the doctor if you are taking the following medicines:

- Medicines for depression or to calm emotional and mental illnesses, such as pimozone, haloperidol, imipramine and lithium.
- Medicines to treat hypertension and migraines, such as clonidine, diltiazem, verapamil, guanfacine or digitalis.
- Medicines which may lower potassium levels. This includes diuretics, such as bendroflumethiazide or hydrochlorothiazide, some laxatives, glucocorticosteroids (used to treat severe asthma and other inflammatory problems), tetracosactides and amphotericin (used to treat fungal infections).
- Medicines to treat severe pain, called opiates, such as morphine and pethidine.
- Pain-killers such as tramadol and indomethacin.
- Medicines to help you sleep, such as barbiturates and benzodiazepines.
- Anesthetics.
- Antihistamines such as promethazine, which make you sleepy.

If you are not sure if any of the above conditions applies to you, consult 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 impair the medicine's activity.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult the doctor before taking the medicine.

Pregnancy

Pride tablets are not recommended during pregnancy and in women of child-bearing age not using appropriate contraception. If you are taking **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 feeding. Consult with your doctor if your baby develops any of these symptoms.

Breastfeeding

Do not breastfeed during treatment with **Pride** tablets. If you are taking **Pride** tablets, talk to your doctor about the best way to feed your baby.

Driving and using machinery 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). If you have been told by your doctor that you have an intolerance to certain sugars, consult with him before taking the medicine (see section 6 “Further information”).

This medicine contains sodium. **Pride** contains less than 1 mmol sodium (23 mg) per tablet, i.e., it is considered “sodium-free” (see section 6 “Further information”).

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 dosage of **Pride** that you should take depends on your illness. Be sure to follow the doctor’s instructions exactly.

Adults

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

Elderly

Your doctor will need to monitor your condition carefully as you are at a higher risk for low blood pressure or sleepiness following 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 the age of 18.

Do not exceed the recommended dosage.

Method of administration

- Take the medicine by mouth (orally).
- 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 dosage 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. The following effects may occur: feeling restless or shaky, rigid muscles, a drowsy or sleepy feeling, 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 the next dose, skip the forgotten dose. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Continue 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 the doctor has explicitly instructed you to do so. Sudden discontinuation of 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 using Pride and refer immediately to a doctor or hospital if:

- You have a high fever, sweating, muscles stiffness, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be the symptoms of a serious but rare side effect called neuroleptic malignant syndrome, which is a potentially fatal complication.
- You have an abnormal, very fast heart rate or chest pain, which could result in a heart attack or life-threatening heart disorder.
- You have pain or swelling in the legs, chest pains or difficulty breathing. These could be symptoms of a blood clot.

Uncommon side effects - effects that may affect up to 1 in 100 users:

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

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

- You get more infections than usual. This can happen because of a blood disorder called agranulocytosis, or a decrease in the number of white blood cells (neutropenia).
- You have frequent infections, such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leukopenia.

Refer to a doctor as soon as possible if you have any of the following side effects:

Very common side effects - may affect more than 1 in 10 users:

- Trembling, muscle stiffness or spasm, slowed movements, more saliva secretion 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 lowers the dosage of **Pride** or prescribes for you an additional medicine).

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), feeling anxious or agitated.
- 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 reaching or maintaining an erection, or in ejaculating.
- Feeling dizzy (which can be due to low blood pressure).

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

- Slowing of the heart rate.
- High blood sugar (hyperglycemia).
- Increase in blood pressure.
- Difficulty in passing urine.
- Feeling confused.
- Nasal congestion.
- Liver problems.
- Osteopenia (low bone mineral density).
- Osteoporosis, when your bones tend to be more brittle.
- You develop a lung inflammation after inhaling food, liquid, saliva or nasal secretions (aspiration pneumonia).
- Blood disorders such as hypertriglyceridemia (high levels of triglycerides in your blood) and hypercholesterolemia (high levels of cholesterol in your blood).

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

- Urticaria (hives).
- Swelling beneath the skin (angioedema).
- Hyponatremia (low sodium levels in your blood).

- Feeling unwell, confused or weak, nausea, loss of appetite, feeling irritable. This could be due to an illness called syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Benign pituitary tumor (such as prolactinoma).

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Restless legs syndrome (uncomfortable feeling in the legs temporarily relieved by movement and whose symptoms get worse at the end of the day).
- Liver tissue damage.
- Increased sensitivity of the skin to sun and ultraviolet light.
- Falls due to reduced balance, which sometimes causes fractures.
- Rhabdomyolysis (muscle breakdown associated with muscle pain).
- High levels of creatine phosphokinase (blood test indicating muscle damage).

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) 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 below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

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.

Each package contains 5, 7, 10, 14, 15, 20 or 30 tablets.

Not all package sizes may be marketed.

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.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

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

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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



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