

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Prazine

25 mg, 100 mg, Coated tablets

PROMAZINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What Prazine is and what it is used for
2. Before you take Prazine
3. How to take Prazine
4. Possible side effects
5. How to store Prazine
6. Further information

#### *1. WHAT PRAZINE IS AND WHAT IT IS USED FOR*

Prazine-coated tablets contain the active substance Promazine, which belongs to the group of medicines called antipsychotics which act on the central nervous system.

Prazine-coated tablets are used in the treatment of acute psychomotor excitation, schizophrenia, delirium tremens, acute alcohol hallucinosis and abstinence syndrome.

Prazine-coated tablets are also used for the treatment of irritability, tension, anxiety and pain in patients with chronic diseases and in patients without the findings of organic disorders, nausea, vomiting and hiccups caused by uremia, with other antineoplastic and radiation therapy.

Prazine-coated tablets are used in preoperative preparation of patients and premedication for General and local anesthesia (it increases the effect of anesthesia and relieves the postoperative hiccups, nausea and vomiting).

## 2. BEFORE YOU TAKE PRAZINE

### **Do not take Prazine-coated tablets:**

- If you are hypersensitive to Promazine, any ingredient of the medicine, or fenotiazine, you are suffering from tumors of the adrenal glands (pheochromocytoma)
- If you have a depression of the central nervous system
- If you have severe liver disease
- If you have bone marrow suppression
- If you previously had a severe reaction to the antipsychotic (Neuroleptic Malignant Syndrome)
- If you have glaucoma
- in children under 12 years
- If you are breast-feeding
- If you are pregnant, especially in the first quarter of pregnancy

Prazine-coated tablets should not be administered to people without consciousness (coma).

Be careful and consult a doctor before initiating treatment with Prazine coated tablets:

- If you are older than 65 years old
- If you are suffering from any kind of cardiovascular disease
- If your doctor said that with you there is the risk of experiencing a stroke
- If you have Parkinson's disease
- If you have had or have problems with your liver (jaundice)
- If you have a serious illness of the respiratory system
- If you have impaired kidney function
- If you have epilepsy
- If you (or someone in your family) have elevated pressure (glaucoma)
- If you have a thyroid hormone deficiency (hypothyroidism)
- If you have a disease of the muscles – myasthenia gravis
- If you have a tumor in the medulla of the adrenal glands-pheochromocytoma
- If you have an enlarged prostate gland
- in children there is a tendency of emergence of neuromuscular and motor response
- If you have a lack of potassium or magnesium in the blood
- If you are taking other medicines for the treatment of psychiatric diseases
- If you have diabetes

In elderly patients suffering from dementia and who are treated with certain antipsychotics, there is a risk of the occurrence of stroke. Therefore, caution should be exercised when applying Prazine-coated tablets in such patients.

### **Taking other medicines with Prazine coated tablets**

Tell your doctor if you are taking or have recently taken any other medicines. Prazine-coated tablets can interact with the following medicines:

- alcohol
- Barbiturates – medicines used in the treatment of disorders of the nervous system
- Opioid analgesics – medicines used in the treatment of pain
- medicines used in the treatment of Parkinson's disease and motor disturbances (amantadine, trihexyphenidyl)
- Antihistamines – medicines used in the treatment of allergies and allergic reactions
- Antacids – medicines that neutralize stomach acid
- Cimetidine – a medicine that prevents the formation of gastric acid
- Lithium – a medicine used to treat some psychiatric illnesses
- Anticonvulsant-medicines used in the treatment of epilepsy
- Tricyclic antidepressants – medicines used in the treatment of depression
- medicines that inhibit the creation and release of thyroid hormones

- antihypertensive agents — medicines used in the treatment of high pressure
- Anti-arrhythmic agents – medicines used in the treatment of cardiac conduction
- Diuretics-medicines used to water tablets,
- medicines that reduce the production of red blood cells-carbamazepine, cotrimoxazol, chloramphenicol, sulphonamides-pirarizon, sertindol, haloperidol, lithium, reboxetin MAOIS (monoamine oxidase inhibitors)
- Medicines used in the treatment of Parkinson's disease – levodopa
- Medicines that Act toxically on the ear – some medicines used to treat bacterial diseases (antibacterial medicines)
- Medicines that can provoke hypersensitivity to light – the tetracyclines, methoxalen
- Antipsychotics – medicines used in the treatment of some psychiatric illness (psychosis)

### ***Taking food and drinks with Prazine***

You must not consume alcohol while taking Prazine pills. Medicine can cause sleepiness, and alcohol can even reinforce that feeling. Alcohol consumption also can affect the disease from which you are suffering.

### ***Pregnancy and breastfeeding***

We do not recommend taking Prazine-coated tablets in pregnancy, especially in the first trimester, unless your doctor decides that this is necessary. There is not enough data about the safety of the application of Promazine during pregnancy.

Breast feeding

Promazine (active substance of Prazine tablets) is excreted into breast milk. Promazine should not be used during breastfeeding.

### ***Driving and using machines***

▲ Trigon- The medicine with a strong influence on the psychophysical abilities (Ban on driving motor vehicles and machinery)

Prazine-coated tablets can (especially at the beginning of the treatment and after the administration of a large dose) affect the psycho-physical abilities, and while taking Prazine-coated tablets you may not operate a motor vehicle and work on the machines.

### ***Other warnings***

Acute withdrawal symptoms, including nausea, vomiting, sweating and insomnia are described after the abrupt cessation of treatment with antipsychotic medicines. Reappearance of psychotic symptoms, as well as involuntary movement disorders (ataxia, dystonia and dyskinesia) are possible.

### ***In case of worsening of blood counts, treatment should be discontinued.***

If you continuously get Prazina coated tablets, you should be regularly inspected, attention should be paid to potential changes to the eye (corneal opacity and lenses and purple pigmentation of the skin, cornea, conjunctiva and retina), the effects on the blood, liver failure, cardiac disorders implementation, especially when co-administered with other medicines that have potential impact on the system.

If you are taking Prazine-coated pills in high doses (relative or absolute), you can notice some motor effects (involuntary movements, balance disorder, muscle jerking), which can be severe in children.

Prazine coated tablets can disrupt regulation of body temperature. Therefore, caution should be exercised in hot weather.

Prazine coated tablets can increase the secretion of prolactin (a hormone secreted by the pituitary gland and stimulates the appearance of milk).

### ***Important information about some of the ingredients of Prazine***

Prazine 25 mg coated tablets contain lactose while Prazine 25 mg coated tablets and Prazine 100 mg coated tablets contain sucrose.

If your doctor told you that you have intolerance to some sugars, before you start taking this medicine, you should consult your doctor.

### 3. HOW TO TAKE PRAZINE

Always use this medicine exactly as described in this leaflet or as prescribed by doctor or pharmacist. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine dose of Prazine-coated tablet and duration of treatment. Follow the instructions and take this medicine exactly as you are said.

In order to achieve a better effect, the treatment of psychotic patients usually begins with intramuscular injections, especially in the control of psychomotor excitation (stress) in the case of hospital patients.

In continued treatment and in mild cases, 10 to 200 mg of promazine is administered orally every 4 to 6 hours. The dose should be gradually adjusted as needed and according to how the patient tolerated the treatment.

Chronic patients, patients who have undergone radiation therapy and all outpatients are given 10 to 100 mg, three to four times a day.

Dosage in elderly patients - Elderly patients are recommended half the usual adult dose.

Patients with stroke symptoms of organic origin and acute states of confusion must first be given a third to half of the usual dose for adults, and then the dose increases, preferably at intervals of seven to ten days, but possibly at intervals of less than two to three days.

Children over 12 years of age are given 1.5 to 6 mg/kg body weight per day, divided into three to four individual doses.

After reaching the clinical improvements you should try to stop your treatment, but it should not be done abruptly.

#### ***If you take more Prazine-coated tablets than you should***

If by mistake you take too high a dose of Prazine-coated tablets, tell your doctor.

#### ***If you forget to take Prazine-coated tablets***

Do not take a double dose to make up for a forgotten dose!

If you forget to take Prazine tablets, take them as soon as possible and then continue to use it according to your usual schedule.

#### ***If you stop taking Prazine***

Take medicine until your doctor tells you otherwise. A doctor will help you to decrease your dose gradually. If you suddenly stop taking Prazine tablets, symptoms may occur again, and you can develop symptoms such as:

- nausea, sweating, insomnia,
- uncontrolled movements.

If you have any further questions on the use of Prazine tablets, ask your doctor, or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects although not everybody gets them.

Promazine belongs to the group of phenothiazine, and reported side effects are associated with that group of medicines.

In patients taking promazine, there have been the following side effects of varying difficulty.

Very common side effects were observed, with more than 1 in 10 patients

Drowsiness, sedation, anticholinergic effects such as dry mouth, nose clogging, decreased urination, wide pupil, then lowered blood pressure, rapid heartbeat, constipation, an urge to urinate or urine retention in the event

of increases in the prostate, blurred vision; postponement of the fuzzy material in the eye (the cornea, lens and retina), movement disorders or symptoms of Parkinson's.

**Uncommon side effects**, were observed in 1 to 10 in 1000 patients

Difficulty urinating; increased skin sensitivity to the Sun, the skin rash-associated with contact dermatitis, with other allergic reactions or with jaundice

**Rare side effects**, were observed in 1 to 10 in 10000 patients

A reduction in the number of blood cells-can appear in the first three months of treatment, and the recovery is activated by one to two weeks after the end of treatment; after recovery it can reappear in the sequel treatment.

Sexual dysfunction

Jaundice-can occur after two weeks of severe itching, you can progress to chronic active hepatitis. In such cases, it may prove necessary to discontinue treatment. Liver function tests may be abnormal and no obvious signs of jaundice.

Neuroleptic Malignant Syndrome (NMS)-can occur at any time during the treatment of a group of medicines for disorders of the nervous system (Neuroleptics), and includes a number of symptoms, such as disorders of the consciousness, the stiffness of muscles, tremors, uncontrollable movements, rapid heartbeat, elevated body temperature, large fluctuations in blood pressure, sweating, excessive secretion of mucus, redness of the face, increased the number of white blood cells, dehydration, electrolyte disorders.

**Other side effects:** a long and painful erection, disorders of pigmentation of the skin.

Some people may be sensitive and on a low dose of the medicine, and paradox effects may appear: agitation, anxiety or insomnia, and other less severe side effects. Elderly people are especially sensitive to the effects of Promazine, especially on the sedative effects, effects on reducing blood pressure and the effects on the temperature regulation. These effects may be associated with dose.

Withdrawal symptoms have been reported, including nausea, vomiting, sweating, insomnia of psychotic symptoms and involuntary movement disorders.

Phenothiazines can cause changes in EKG and cardiac arrest and sudden unexplained death.

The incidence of the following side effects is not known, or the frequency cannot be determined on the basis of the available data.

In the case of the following side effects treatment should immediately stop.

- The lack of or deficiency of blood cells (neutrophils), decreased number of white blood cells (leukocytes).
- Extra pyramidal Symptoms (a group of symptoms such as tremors, slow walk, the tiny steps, reduced mimics, epileptic seizures, confusion)
- Neuroleptic Malignant Syndrome (a group of symptoms such as an elevated body temperature, changes in consciousness, the stiffness of the muscles, disorders of the autonomic nervous system)

**Other side effects**

- Darkening of the cornea and lens of the eye.
- Disorders of heart rhythm, the ECG changes (there have been cases of sudden death).
- Decreased blood pressure, cases of blockage of the veins (venous thromboembolism), including cases of blockage of the veins in the lungs (pulmonary embolism) and cases of blockage of leg vein (deep vein thrombosis).
- Jaundice
- Allergic reaction on the skin, rash, hypersensitivity to light (photosensitivity reaction), contact dermatitis.
- Symptoms of withdrawal with newborns
- Symptoms such as dry mouth, constipation, abnormal urination and blurred vision.

- Lowered blood pressure and body temperature regulation disorders are dose-dependent side effects of the medicinal product, and can cause severe lows of body temperature or the temperature increases in the elderly.

### **Reporting of suspected side effects**

In case of any side effects following administration of the medicinal product, it is necessary to inform your doctor or pharmacist. This implies all possible unwanted reactions, which are not listed in this leaflet, as well as those that are.

## **5. HOW TO STORE PRAZINE**

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Keep at temperature up to 25 ° C, protected from moisture.

The shelf life of the medicine is 36 months.

Prazine-coated tablets should not be used after the expiry date stated on the carton.

## **6. FURTHER INFORMATION**

### **What Prazine-coated tablets contain?**

Prazine-coated tablets 25 mg

One coated tablet contains 25 mg of Promazine chloride.

Auxiliary substances:

Core: lactose monohydrate; sucrose; povidone K25; Silicon, silica colloidal anhydrous; TALC; corn starch; magnesium stearate.

Coating: cellulose acetate phthalate; diethyl phthalate

Sugar-coating: sucrose; TALC; titanium dioxide; povidone K25; MACROGOL 6000; iron oxide, yellow.

### **PRAZINE-coated tablets 100 mg**

One coated tablet contains 100 mg of Promazine chloride.

Core: sucrose; povidone K25; Silicon, silica colloidal anhydrous; TALC; corn starch; magnesium stearate.

Coating: cellulose acetate phthalate, diethyl phthalate.

Sugar-coating: sucrose; TALC; povidone K25; MACROGOL 6000; iron oxide red.

### **How Prazine-coated tablets look like and contents of the Pack?**

Prazine-coated tablets 25 mg coated tablets are yellow, smooth and flat surfaced.

Prazine-coated tablets 100 mg are red to reddish-brown-coated tablets, smooth and flat surfaced.

50 tablets (5 PVC/PVDC//Al blister with 10 coated tablets).

### **Regime of dispensing**

The medicine is issued on doctor's prescription

### **Manufacturer**

PLIVA Hrvatska d.o.o.

Prilaz baruna Filipovića 25

10 000 Zagreb, Croatia

### **Manufacturer of the medicinal product**

PLIVA Hrvatska d.o.o.

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10 000 Zagreb, Croatia