

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Δ MODITEN

1 mg coated tablets  
2.5 mg coated tablets  
5 mg coated tablets

### FLUPHENAZINE

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

#### 1. WHAT MODITEN IS AND WHAT IT IS USED FOR

Moditen belongs to a group of antipsychotic medicines (called Neuroleptics). These medications act on neural pathways and specific areas of the brain and help correct some chemical imbalances in the brain that cause the symptoms of your illness.

Moditen is intended for the treatment of mental disorders that are characterized by hearing, seeing and feeling of non-existent things, wrong thinking, unusual skepticism and lack of contact with the environment.

It is also intended for the treatment of mania and control of hyperactivity, agitation, aggression and other behavioral disorders as well as and disease states that are characterized by increased emotional tension, fear, irritability and anxiety.

#### 2. BEFORE YOU TAKE MODITEN

Inform the doctor if you are taking other medicines, have a chronic disease, a metabolic disorder, hypersensitive to some of the medicines or have had an allergic reaction to some of them.

***You should not take Moditen:***

- If you are hypersensitive to fluphenazine or to any other ingredients of Moditen,
- If you have an obvious or suspected subcortical brain damage,
- If you have severe disorders of consciousness,
- Narrowing of cerebral vessels,
- Tumor near the kidneys (called pheochromocytoma)
- Serious problems with your liver, heart or kidneys.

Also you should not take Moditen in cases of acute poisoning with central nervous system depressants (alcohol, antidepressants, Neuroleptics, tranquilizers, anxiolytics, hypnotics and narcotics).

***Be careful with Moditen***

Before taking Moditen, tell your doctor if you have cardiovascular disease (especially if you have an irregular heart rhythm — the arrhythmia), kidney or liver disease, pulmonary disease, epilepsy, a disease of the thyroid gland (hyperthyroidism), breast tumor (or if you've ever had it), Parkinson's disease, a blood disease, narrow angle glaucoma (increased blood pressure), Myasthenia Gravis, prostate problems, and if you are exposed to high temperatures or organophosphoric insecticides.

Tell the doctor if anyone in your family has or had difficulties because of an irregular heart rhythm (arrhythmia).

Also tell your doctor if you or someone in your family has a history of blood clots, as well as medications similar to those that are connected with the growing of the blood clots.

If you are elderly and weakened, a doctor will prescribe the lowest effective dose.

Whereas, with the fluphenazine, as with all fenotiazine, you can develop inflammation of the lungs, tell your doctor if you had breathing difficulties during taking Moditen.

If you are about to have a surgery, tell the doctor that you are taking Moditen because the medicine enhances the action of general anesthetics and an inhibitor of neuromuscular transmission.

Since during the treatment you may experience blood disorders (decreased number of white and / or red blood cells), the doctor will also ask for a blood test.

If during treatment with Moditen you experience involuntary movements of tongue, face, lips, torso and limbs (they could be signs of a rare condition called tardive dyskinesia), stop taking the medicine immediately and contact your doctor.

Avoid taking other medicines from the group of antipsychotics at the same time.

Like other medicines, antipsychotic fluphenazine is associated with Neuroleptic malignant syndrome. It's a rare response hypersensitivity reactions characterized by fever, muscle stiffness, inability or difficulty in movement, low blood pressure, rigor and coma. Fever is often an early sign of this syndrome. If you develop any of the above symptoms while you are taking medication, stop taking Moditen and contact your doctor or go to the nearest hospital.

If during the treatment you are taking antiparkinsonic, and abruptly stop taking Moditen, you need to continue taking the antiparkinsonic for a few more days.

Moditen is not effective in the treatment of disorders of the behaviour of mentally challenged persons.

### ***Taking other medicines with Moditen***

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that are purchased without a prescription.

You should not take Moditen if you are being treated with medicines that are known to affect heart rhythm, or medications that cause electrolyte disturbances (e.g., water tablets).

Simultaneous use of Moditen and other medicines can change the action of these medicines, and some medicines can change the action of Moditen. Medicines for the treatment of heart disease (anti-arrhythmic agents, and beta blockers), medicines for the treatment of allergic diseases (antihistamines), other antidepressants, antipsychotics, sleeping pills (hypnotics), sedatives, narcotics, birth control, and other medicines that contain the following active substances: Carbamazepine, griseofulvin, phenylbutazone, rifampicin, paracetamol, Chloramphenicol and Disulfiram.

If you have diabetes, Parkinson's disease or epilepsy, doses of medicines to treat these diseases need to be adjusted after the start of treatment with Moditen.

If you are taking medicines to prevent blood clotting, Moditen can reinforce their action. That's why a doctor will often check your blood counts.

If the blood pressure is greatly reduced, only norepinephrine can be given intravenously. Adrenaline should not be used because when administered with phenothiazines, adrenaline lowers blood pressure rather than to increase it. This information is very important in case of surgery or anesthesia.

Do not take Moditen with medicines to treat irregular heart rhythm (anti-arrhythmic agents). You can take them only under a doctor's supervision.

It is not recommended to take Moditen and alcohol at the same time.

The only remedies which may not get along with Moditen are the ones approved by Your doctor.

### ***Taking food and drinks with Moditen***

Food has no influence on the effect of the medicine.

During treatment with Moditen don't drink alcohol because it may cause drowsiness.

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

Consult a doctor or pharmacist before taking any medicine. Tell your doctor if you are pregnant, you suspect a pregnancy or want to become pregnant. If you are pregnant, do not take Moditen, unless your doctor considers it necessary.

The following symptoms may occur in neonates born to mothers who used Moditen during the last quarter of pregnancy (during the last three months of pregnancy): tremors, stiffness and/or muscle weakness, drowsiness, restlessness, problems with breathing difficulties, and the difficulties in one's diet. If your baby has some of these symptoms, you should contact your doctor.

Breast-feeding is not recommended during treatment with Moditen because the medicine passes into breast milk.

### ***The management of vehicles and machines***

Δ Trigonon, a medicine with the possible influence on the psychophysical abilities (a warning when driving and using machines).

Moditen can cause drowsiness, especially at the beginning of the treatment. If you feel groggy or sleepy when you start taking this medicine, do not drive, and do not use the tools and machines for as long as these effects do not go away. Doctor will assess your ability to drive in accordance with the basic disease and the effects of treatment.

### **Other warnings**

Moditen contains lactose and sucrose. If your doctor told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

Moditen 2.5 mg coated tablets also contain tartrazin (At) that can cause allergic reactions.

### **3. HOW TO TAKE MODITEN**

The dose is dependent on diseases and symptoms, so a doctor will tell you how many tablets to take per day and for how long.

Schizophrenia, mania, hypomania, and other psychotic disorders

The daily dose is 2.5 mg to 10 mg, taken as a single dose or divided into two or three doses. If necessary, a doctor may increase your daily dose up to 20 mg, exceptionally up to 40 mg.

The daily dose of 1 mg to 5 mg, which can be taken once a day, usually is sufficient to maintain the therapeutic effect.

#### **Anxiety and other behavioral disorders non-psychotic**

The daily dose of Moditen is 1 mg to 2 mg, and a doctor can gradually increase it to 4 mg a day.

#### **Elderly patients**

Schizophrenia, mania, hypomania, and other psychotic disorders

The daily dose is 2.5 mg to 10 mg, 2 to 3 divided doses.

#### **Anxiety and other behavioral non-psychotic disorders**

For most elderly patients doses of 1 mg up to 2.5 mg of Moditen a day are enough.

#### **Agitation and emotional disorders in old age**

The daily dose of Moditen is 1 mg up to 2.5 mg.

Moditen take in accordance with the instructions of the doctors, with or without food.

#### **Children and adolescents under 18 years of age**

Fluphenazine should not be used because of the lack of data on safety and efficacy.

#### **Use in patients with impaired renal function**

In patients with mild to moderate chronic renal insufficiency (creatinine clearance > 0.5 ml/s) should be applied the lower doses (2.5 mg to 5 mg).

#### **Use in patients with impaired hepatic function**

Fluphenazine should not be used in patients with disorders of the liver or liver failure.

Do not stop taking the medicine if you are feeling better. It is very important that you are taking it for as long as prescribed by a doctor.

### ***If you take more medicine than you should***

If you take more tablets than prescribed (or if someone else has taken your tablets), immediately contact your doctor or the nearest hospital.

### ***If you forget to take the medicine***

You should never take a double dose in order to replace the missed dose.

If you forget to take the medicine at the scheduled time, take it as soon as you remember, and then proceed with the taking it as you used to.

### ***What happens if you stop using Moditen?***

You should not abruptly stop taking the medicine. It is very important that you take it as prescribed by your doctor.

If you have any additional questions about the use of this preparation, consult a doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Moditen can cause side effects.

Side effects are classified into the following groups according to frequency:

**Very common:** occurs in more than 1 in 10 patients who take the medicine

**Common:** occurs in 1 to 10 in 100 patients

**Uncommon:** occurs in 1 to 10 in 1000 patients

**Rare:** occurs in 1 to 10 to 10000 patients

**Very rare:** occurs in less than 1 in 10000 patients

**Unknown frequency:** cannot be estimated on the basis of the available data.

#### **Common:**

- extra pyramidal disorders (abnormal muscle movements or muscle hardness, trembling, and anxiety, the fast and the circular movements of the eye, increased muscle reflexes). These symptoms are usually transient and disappear after you reduce the dose or stop treatment. By giving the antiparkinsonic can be prevented and mitigated.
- rhythmic involuntary movements of the face, mouth, lips, hull and the limbs (they may be signs of a rare condition called tardive dyskinesia). In such a case, immediately discontinue treatment and contact your doctor.

#### **Uncommon:**

- fast heart rhythm,
- headache,
- blurred vision, increased pressure in the eye,
- the feeling that the nose is clogged,
- nausea, loss of appetite, excessive drooling, dry mouth, constipation, blocked the passage of intestinal contents (paralytic ileus), the need for more frequent urination and/or uncontrolled urination, perspiration,
- increase breast in men; in some patients taking similar medications appeared galactorrhoea (spontaneous leakage of milk from the breasts); disorders of libido and erection difficulties, irregular or absent menstrual cycle, false positive pregnancy test,
- increased appetite and weight gain
- milder increase in blood pressure, fluctuations of blood pressure

#### **Rare:**

- Disorders of the heart (prolonged QT interval and T-wave), irregular heartbeat (ventricular arrhythmias, such as ventricular tachycardia and ventricular fibrillation)

- fever, muscle rigidity, the inability or difficulty with movement, lowering of blood pressure, stupor and coma (it can be signs of a condition called Neuroleptic Malignant Syndrome). In such a case, immediately discontinue treatment and contact your doctor or nearest hospital,
- Visual impairment (or corneal opacities),
- incontinence of urine (and during the night),
- pigmentation of the skin, hypersensitivity reactions (photosensitivity), allergic dermatitis, hives, increased the activity of glands that secrete sebum (Seborrhea), reddening of the skin (erythema), skin rash (eczema), severe inflammation of the skin characterized by peeling of the skin (exfoliative dermatitis),
- jaundice caused by bile stasis,
- painful erections, difficulty with ejaculation,
- drowsiness, lethargy (a condition similar to deep sleep).

**Very rare:**

- abnormal or irregular heart rhythm (arrhythmia, atrial),
- severe allergic reactions in the form of asthma, edema of the throat and angioedema (swelling of the skin and mucous membranes).

**Not known:**

- disturbances of the heart rhythm (Torsades de pointes), cardiac arrest,
- blood disorders (leucopenia, agranulocytosis, thrombocytopenia, Eosinophilia and pancytopenia); that's why the doctor will periodically check the blood count,
- blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness of the leg), which can travel through the blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms, seek doctor's advice.
- anxiety, agitation, abnormal dreams, depression, suicidal tendency.

In hospitalized patients who received fenotiazine a few cases of sudden, unexpected and unexplained deaths were reported.

In older people with dementia there is a small increase in the number of deaths in patients taking antipsychotics, compared with those who did not receive antipsychotics.

***Reporting of side effects***

In case of any adverse reaction following administration of the medicinal product, it is necessary to inform your doctors or pharmacists. This implies all possible unwanted reactions, which are not mentioned in this instruction leaflet, as well as those that are.

***5. HOW TO STORE MODITEN***

Keep out of the reach and sight of children.

Store at the temperature up to 25 ° C, protected from light and moisture.

You may not use Moditen medicine after the expiry date marked on the box.

The expiry date refers to the last day of that month. Shelf life of the medicine is a 4 years from date of manufacture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

***6. FURTHER INFORMATION***

***What Moditen contains?***

**Moditen 1 mg coated tablets**

Active substance: 1 coated tablet contains 1 mg of fluphenazine hydrochloride.

Other substances: lactose monohydrate, maize starch, povidone, talc, magnesium stearate in the Tablet core, and sucrose, talc, Arabic gum, pink color (E127), capol 600 in the slipstream.

**Moditen 2.5 mg coated tablets**

Active substance: 1 coated tablet contains 2.5 mg of fluphenazine hydrochloride.

Other substances: lactose monohydrate, maize starch, povidone, talc, magnesium stearate in the Tablet core, and sucrose, Arabic Gum, talc, yellow color (At), capol 600 in the slipstream.

**Moditen 5 mg coated tablets**

Active substance: 1 coated tablet contains 5 mg of fluphenazine hydrochloride.

Other substances: lactose monohydrate, maize starch, povidone, talc, magnesium stearate in the Tablet core, and Arabic Gum, sucrose, talc, titanium dioxide (E171), capol 600 in the slipstream.

***How Moditen looks like and contents of the Pack?***

- Coated tablets 1 mg are: round, biconvex, purple in color.
- Coated tablets 2.5 mg are: round, biconvex, yellow in color.
- Coated tablets of 5 mg are: round, biconvex, white in color.

There are boxes with 25-coated tablets of 1 mg in a brown glass vial; 100-coated tablets of 2.5 mg in a brown glass vial and 100 coated tablets of 5 mg in a brown glass vial.

***Regime of dispensing***

The medicine is issued on doctor's prescription

***Manufacturer***

KRKA tovarna zdravil d.d. Novo mesto  
Šmarješka cesta 6, Novo mesto, Slovenia

***Manufacturer of the medicinal product***

KRKA tovarna zdravil d.d. Novo mesto  
Šmarješka cesta 6, Novo mesto, Slovenia