

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

The medicine is dispensed with a doctor's prescription only

**MODAL[®] Capsules
MODAL[®] Forte Tablets**

Active ingredient:

Each Modal capsule contains: Sulpiride 50 mg

Each Modal Forte tablet contains: Sulpiride 200 mg

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems that their medical condition is similar to yours.

1. What is the medicine intended for?

Modal capsules: an antidopaminergic medicine for the treatment of vertigo (dizziness) and prepsychotic states.

Modal Forte tablets: an antidopaminergic medicine for the treatment of vertigo (dizziness) and prepsychotic states. In high doses, for the treatment of depression and apathy in psychiatric patients.

Therapeutic group: benzamides

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 the medicine contains (for the list of the additional ingredients, see section 6).
- You suffer from pheochromocytoma (a tumor of the adrenal gland), prolactin-dependent tumors, e.g., in the pituitary gland or breast cancer, or porphyria (a rare metabolic disease).
- You are taking levodopa or ropinirole (or other medicines for the treatment of Parkinson's disease).

Special warnings regarding the use of this medicine:

- Antipsychotic medicines might cause a combination of fever, muscle stiffness and symptoms such as sweating and faster breathing. These symptoms may be indicative of neuroleptic malignant syndrome. If you experience these symptoms, stop the treatment with the medicine and refer to the doctor immediately.
- In elderly patients, as with other neuroleptic medicines, sulpiride should be used with caution. Elderly patients have a greater tendency to experience low blood pressure when standing up, drowsiness and extrapyramidal effects such as tremor and muscle stiffness.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

Before the treatment with Modal (capsules or tablets) inform the doctor:

- If you have bouts of aggressive behavior or are very agitated.
- If you suffer from kidney function problems.
- If you suffer or a member of your family suffers from heart function problems.
- If you ever had a stroke.
- If you or someone in your family had or has a tendency to blood clots (this medicine may lead to formation of blood clots).

- If you are aged 65 or over.
- If you suffer from dementia.
- If you suffer from Parkinson's disease.
- If you have low or imbalanced levels of blood electrolytes, e.g.: potassium (hypokalemia), calcium and magnesium.
- If you have epilepsy or have had convulsions.
- If you have low white blood cell levels (agranulocytosis). This condition may cause you to get infections more easily.
- If you suffer from frequent infections, such as: fever, severe chills, sore throat or mouth ulcers. These can indicate a blood system problem called "leukopenia".
- If you suffer from high blood pressure.
- If you suffer or have suffered in the past from glaucoma.
- If you suffer from bowel obstruction (ileus).
- If you have difficulty passing urine.
- If you have an enlarged prostate gland.
- If you suffer from a digestive problem called congenital digestive stenosis.
- If you or someone in your family had in the past stomach problems.
- If you or your family had in the past breast cancer.
- If you suffer from diabetes or have risk factors for diabetes. The doctor may monitor the blood glucose levels during the treatment.

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially if you are taking:

- Levodopa or ropinirole (or other medicines for treatment of Parkinson's disease): do not use the medicine if you are taking these medicines.
- Medicines for the treatment of irregularities in heart rhythm, e.g., amiodarone, beta-blockers (e.g. sotalol), disopyramide, quinidine.
- Medicines to treat heart or vascular problems or high blood pressure, such as: clonidine, calcium channel blockers (e.g. diltiazem, verapamil, bepridil), guanfacine, vincamine and digitalis such as digoxin.
- Other medicines for the treatment of psychotic states (e.g. schizophrenia), such as: pimozide, haloperidol, thioridazine, sultopride.
- Lithium (used for the treatment of some mental disorders).
- Medicines effecting on the central nervous system (e.g.: medicines for calming, for sleeping, to treat mental and emotional problems, for epilepsy, to lower anxiety, benzodiazepines, barbiturates, opioid pain relievers).
- Certain antidepressants such as: imipramine.
- Certain diuretics, certain antidiarrheals (these medicines may lower the blood potassium level).
- Certain antibiotics for the treatment of infections, e.g.: pentamidine, erythromycin, amphotericin B, sparfloxacin.
- Cisapride (to treat digestive problems), tetracosactide.
- Steroids to reduce an inflammatory reaction, e.g.: prednisolone, betamethasone, dexamethasone.
- Sucralfate (to treat digestive system ulcers) and medicines for digestive problems and heartburn, such as: antacids (which contain aluminum or magnesium): take Modal (tablets or capsules) at least two hours before taking these medicines.
- Pain relievers (that can also be present in medicines for colds and influenza); methadone; halofantrine (to treat malaria), medicines containing alcohol.
- Certain antihistamines (to treat allergies), e.g.: chlorphenamine, promethazine, ketotifen.
- Metoclopramide - when used concurrently with Modal (capsules or tablets) there may be a change in the response to the treatment with metoclopramide.

Use of the medicine and alcohol consumption: Do not drink wine or alcoholic beverages during the treatment period with the medicine, and also do not use medicines containing alcohol when using the medicine. Alcohol may increase the effects of the medicine, for instance, its sedative effect.

Pregnancy and breastfeeding:

Pregnancy

Consult the doctor before using this medicine if you are pregnant, think you are pregnant or are planning a pregnancy. There is very limited information on the use of sulpiride during pregnancy. The safety of the use of sulpiride during pregnancy has not yet been established. The use of sulpiride is not recommended for pregnant women or for women of childbearing age who are not using contraceptive means. The following symptoms might appear in babies whose mothers used the medicine during the last three months of pregnancy (third trimester): trembling, muscle stiffness or weakness, sleepiness, agitation, breathing problems and feeding difficulty. If your baby develops these symptoms, contact the doctor.

Breastfeeding

Do not breastfeed during the treatment with the medicine. The medicine passes into the breastmilk. There is insufficient information on the effect of the medicine on breastfed babies. Consult the doctor before using the medicine.

Driving and use of machines: The use of this medicine may impair alertness and cause sleepiness, dizziness, visual disturbances and may impair the abilities required for performing dangerous tasks, such as operating machines or driving a vehicle. If you feel this way, do not drive or operate machinery. In any case, employ caution when driving a vehicle, operating dangerous machinery and for any activity requiring alertness. As for children, they should be warned against riding a bicycle or playing near roads, etc.

Important information about some of the medicine's ingredients:

Modal Forte tablets contain lactose. If you are sensitive to lactose, or if the doctor told you that you have an intolerance to some sugars, inform the doctor before taking this medicine (please see section 6).

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

Use this medicine at set times as determined by the attending doctor.

The dosage will be determined by the doctor according to the treatment purpose and your state of health.

Do not exceed the recommended dose. If you feel that the effect of the medicine is too strong or too weak, do not change the dosage independently, rather refer to the doctor.

Do not chew! Swallow the medicine with water.

Modal capsules: there is no information regarding opening the capsule and dispersing its contents.

Modal Forte tablets: may be halved according to the scored line. There is no information regarding crushing/chewing.

Do not retain the medicine in your mouth beyond the time necessary to swallow it.

The medicine may be taken with food.

Tests and follow-up: before and during the treatment the doctor may send you for various tests, such as: heart function, level of blood electrolytes (salts) or additional blood tests.

If you have accidentally taken a higher dosage: If you (or any other person) have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the medicine's package with you. Overdose symptoms include: restlessness, confusion or agitation, decrease in level of consciousness, trembling, muscle stiffness or spasms, movement difficulties, uncontrolled movements (for instance in eyes, neck, arms and legs), increased saliva production. In some cases, there may also be: dizziness, lightheadedness

and fainting (as a result of low blood pressure), coma. Serious consequences have been reported for concurrent use with other medicines affecting the brain.

If you forgot to take the medicine at the set time, take the dose as soon as you remember, however, if it is nearly time for the next dose, skip the forgotten dose. Do not take a double dose! Adhere to the treatment according to your doctor's recommendation.

If you stop taking the medicine: even if your state of health improves, do not stop the treatment with the medicine without consulting the doctor. Do not stop taking this medicine if you feel better. If you stop taking the medicine suddenly, your illness might return and you might also experience undesirable effects such as: nausea, vomiting, sweating, difficulty sleeping. In some cases also: restlessness, uncontrolled movements. The doctor will gradually reduce the medicine dosage, until complete cessation, in order to avoid these symptoms.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Legend for frequency of the side effects: Common side effects (appear in 1-10 users out of 100); Uncommon side effects (appear in 1-10 users out of 1,000); Rare side effects (appear in 1-10 users out of 10,000); Very rare side effects (appear in less than 1 user out of 10,000); Side effects of unknown frequency (effects whose frequency has not yet been determined).

Stop the treatment and refer to the doctor or a hospital emergency room immediately, if the following side effects appear:

Common side effects:

- Tremor, stiffness and shuffling (Parkinsonism); trembling, muscle spasms, slow movement (extrapyramidal effects).

Uncommon side effects:

- Uncontrolled movements (mainly of the tongue, mouth, jaw, arms, legs).
- Frequent infections, such as: fever, severe chills, sore throat or mouth ulcers. These can indicate a blood system problem called "leukopenia".

Rare side effects:

- Heart problems such as: strong, irregular, rapid or very slow heartbeats; breathing problems such as: wheezing, shortness of breath, chest tightness and chest pains.

Side effects of unknown frequency:

- Severe allergic reactions (anaphylactic reaction or shock) which may include: urticaria, rash, itching, shortness of breath or breathing difficulties, wheezing, chills, swelling of tissues and low blood pressure.
- Heart problems such as abnormal fast heartbeat, life-threatening irregular heartbeat including cardiac arrest, alteration of the heart rhythm called 'prolonged QT interval', seen in an ECG, or torsade de pointes.
- Spasms (convulsions).
- High fever, sweating, muscle stiffness, rapid heartbeats, rapid breathing, confusion, drowsiness, agitation. These can be signs of a serious but rare side effect called: neuroleptic malignant syndrome.
- Blood clots in the veins, particularly in the legs (the symptoms include: swelling, pain and redness in the leg). If the clot reaches the lungs it may cause chest pain and breathing difficulties. If left untreated, it could lead to a blockage of the main lung artery (pulmonary embolism). The Symptoms

include irregular heartbeats and also breathing problems such as wheezing, shortness of breath, tightness and/or pain in the chest.

- Blood disorders (e.g. agranulocytosis) or decrease in the number of white blood cells (neutropenia) which cause higher vulnerability to infections, and therefore you must contact the doctor immediately in any case of infection or fever.
- A small increase in the number of deaths has been reported in elderly people with dementia who take antipsychotics compared with those not receiving antipsychotics.
- Unexplained sore throat or swelling in the neck, armpit and/or groin.
- Muscle breakdown that may lead to kidney damage (rhabdomyolysis).
- Increased level of creatine phosphokinase in blood (CPK) which can indicate muscle damage.
- Fever.

Refer to the doctor immediately if the following side effects appear:

- Common side effects: restlessness, akathisia (inability to stand still).
- Uncommon side effects: the feeling of dizziness, lightheadedness or fainting as a result of low blood pressure (particularly when sitting up or standing up quickly); increased saliva production, increased muscle tension and decreased ability to stretch (hypertonia); involuntary and uncontrolled movements.
- Rare side effects: eye rolling.
- Side effects of unknown frequency: neck twisted to one side; tightness and stiffness of the jaw; decreased movement ability of the body or muscles, stiff muscles, shaking, confusion.
- Increase in blood pressure.
- Feeling unwell, confused or weak, nausea, loss of appetite and irritability. These symptoms could indicate an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH).
- Decrease in blood sodium level (seen in blood tests).
- Liver problems (seen in blood tests) such as hepatocellular, cholestatic or mixed liver injury.
- Aspiration pneumonia - a condition in which an infection develops in the lungs after inhaling food, liquid, saliva or nasal secretions.

Refer to the doctor or pharmacist if the following side effects worsen or continue more than a few days:

- Common side effects: increase in liver enzymes (seen in blood tests) that can indicate liver problems, increase in prolactin level, breast pain (in men and women) and/or abnormal secretion of breast milk (in men and women); weight gain; feeling of drowsiness or sleepiness; insomnia; rash and constipation.
- Uncommon side effects: breast enlargement in women; absence of menstrual periods; sexual function problems.
- Side effects of unknown frequency: breast enlargement in men; uncontrolled movements of the mouth, tongue and limbs appearing later in the course of the treatment or even after the end of the treatment (tardive dyskinesia). There have been reports of sudden death, possibly caused by heart function problems.

Side effects and drug interactions in children

Parents must inform the attending physician of any side effect and of any other medicine given to the child.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the link:

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

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, 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) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.

6. Additional information

In addition to the active ingredient, Modal capsules also contain the following inactive ingredients:

Cellulose microcrystalline, magnesium stearate, titanium dioxide (E171), FD&C Blue 2 (E132), gelatin.

In addition to the active ingredient, Modal Forte tablets also contain the following inactive ingredients:

Potato starch, lactose, cellulose microcrystalline, silicon dioxide, magnesium stearate, methylcellulose, talc.

Each tablet contains 27 mg lactose.

What does the medicine look like and what does the package contain?

Modal Capsules: light blue (marine blue) capsules containing a white powder, packed in blister packs of 30 capsules per box.

Modal Forte tablets: White tablets with a scored line with 'Modal F' imprinted on them, packed in blister packs of 40 tablets per box.

Manufacturer and Registration Holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Modal capsules: 0292721906, Modal Forte tablets: 0292921895

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