

Patient Leaflet According to the Pharmacists' Regulations (Preparations) –
1986

This medicine is sold 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 inactive ingredients, please 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 your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

1. What is the medicine intended for?

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

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

Therapeutic group: benzamides

2. Before using the medicine

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (for a list of inactive ingredients, please see section 6).
- Do not use if you suffer from pheochromocytoma (tumor of the adrenal gland), prolactin-dependent cancerous tumors, e.g. pituitary gland cancer or breast cancer, or porphyria (a rare metabolic disease).
- Do not use the medicine if you are taking levodopa or ropinirole (or other medicines for treatment of Parkinson's disease).

Special warnings regarding the use of this medicine:

- Patients aged 65 and over may be more sensitive to the effects of the medicine.
- Be careful not to become overheated during physical exercise, in hot weather and in a hot shower (may cause a heatstroke). If you become overheated, contact your doctor.
- If you are sensitive to any type of food or medicine, inform your doctor before taking this medicine.

Before starting the treatment, tell your doctor:

- If you have bouts of aggressive behavior or are very agitated.
- If you suffer from problems in the functioning of your kidneys.
- If you suffer or a member of your family suffers from problems in the heart function.
- If you have ever had a stroke.

- If you or someone in your family had or has a tendency to blood clots (this medicine is liable to cause forming 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, calcium and magnesium.
- If you suffer from epilepsy or have had convulsions.
- If you have low white blood cell levels (agranulocytosis). This condition may cause you to be more vulnerable to infections.
- If you suffer from frequent infections, such as: fever, severe chills, sore throat or mouth ulcers. These can indicate a blood system disorder called "leukopenia".

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines, because Modal may affect the efficacy of other medicines and other medicines may affect the efficacy of Modal. (It should be noted that the following list mentions the active ingredients in the medicines. If you are not sure whether you are using one of these medicines please check with your doctor or pharmacist).

- 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 treatment of heart arrhythmia, e.g. amiodarone, beta blockers (e.g. sotalol), disopyramide, quinidine.
- Medicines to treat heart problems or high blood pressure, such as: clonidine, calcium channel blockers (e.g. diltiazem, verapamil), digitalis such as digoxin.
- Other medicines for treatment of psychotic states (e.g. schizophrenia), such as: pimozide, haloperidol, thioridazine.
- Lithium (used for treatment of certain mental disorders).
- Medicines acting on the central nervous system (e.g.: sedatives, sleeping pills, medicines to treat mental and emotional problems, epilepsy, medicines to lower anxiety, benzodiazepines, barbiturates, opioid analgesics).
- Certain antidepressants such as: imipramine.
- Certain diuretics, certain antidiarrheals (the medicines may lower the blood potassium level).
- Certain antibiotics for treatment of infections, e.g.: pentamidine, erythromycin, amphotericin B.
- Cisapride (to treat digestive problems), tetracosactide.
- Steroids to reduce 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.
- Analgesics (that can also be present in medicines for colds and influenza); methadone; halofantrine (to treat malaria), preparations containing alcohol.
- Certain antihistamines (to treat allergies), e.g.: chlorphenamine, promethazine, ketotifen.

Use of the medicine and alcohol consumption: Do not drink wine or alcoholic beverages during the treatment with the medicine, and 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:

- Consult your doctor before use of this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant.
- Do not breastfeed during treatment with the medicine. Small amounts of the medicine might pass into the breast milk.

The following symptoms might appear in babies whose mothers used the medicine in the last three months of pregnancy (third trimester): trembling, muscle stiffness or weakness, sleepiness, agitation, breathing problems, feeding difficulty. If your baby develops these symptoms, contact your doctor.

Driving and use of machines: The use of this medicine is liable to impair alertness and cause drowsiness. If you feel this way, do not drive or operate machinery. In any case, employ caution in driving a vehicle, operating dangerous machinery and in 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 intolerance to certain sugars, inform your doctor before taking this medicine (please see section 6).

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and the manner of treatment will be determined by the doctor only.

Use this medicine at set times as determined by your doctor.

The dosage will be determined by your doctor according to the purpose of the treatment 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 by yourself, but contact your 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 cut in half using 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.

This medicine may be taken with food.

Tests and follow-up: before starting the treatment and during the treatment your doctor may refer you for various tests such as: heart functions, level of blood electrolytes (salts) or other 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, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

Overdose symptoms include: restlessness, confusion or agitation, reduced level of consciousness, trembling, muscle stiffness or spasms, movement difficulties, uncontrolled movements (for instance in eyes, neck, arms and legs), producing more saliva than usual. In some cases, there may also be the following symptoms: dizziness, lightheadedness and fainting (as a result of low blood pressure), coma.

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 two doses together!

Continue with the treatment as recommended by your doctor.

If you stop taking the medicine: even if your state of health improves, do not stop the treatment with this medicine without consulting your 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 your doctor or pharmacist.

4. Side effects

Like 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 been determined yet).

Stop the treatment and contact your 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).

Rare side effects:

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

Side effects of unknown frequency:

- Severe allergic reaction (anaphylactic reaction or anaphylactic shock) whose symptoms may include: breathing difficulties, dizziness, cold and clammy skin, pale skin color, rapid heartbeats, urticaria.
- Low blood pressure; heart problems (rhythm disorders such as QT interval prolongation seen on ECG or torsade de pointes and cardiac arrest); fits (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.
- Shortness of breath or breathing difficulties; blood disorders (e.g. agranulocytosis) or decrease in number of white blood cells (neutropenia, leukopenia) which cause higher vulnerability to infections, and therefore you must contact the doctor immediately in any case of infection or fever. Leukopenia is uncommon.

Contact your doctor immediately if the following side effects appear:

- Common side effects: restlessness, akathisia (inability to stand still).
- Uncommon side effects: feeling of dizziness, lightheadedness or faintness as a result of low blood pressure (particularly when sitting up or standing up quickly); increased muscle tension and decreased ability to stretch (hypertonia); involuntary and uncontrolled movements.
- Rare side effects: eye rolling.

- Side effects of unknown frequency: neck inclined to one side; tightness and stiffness of the jaw; decreased movement capacity of the body or muscles; confusion.

Contact your doctor or pharmacist if the following side effects worsen or continue for more than a few days:

- Common side effects: increased prolactin level, breast pain and/or abnormal secretion of breast milk (in men and women); weight gain; feeling of drowsiness or falling asleep; difficulty sleeping; rash.
- Uncommon side effects: breast enlargement in women; absence of menstrual periods; sexual function disorders; producing more saliva than usual; uncontrolled movements (principally of the tongue, mouth, jaw, arms, legs).
- Side effects of unknown frequency: breast enlargement in men; uncontrolled movements of the mouth, tongue, limbs appearing later in the course of the treatment or even after the end of the treatment (tardive dyskinesia); increase in liver enzymes (seen in blood tests) that can indicate liver problems.

Very rare side effects: sudden death, which may be caused by problems in the functioning of the heart and in elderly patients suffering from dementia and treated with antipsychotic medicines.

Side effects and drug interactions in children

Parents must inform the attending doctor of any side effect as well as any additional medicine given to the child.

If a side effect appears, if one of the side effects worsens, or you suffer from a side effect not mentioned in the leaflet, or if there is any change in your general feeling, consult your doctor immediately.

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 to an online form for reporting side effects, or by entering the link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 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, FD&C Blue 2 (E132), titanium dioxide (E171), gelatin.

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

Cellulose microcrystalline, magnesium stearate, lactose, potato starch, methylcellulose, talc, silicon dioxide.

Each tablet contains 27 mg of lactose.

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

Modal Capsules: marine blue capsules containing a white powder, packed in blisters; 30 capsules per box.

Modal Forte Tablets: white tablets with a scored line with 'Modal F' imprinted on them, packed in blisters; 40 tablets per box.

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

This leaflet was checked and approved by the Ministry of Health in June 2016.

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