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

The medicine is dispensed with a doctor's prescription only

Surmontil 25 mg

SANOFI

Active ingredient:
Each tablet contains Trimipramine 25 mg (as maleate)
For a list of inactive ingredients, see section 6.

Read this leaflet carefully in its entirety before using the medicine. Keep this leaflet; you may need to read it again. 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 your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
If a side effect worsens, or if a side effect not mentioned in this leaflet occurs, please refer to the doctor or pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

Surmontil is intended to treat depression.

Therapeutic group:
Non-selective monoamine reuptake inhibitors.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- you have a known sensitivity to trimipramine or to any of the ingredients of the medicine (see section 6 for further information regarding the ingredients of the medicine).
- you suffer from an intolerance or allergy to gluten, due to the presence of wheat starch.
- you suffer from narrow-angle glaucoma (increased intraocular pressure).
- you suffer from difficulty urinating due to prostate problems or other problems.
- you recently suffered from a myocardial infarction.
- you are taking sultopride (medicines for the treatment of schizophrenia).
- you are being concomitantly treated with medicines from the monoamine-oxidase inhibitor group (for depression) or are within 14 days of discontinuing treatment with them.

This medicine is **generally not intended for use in the following cases,** unless explicitly instructed by the doctor:
Treatment with medicines affecting the cardiovascular system (clonidine and the like, adrenaline, noradrenaline, dopamine given by injection).
In case of doubt, consult with the doctor before taking the medicine.

Special warnings regarding use of the medicine
Do not discontinue treatment abruptly.
As with other antidepressants, the effect of the medicine will only be apparent after a few days.
This medicine can be taken if you suffer from celiac disease. Wheat starch can contain gluten, but in negligible quantities, and is therefore considered safe for celiac patients.

Suicidal thoughts and aggravation of depression or anxiety
If you are depressed or suffering from anxiety, you may have self-destructive thoughts. This can worsen at the beginning of treatment with antidepressants, since these medicines take about two weeks, and sometimes longer, to begin to take effect.
These effects are likely to occur in the following cases:
- You have already had suicidal or self-destructive thoughts in the past.
- You are a young adult. A clinical study has shown an increased risk of suicidal behavior among adults below the age of 25 suffering from psychiatric problems, who were treated with antidepressants.

If you are having self-destructive or suicidal thoughts, immediately contact a doctor or proceed to the hospital. It may be helpful if you tell a relative or close friend that you are suffering from depression or anxiety, and ask him to read this leaflet, and to tell you if he thinks your depression or anxiety has worsened or if he is concerned about changes in your behavior.

❗ Before treatment with the medicine, inform the doctor if you suffer from:
- heart disease
- seizures (in the past or present), or epilepsy
- prostate problems
- kidney or liver disease
- chronic constipation
- diabetes or risk of diabetes
- you are taking other medicines that affect serotonin levels (combining Surmontil with these medicines may be fatal).
- risk factors that may cause heart rate disturbances, such as:
  - congenital prolongation of QT intervals, slow pulse (bradycardia).
  - use of medicines that can cause a prolongation of the QT interval, slow pulse or hypokalemia.
  - electrolyte imbalance (e.g., low blood potassium levels [hypokalemia], low blood magnesium levels [hypomagnesemia]).

In case of doubt, consult with the doctor before taking the medicine.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not take concomitantly and within 14 days of completing treatment with monoamine-oxidase inhibitors (preparations for treating depression, e.g., iproniazid, nialamide).
Do not take the medicine with sultopride (a medicine for the treatment of schizophrenia).
This medicine should generally not be taken concomitantly with medicines affecting the cardiovascular system (clonidine and the like, adrenaline, noradrenaline, dopamine given by injection), unless the doctor has explicitly instructed otherwise.
Concomitant use with medicines that can increase serotonin levels (e.g., SSRIs, SNRIs, MAOIs, lithium, triptans, tramadol, linezolid, L-tryptophan, St. John's Wort - *Hypericum perforatum*) may cause serotonin syndrome. Close supervision is required when these medicines are given together with Surmontil.
Take Surmontil with caution with medicines that prolong the QT interval (e.g., class 1A and class III antiarrhythmics, macrolides [a kind of antibiotic], fluoroquinolones [a kind of antibiotic], certain antifungals, certain antipsychotics) and together with medicines that cause a drop in blood potassium levels (hypokalemia) (e.g., diuretics, laxatives, steroids, tetracosactide) or to a drop in heart rate (bradycardia) (e.g., beta blockers, diltiazem, verapamil, clonidine, digitalis).

❗ Use of the medicine and alcohol consumption
Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

❗ Pregnancy and breastfeeding
It is preferable not to use this medicine during pregnancy. If you are pregnant, consult the doctor regarding continued treatment with the medicine.
This medicine passes into breast milk in small quantities. Avoid breastfeeding during the course of treatment.
If you are pregnant or breastfeeding, consult the doctor before using medicines.

❗ Driving and use of machines
Do not drive or operate dangerous machines while using the medicine, since use of the medicine may impair alertness.

❗ Important information regarding some of the ingredients of the medicine
The preparation contains wheat starch. If you suffer from an intolerance or allergy to gluten, consult the doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure.
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.

Taking the medicine
- Swallow the tablet whole with water, during a meal or between meals.
- If you have been told to take Surmontil once a day, do so before going to sleep.

Duration of treatment: treatment is generally for a few months (approximately 6 months). The exact duration of treatment and treatment regimen will be determined by the doctor only.

Tests and follow up
Patients with diabetes or with risk of diabetes should monitor blood sugar levels throughout the course of treatment.

If you accidentally took a higher dosage or if a child accidentally swallowed the medicine, refer to a doctor or proceed to a hospital emergency room immediately and bring the package of the medicine with you. Symptoms of overdose: convulsions, confusion, heart rate disturbances (QT interval prolongation, torsade de pointes). Taking an overdose can lead to death.

If you forgot to take the medicine: If you forgot to take this medicine, take the dose when you remember and continue as usual, but if it is almost time for the next dose, skip the forgotten dose. Do not take a double dose to compensate for a forgotten dose.
Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment of the medicine without consulting the doctor or pharmacist.

If you stop taking the medicine
In rare cases, withdrawal symptoms can occur upon discontinued use of the medicine (headache, weakness, nausea, anxiety, sleeping problems). Do not discontinue use without consulting a doctor.
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 any further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Surmontil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to a doctor immediately upon development of serotonin syndrome symptoms, such as: muscle contractions, muscle rigidity, muscle spasms, unexplained fever, rapid heart rate, changes in blood pressure, excessive sweating, tremor, flushing, dilated pupils, diarrhea, anxiety, nervousness, confusion, coma.
Changes in blood test results may occur (hypereosinophilia, leukopenia, thrombocytopenia, agranulocytosis) which may cause unexplained fever, symptoms of infection, nosebleed or bleeding from the gums – **if you experience these effects, refer to the doctor immediately.**

Additional side effects:
- dryness of the mouth
- constipation
- drowsiness (primarily at the beginning of treatment)
- weight gain
- a drop in blood pressure and a feeling of weakness and dizziness when changing from a lying/sitting position to standing
- blurred vision (impaired ability to focus vision between near and far)
- rapid heartbeats
- heart rate disturbances (QT interval prolongation, torsade de pointes)
- sweating
- difficulty urinating
- breast enlargement, milk secretion outside periods of breastfeeding, hot flushes
- impotence
- allergic skin reaction
- difficulty speaking fluently
- high blood sugar levels. Epidemiological studies have shown an increased risk for diabetes among patients receiving medicines that belong to the same group as Surmontil.

An increase in the risk of bone fractures has been observed in patients taking this type of medicine.
When taking a high dosage:
Heart problems (problems with conduction and cardiac rhythm)
Rare:
Tremor, convulsions in certain patients, transient confusion
Extremely rare:
Serious liver problems (hepatitis), fainting.
If any of the side effects worsen, or if you suffer from any side effect not listed in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the blister and carton. The expiry date refers to the last day of that month. Store the blister in the carton package, protected from light and moisture at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, a Surmontil tablet contains:
Wheat starch, silica colloidal hydrated, magnesium stearate.
What the medicine looks like and the contents of the pack:
The tablets are packaged in a tray (blister). 50 tablets per box.
Surmontil tablets are: round, white.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

License holder and address: sanofi-aventis Israel ltd., 10 Beni Gaon Street, Netanya.
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This leaflet was checked and approved by the Ministry of Health in August 2014.
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