

**PACKAGE LEAFLET:
INFORMATION FOR THE USER
Surmontil 50mg
Hard Capsules**

Trimipramine (as maleate)

Is this leaflet hard to see or read?

Phone +353 (0)1 428 7777 for help

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Surmontil Capsules are and what they are used for
2. What you need to know before you take Surmontil Capsules
3. How to take Surmontil Capsules
4. Possible side effects
5. How to store Surmontil Capsules
6. Contents of the pack and other information

1. What Surmontil Capsules are and what they are used for

The name of your medicine is Surmontil 50mg Hard Capsules (called Surmontil Capsules in this leaflet). Surmontil Capsules contain a medicine called trimipramine (as maleate). This belongs to a group of medicines called antidepressants. Surmontil Capsules can be used to treat depression. They are especially useful for treating depression in people who also have problems sleeping, stress (anxiety) or feel irritable and restless (agitation).

2. What you need to know before you take Surmontil Capsules

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to trimipramine or any of the other ingredients of Surmontil Capsules (listed in Section 6 Further information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue
- You are hypersensitive to other tricyclic antidepressants
- You have recently had a heart attack You have any other heart problems including slow or uneven heartbeat
- You have severe liver problems
- In cases of urinary disorders, such as urinary retention or enlargement of the prostate gland (prostate hyperplasia) with formation of residual urine You suffer from any kidney or urethra problems
- You have glaucoma (painful eyes with blurred vision)
- You have mania (signs include very high mood, energy, and unusual behaviour)

- You are concomitantly taking so-called irreversible MAO inhibitors
- You are taking a medicine called Selegiline used to treat Parkinson's disease
- You are taking a medicine called Sultopride, used to treat schizophrenia

This medicinal product contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product. Do not take this medicine if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Surmontil Capsules.

Warnings and precautions

Trimipramine may only be used with special caution in the following cases:

Severe liver or kidney damage

In cases of sudden manic episodes, Trimipramine treatment must be discontinued and suitable treatment instituted.

Since trimipramine may lower the seizure threshold, EEG monitoring (EEG = electroencephalography, measurement of brain action currents) is recommended for epileptics or suspected epileptics (see "Other medicines and Surmontil "). If cramps occur, the treatment must be stopped.

Sudden discontinuation of long-term high-dose treatment with Trimipramine should be avoided, as it may cause withdrawal symptoms such as headaches, feeling sick, anxiety, agitation, sweating, nausea, vomiting and sleep disorders (see "If you stop taking Surmontil").

Heart function should be monitored regularly in patients with heart disease and elderly patients, as this class of substances increases the risk of accelerated heartbeat, low blood pressure and quinidine-like effects.

Take special care with Surmontil Capsules

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Check with your doctor or pharmacist before taking this medicine if:

- You are elderly
- You are weak or lacking strength (debilitated)
- You suffer from a blood disorder (blood dyscrasias)
- You have previously suffered brain damage
- You are receiving Electroconvulsive therapy (ECT)
- You have or have ever had fits or seizures
- You have thyroid problems
- You are a diabetic or are at risk of becoming a diabetic
- You are taking a medicine called buprenorphine (used to treat severe pain or drug dependence). This combination can lead to serotonin syndrome, a potentially life-threatening disease (see "Taking other medicines").

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Surmontil Capsules.

Other medicines and Surmontil

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Surmontil Capsules can affect the way some other medicines work. Also, some medicines can affect the way Surmontil Capsules work.

The effects of alcohol and the simultaneous use of other central nervous system (CNS) depressants, such as:

- Morphine derivatives (painkillers, cough suppressants and replacement therapy),
- Sleeping pills and sedatives (such as barbiturates, benzodiazepines),
- Sedative antihistamines (antiallergics that can cause fatigue),
- Neuroleptics (drugs for the treatment of schizophrenia and psychosis),
- Central antihypertensives (certain drugs used to treat high blood pressure, e.g. alprazolam, clonidine),
- Baclofen (medicine to relax skeletal muscles in spinal cord injury or multiple sclerosis),
- Thalidomide (drug for the treatment of multiple myeloma) can cause increased CNS depression.

Consuming alcoholic beverages and other medicinal products containing alcohol should be avoided.

Simultaneous administration of other substances that also suppress the effect of acetylcholine (anticholinergic effect) may be expected to intensify in central effects (especially delirium).

Trimipramine may increase the undesirable peripheral effects, such as urinary retention, an acute flare up of glaucoma, constipation and dry mouth of atropine-like drugs (e.g. ipratropium bromide, tiotropium bromide, trospium chloride, butylscopolamine).

The efficacy of substances which directly or indirectly lead to excitation of the sympathetic nervous system (sympathomimetic amines, e.g. adrenaline, noradrenaline, dopamine) can be enhanced by simultaneous administration of Trimipramine. This can lead to seizure-like high blood pressure and cardiac arrhythmia.

Trimipramine may weaken the efficacy of guanethidine or clonidine type antihypertensives, with the risk of excessive hypertension (rebound hypertension) in patients treated with clonidine.

If antihypertensive medicines (except clonidine and related substances) are taken at the same time, their antihypertensive effect can be enhanced. There is an increased risk of a sudden drop in blood pressure at the transition from lying down to standing.

The dosage of antiepileptic agents (medicines for seizures in epileptics) should be adjusted if necessary, since trimipramine can lower the seizure threshold and an increased seizure tendency can be expected. These patients must be monitored clinically.

A combination therapy with antipsychotics (medicines for mental disorders with split consciousness) can increase the plasma concentration of the tricyclic antidepressant.

If valproic acid is administered, patients must be clinically monitored and, if necessary, the dosage of Trimipramine must be adjusted.

Do not take Surmontil Capsules and talk to your doctor if you are taking any of the following medicines:

- MAOI (Monoamine Oxidase Inhibitors) medicine such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease) or have taken them in the last 2 weeks.
- Sultopride, used in the treatment of schizophrenia
- Medicines used to treat high blood pressure such as clonidine
- Adrenaline, noradrenaline, ephedrine or isoprenaline – used in an emergency

Tell your doctor if you are taking any of the following medicines:

- Atropine and other atropinic drugs such as antispasmodics, disopyramide used to treat heart conditions, certain antipsychotic drugs (phenothiazine neuroleptics)
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat high blood pressure
- Phenylephrine or phenylpropanolamine – found in cold and flu preparations
- Medicines used to treat epilepsy
- Medicines used to treat depression such as citalopram, fluoxetine, fluvoxamine, paroxetine, sulpiride or sertraline
- Antipsychotic drugs such as haloperidol, pimozide, sertindole, ziprasidone
- Baclofen, a muscle relaxer
- SSRI's (Selective serotonin reuptake inhibitors) and SNRI's (Serotonin norepinephrine reuptake inhibitors) both classes of antidepressant drugs used to treat depression
- Lithium, used to treat manic episodes

- Tramadol, used to treat severe pain
- Triptans, types of medicines used to treat migraines and cluster headaches
- Antifungal medicines used to treat fungal infections
- Laxatives, used to increase bowel movements
- Medicines used to treat sleep disorders such as L-tryptophan
- St. Johns Wort (*hypericum perforatum*) used in the treatment of depression

Buprenorphine (used to treat severe pain or drug dependence) - this medicine may interact with Surmontil 50 mg capsules and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Anaesthetics

If you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are taking Surmontil Capsules.

Taking Surmontil Capsules with food and drink

The consumption of alcohol should be completely avoided while you are taking Surmontil Capsules.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is not recommended to take trimipramine during pregnancy unless clearly necessary and only after careful consideration of the risk/benefit.

If you have taken this medicine during the last part of the pregnancy, your baby may have adaptation difficulties and withdrawal symptoms such as irritability, low muscle tension, tremor, seizures irregular breathing, poor drinking and constipation.

Your doctor will advise you whether to start/continue/stop breast-feeding, or stop using this medicine taking into account the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

There is a potential hazard when driving or operating machinery due to impaired alertness. Trimipramine can cause blurry vision and sedation. Even when used as intended, the reaction capacity can be altered to such an extent that, for example, the ability to actively participate in road traffic or to operate machinery is impaired. You will then no longer be able to react quickly enough to unexpected and sudden events.

3. How to take Surmontil Capsules

Always take Surmontil Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the capsules whole with a drink of water
- If you have been told to take Surmontil Capsules only once each day then you should take it before going to bed
- It may take 7 to 10 days before you feel the full benefit of the medicine
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults:

Depression

- Adults usually start by taking 1 to 2 capsules (50mg to 100mg) each day
- Your doctor may then increase the dose to 150mg or 300mg each day depending on your condition
- Once you start to feel better, the usual daily dose then stays the same at 75mg to 150mg each day

Elderly:

- Elderly usually start by taking 25mg to 50mg each day
- Your doctor may then increase this dose slowly depending on your condition
- Once you start to feel better, the usual daily dose then stays the same at 25mg to 75mg each day

Patients with kidney or liver problems:

- Your doctor will start you on a lower dose if you suffer from kidney or liver problems.

Children and adolescents:

- Do not give this medicine to children or adolescents under the age of 18 years.

If you take more Surmontil Capsules than you should

If you take more Surmontil Capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: fits (seizures), collapse and falling into a coma.

If you forget to take Surmontil Capsules

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

If you stop taking Surmontil Capsules

Keep taking Surmontil Capsules until your doctor tells you to stop. Do not stop taking Surmontil Capsules just

because you feel better. This is because your illness may come back. When your doctor tells you to stop taking these capsules he/she will help you stop taking them gradually. Stopping your medicine too quickly could cause sleep problems, feeling irritable and sweating more than usual.

4. Possible side effects

Like all medicines, Surmontil Capsules can cause side effects, although not everybody gets them.

Stop taking Surmontil Capsules and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty swallowing or breathing, itching of the skin and nettle rash. This may mean you are having an allergic reaction to Surmontil Capsules.

Talk to your doctor straight away if you notice the following side-effects:

- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- Yellowing of the eyes or skin. This could be a liver problem (such as jaundice)
- Overactive behaviour or thoughts (mania or hypomania)
- Numbness or weakness in the arms and legs (peripheral neuropathy)
- Feeling that someone is 'out to get you'
- Getting infections more easily than usual. This could be because of a blood disorder (agranulocytosis, leukopenia, eosinophilia)
- Bruising more easily than usual. This could be because of a blood disorder called thrombocytopenia
- Seizures
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)

Below is a list of other side effects that have been reported:

Especially at the beginning of the treatment:

- Drowsiness, dizziness, seizures, speech disorders, diseases of the peripheral nerves (polyneuropathy), sedation and extrapyramidal disorders such as restlessness in sitting, gait disorders, motor dysfunctions, orthostatic hypotension (disturbance of the circulation regulation with drop in blood pressure, short unconsciousness (syncope)
- Confusion
- Constipation
- Stomach upset
- Dry mouth
- Hair loss (alopecia)
- Weight gain
- Tremor (shaking)
- Blurred vision
- Rapid heartbeat
- Sweating more than usual
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension)
- Sexual problems including erectile dysfunction
- Difficulty in urination (passing water)
- Skin rash
- Bone fractures - an increased risk of bone fractures has been observed in patients taking this type of medicine.

- Hyperglycaemia (abnormally high blood sugar levels)
- Heart problems (such as QT interval prolongation/torsade de pointes)
- Increased water absorption in the body (syndrome of inadequate ADH secretion), blood sugar drops below normal levels (hypoglycaemia).

Similar to related drugs: an increase in the prolactin blood level and/or secretion from the mammary gland (galactorrhea)

- Breast enlargement (Macromastia)
- Sexual dysfunction
- Elevated blood sugar levels, increased risk of developing diabetes (see section 2 under “Warnings and precautions”)
- Hot flush
- Cytolytic or cholestatic hepatitis (inflammation of the liver including bile stasis)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Surmontil Capsules

Keep this medicine in a safe place out of the reach and sight of children.

Do not use Surmontil Capsules after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package in order to protect from light. 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. Contents of the pack and other information

What Surmontil Capsules contain

- Each Surmontil Capsule contains 50mg of the active substance trimipramine (as maleate).
- Other ingredients include maize starch, microcrystalline cellulose (E460), anhydrous colloidal silica, magnesium stearate, gelatin, titanium dioxide (E171), indigo carmine (E132), iron oxide yellow (E172). The printing ink contains Opacode-S/I/8100 Black:(shellac, soya lecithin (E322), antifoam DC1510 and black iron oxide (E172).

What Surmontil Capsules look like and contents of the pack

Surmontil 50mg Hard Capsules are opaque, Body white, cap green, hard capsules with SU50 printed in black. The powder is off-white or slightly cream. They are supplied in blister packs of 28 capsules.

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

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