

Surmontil[®]

Trimipramine (as trimipramine maleate)

Consumer Medicine Information (CMI)

This leaflet answers some common questions about Surmontil. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Surmontil against the benefits they expect it will have for you.

If you have any concerns about taking this medicine ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Surmontil is used for

Surmontil contains the active ingredient trimipramine (as trimipramine maleate). Trimipramine belongs to a group of medicines called tricyclic antidepressants.

Surmontil is used to treat major depression.

Medicines for depression are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Ask your doctor if you have any questions about why Surmontil has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take Surmontil:

- **if you have had an allergic reaction to it, to any other antidepressant medicines or to any of the ingredients listed near the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

- **if you are taking another antidepressant medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.**

Taking Surmontil with a MAOI may cause a life-threatening reaction.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these MAOI medicines.

- **if you have suffered a recent heart attack or have other heart problems.**
- **if you have severe liver disease.**
- **if you suffer from maniac behaviour such as episodes of over-activity, elation or irritability.**
- **if the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

- **if the packaging is torn or shows signs of tampering.**

Do not give Surmontil to children and adolescents (less than 18 years old).

The safety and efficacy of Surmontil in this age group has not been established.

If you are not sure whether you should be taking Surmontil, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- alcoholism
- epilepsy
- brain damage
- glaucoma (high pressure in the eye)
- overactive thyroid gland
- liver disease
- prostate problems
- tendency for mood changes
- history of suicide-related events.

Do not take Surmontil if you are pregnant or breastfeeding.

If you have not told your doctor about any of these things, tell them before you take Surmontil.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Surmontil. These include:

- other MAOI antidepressant medicines
- medicines which numb the skin
- medicines which cause sleepiness
- alcohol
- medicines which relieve pain
- medicines which reduce high blood pressure
- stimulants, including medicines such as amphetamines.

These medicines may be affected by Surmontil or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has a more complete list of medicines to avoid while taking Surmontil.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Surmontil.

How to take it

Your doctor will tell you how many capsules you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Swallow the capsules whole with a glass of water.

When to take it

Usually, Surmontil is taken two hours before bedtime so that daytime drowsiness is minimized.

However, your doctor may tell you to take it during the day as well.

How long to take it

Continue taking your dosage until your doctor tells you to stop.

Most antidepressants take time to work, so do not be discouraged if you do not feel better straight away.

It may take several weeks to feel the full benefit of this medicine.

If you forget to take it

If you normally take the capsules only at bedtime and a dose is missed, do not take the missed dose the next morning until you have checked with your doctor.

It may cause some side effects during the day if you take the whole dose in the morning.

If you are also taking Surmontil during the day and you miss a dose, take it as soon as you remember, and then go back to taking it as you would normally.

However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not double a dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone Australia: 13 11 26, or New Zealand: 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Surmontil. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include convulsions and feeling faint.

While you are taking it

Things you must do

Tell your doctor if you feel the medicine is not helping your condition.

Watch carefully for signs of whether your depression or anxiety is getting worse,

especially in the first few weeks of treatment or when the dosage is changed.

Tell your doctor immediately if you experience any of the following symptoms especially if they are severe, if they did not occur before or if they happen suddenly:

- anxiety or agitation
- panic attacks
- difficulty sleeping
- hostility or impulsiveness
- restlessness
- over-activity or uninhibited behaviour
- thoughts of suicide.

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

All thoughts or talk about suicide or violence are serious.

If you or someone you know is showing the following warning signs of suicide, contact your doctor or a mental health advisor immediately or go to the nearest hospital for treatment.

Warning signs of suicide include:

- thoughts or talk about death or suicide
- thoughts or talk about self-harm or doing harm to others
- any recent attempts of self-harm
- an increase in aggressive behaviour, irritability or agitation.

Families and carers should be aware of the above signs, especially during the initial few months of treatment or at times of dosage increase or decrease.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change you treatment unnecessarily.

Tell your doctor or dentist if your mouth feels dry and this lasts for more than 2 weeks.

Surmontil may cause dry mouth, thereby increasing the chance of dental disease including tooth decay and gum disease. Dry mouth can be relieved by frequent sips of water, sucking sugarless lollies or chewing sugarless gum.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Surmontil.

Tell your doctor if you become pregnant while taking Surmontil.

Things you must not do

Do not drive, operate machinery or do things that could be dangerous until you know how Surmontil affects you.

It may cause drowsiness or dizziness in some people.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Do not use Surmontil to treat any other complaints unless your doctor says so.

Things to be careful of

Be careful when drinking alcohol while taking Surmontil.

This medicine and alcohol in combination can make you more dizzy or drowsy. Your doctor may suggest you avoid alcohol while you are being treated for depression.

People with cardiovascular problems or the elderly may become confused when taking Surmontil. Families and carers should be aware of this. Special care may be needed.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Surmontil.

Surmontil helps treat most people with depression, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- dizziness, lightheadedness
- headache
- drowsiness
- stomach upsets, indigestion
- sleeping difficulties, insomnia
- dry mouth and nose
- dry eyes
- constipation.

These are the more common side effects of your medicine.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- fast /irregular heart beat
- confusion
- blurred vision
- difficulty urinating
- involuntary movements of face, arms, legs; shaking, trembling or muscle spasms
- sudden mood changes to euphoria or irritability
- overactiveness
- tingling or numbness in the hands or feet
- faintness
- convulsions or fits.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep it in a cool dry place where the temperature stays below 25°C.

Disposal

If your doctor tells you to stop taking Surmontil or you find that the expiry date has passed, ask your pharmacist what to do with any medicine you may have left.

Product description

What it looks like

Surmontil capsules are white and green printed with "SU 50". Each box contains 50 capsules

Ingredients

Active ingredient:

Each capsule contains 50 mg trimipramine (as trimipramine maleate).

Inactive ingredients:

- starch - maize
- magnesium stearate
- cellulose - microcrystalline
- silica – colloidal anhydrous
- gelatin
- titanium dioxide
- indigo carmine
- iron oxide yellow
- Opacode S-1-8152 HV Black.

Surmontil capsules do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

In Australia:
Aspen Pharmacare Australia Pty
Ltd
34-36 Chandos St
St Leonards NSW 2065

In New Zealand:
Pharmacy Retailing (NZ) Ltd
t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks, Auckland

Australian Registration Number:
50 mg capsules - AUST R 55559

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