

An increased risk of bone fractures has been observed in patients taking this kind of medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trimipramine Capsules

Keep out of the sight and reach of children.

Do not use Trimipramine 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. Keep the blister pack in the carton 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.

If this medicine becomes discoloured or shows any other sign of deterioration, please contact your pharmacist who will advise you on what to do.

6. Further information

What Trimipramine Capsules contain

- Each Trimipramine Capsule contains 50 mg 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 Trimipramine Capsules look like and contents of the pack

Trimipramine 50 mg Capsules are white and green with SU50 printed in black. They are supplied in blister packs of 28 capsules.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm A/S, Energivej 15, 5260 Odense S, DK

Repacked by Orifarm Supply s.r.o., Palouky 1366, 253 01 Hostivice, CZ

Manufactured by Famar Health Care Services Madrid S.A.U., Avenida de Leganes 62, 28923 Alcorcón, Madrid, ES

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.

Trimipramine 50 mg capsules
PL 46927/0016

POM

Leaflet revision date: 26/10/2021

Blind or partially sighted?
Is this leaflet hard to see
or read?

Call +45 63952700
to obtain the leaflet in a
format suitable for you.

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Trimipramine 50 mg Capsules

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

- Please note that the leaflet also contains information about other strengths, Trimipramine 10 mg capsules and Trimipramine 25 mg capsules.
- 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 Trimipramine Capsules are and what they are used for
2. Before you take Trimipramine Capsules
3. How to take Trimipramine Capsules
4. Possible side effects
5. How to store Trimipramine Capsules
6. Further information

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



The name of your medicine is Trimipramine 50 mg Capsules (called Trimipramine in this leaflet). Your capsules contain a medicine called trimipramine. This belongs to a group of medicines called antidepressants.

Trimipramine 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. Before you take Trimipramine Capsules



Do not take this medicine and tell your doctor if:

- x You are allergic (hypersensitive) to trimipramine or any of the other ingredients of Trimipramine Capsules (listed in Section 6 Further Information). Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue
- x You have had a heart attack
- x You have had any other heart problems including slow or uneven heart beat
- x You have severe liver problems
- x You have mania (signs include very high mood, energy and unusual behaviour)
- x You are breast-feeding

Do not take this medicine if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Trimipramine.



Take special care with Trimipramine

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.

If you have diabetes or are at risk of getting diabetes, your doctor may do blood tests to monitor your blood sugar levels.

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

- ▲ You are elderly
- ▲ You have an enlarged prostate gland
- ▲ You have glaucoma (painful eyes with blurred vision)
- ▲ You have or have ever had fits or seizures
- ▲ You have thyroid problems

The use of Buprenorphine together with trimipramine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Trimipramine").

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



Taking other medicines

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 Trimipramine can affect the way some other medicines work. Also some medicines can affect the way Trimipramine work.

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

- MAOI (MonoAmine Oxidase Inhibitors) medicine such as tranylcypromine, phenelzine and isocarboxazid (for Parkinson's disease), **or have taken them in the last 2 weeks**
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat high blood pressure
- Adrenaline, noradrenaline, ephedrine or isoprenaline – used in an emergency
- Phenylephrine or phenylpropanolamine – found in cold and flu preparations
- Medicines used for chest pain (angina) or high blood pressure such as diltiazem, verapamil, clonidine, digitalis
- Medicines used for depression (SSRIs such as citalopram, paroxetine, fluoxetine) tricyclics and triptan derivatives, lithium, St John's Wort

- Pain killers such as tramadol
- **Buprenorphine/opioids.** These medicines may interact with trimipramine 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.
- Macrolide antibiotics, antifungals or fluoroquinolones.

Anaesthetics

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

Taking Trimipramine Capsules and drink

You should avoid drinking alcohol while taking Trimipramine capsules.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

Do not breast-feed if you are taking Trimipramine capsules.



Driving and using machines

Trimipramine capsules may make you feel sleepy or less alert. If this happens, do not drive or use any tools or machines.

3. How to take Trimipramine Capsules

Always take Trimipramine 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 Trimipramine 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 50 mg to 75 mg each day.
- Your doctor may then increase the dose to 150 mg or 300 mg each day depending on your condition
- Once you start to feel better, the usual daily dose then stays the same at 75 mg to 150 mg each day

Elderly:

- Elderly usually start by taking 10 mg to 25 mg three times each day
- Your doctor will then increase this slowly
- Once you start to feel better, the usual daily dose stays the same at 35 mg to 75 mg each day

Children:

Children should not take Trimipramine

If you take more Trimipramine than you should

If you take more Trimipramine 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 Trimipramine

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 Trimipramine

Keep taking Trimipramine until your doctor tells you to stop. Do not stop taking Trimipramine 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, Trimipramine capsules can cause side effects, although not everybody gets them.

Stop taking Trimipramine 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 Trimipramine.

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)
- Convulsions/fits
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Increased thirst and passing water (urine) more often than normal. You may also feel tired and hungry. This could be due to high blood sugar levels or a condition called diabetes
- An uneven or fast heartbeat.

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

- Feeling drowsy or sleepy
- Constipation
- Dry mouth
- 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
- Delay when starting to pass water (urine)
- Skin rash

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An increased risk of bone fractures has been observed in patients taking this kind of medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Surmontil capsules

Keep out of the sight and reach 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. Keep the blister pack in the carton 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.

If this medicine becomes discoloured or shows any other sign of deterioration, please contact your pharmacist who will advise you on what to do.

6. Further information

What Surmontil capsules contain

- Each Surmontil capsule contains 50 mg 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/1/8100 Black: shellac, soya lecithin (E322), antifoam DC1510 and black iron oxide (E172).

What Surmontil capsules look like and contents of the pack

Surmontil 50 mg capsules are white and green with SU50 printed in black. They are supplied in blister packs of 28 capsules.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm A/S, Energivej 15, 5260 Odense S, DK

Repacked by Orifarm Supply s.r.o., Palouky 1366, 253 01 Hostivice, CZ

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**Surmontil 50 mg capsules
PL 46927/0016**

Leaflet revision date: 26/10/2021

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**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Surmontil® 50 mg capsules

(trimipramine maleate)

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

- Please note that the leaflet also contains information about other strengths, Surmontil 10 mg capsules and Surmontil 25 mg capsules.
- 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.
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In this leaflet:

1. What Surmontil capsules are and what they are used for
2. Before you take Surmontil capsules
3. How to take Surmontil capsules
4. Possible side effects
5. How to store Surmontil capsules
6. Further information

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



The name of your medicine is Surmontil 50 mg capsules (called Surmontil capsules in this leaflet). Your capsules contain a medicine called trimipramine. 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. Before you take Surmontil capsules



Do not take this medicine and tell your doctor if:

- x 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, swelling or breathing problems, swelling of your lips, face, throat or tongue
 - x You have had a heart attack
 - x You have had any other heart problems including slow or uneven heart beat
 - x You have severe liver problems
 - x You have mania (signs include very high mood, energy and unusual behaviour)
 - x You are breast-feeding
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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.

If you have diabetes or are at risk of getting diabetes, your doctor may do blood tests to monitor your blood sugar levels.

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

- ▲ You are elderly
- ▲ You have an enlarged prostate gland
- ▲ You have glaucoma (painful eyes with blurred vision)
- ▲ You have or have ever had fits or seizures
- ▲ You have thyroid problems

The use of Buprenorphine together with trimipramine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Trimipramine").

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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.

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- Medicines used to treat high blood pressure
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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 and drink

You should avoid drinking alcohol while taking Surmontil capsules.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Do not breast-feed if you are taking Surmontil capsules.



Driving and using machines

Surmontil capsules may make you feel sleepy or less alert. If this happens, do not drive or use any tools or machines.

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
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- 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 50 mg to 75 mg each day.
- Your doctor may then increase the dose to 150 mg or 300 mg each day depending on your condition
- Once you start to feel better, the usual daily dose then stays the same at 75 mg to 150 mg each day

Elderly:

- Elderly usually start by taking 10 mg to 25 mg three times each day
- Your doctor will then increase this slowly
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Children:

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