

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Surmontil® 10mg Tablets

(trimipramine maleate)

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.

The name of your medicine is Surmontil 10mg Tablets but will be referred to as Surmontil throughout this leaflet. Please note that this leaflet also contains information about other strength Surmontil 25mg Tablets.

In this leaflet:

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

1. What Surmontil is and what it is used for

Your tablets contain a medicine called trimipramine. This belongs to a group of medicines called antidepressants.

Surmontil 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

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 (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
- X You have had a heart attack
- X You have had any other heart problems including slow or uneven heartbeat
- 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 Surmontil.

Take special care with Surmontil 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 Surmontil can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Surmontil').

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

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 Surmontil can affect the way some other medicines work. Also some medicines can affect the way Surmontil works.

Tell 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**
- 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 Surmontil 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 floroquinolones.

Anaesthetics

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

Taking Surmontil with food and drink

You should avoid drinking alcohol while taking Surmontil.

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.

Driving and using machines

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

Important information about some of the ingredients of Surmontil

Surmontil contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Surmontil

Always take Surmontil 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 tablets whole with a drink of water

- If you have been told to take Surmontil only once each day then you should take it before going to bed
- It may take 7 to 10 days before 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 50mg to 75mg 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 10mg to 25mg 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 35mg to 75mg each day

Children:

Children should not take Surmontil.

If you take more Surmontil than you should

If you take more Surmontil 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

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

Keep taking Surmontil until your doctor tells you to stop. Do not stop taking Surmontil just because you feel better. This is because your illness may come back. When your doctor tells you to stop taking these tablets 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 can cause side effects, although not everybody gets them.

Stop taking Surmontil 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.

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

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

Keep out of the sight and reach of children.

Do not use after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

Store in the original container to protect from light.

Do not store above 25°C.

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 the tablets become discoloured or show any signs of deterioration, you should seek the advice of your pharmacist.

6. Further information

What Surmontil contains

The active ingredient in Surmontil is trimipramine.

Each tablet contains 10mg trimipramine (as maleate).

Other ingredients are: potato starch, calcium hydrogen phosphate dihydrate, talc, magnesium stearate, lactose monohydrate, hypromellose, titanium dioxide (E171) and macrogol.

What Surmontil looks like and contents of the pack

Surmontil are white to off-yellow, circular, biconvex film-coated tablet, one faced impressed 'SURMONTIL' just inside the perimeter around a centrally impressed '10', reverse face has an incomplete score line.

The tablets are available as blister packs of 100 tablets.

Manufactured by: Famar Health Care Services Madrid S.A.U., Alcorcon, Spain.

Procured from within the EU and

repackaged by the Product Licence

holder: B&S Healthcare, Unit 4, Bradfield

Road, Ruislip, Middlesex, HA4 0NU, UK.

Surmontil® 10mg Tablets; PL 18799/2856

Leaflet date: 23.12.2022

POM

Surmontil is a registered trademark of SANOFI.

**Blind or partially sighted?
Is this leaflet hard to see or
read? Call 0208 515 3763 to
obtain the leaflet in a format
suitable for you.**

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Trimipramine 10mg tablets

(trimipramine maleate)

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.

The name of your medicine is Trimipramine 10mg tablets but will be referred to as Trimipramine throughout this leaflet. Please note that this leaflet also contains information about other strength Trimipramine 25mg tablets.

In this leaflet:

1. What Trimipramine is and what it is used for
2. Before you take Trimipramine
3. How to take Trimipramine
4. Possible side effects
5. How to store Trimipramine
6. Further information

1. What Trimipramine is and what it is used for

Your tablets 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

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 (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
- X You have had a heart attack
- X You have had any other heart problems including slow or uneven heartbeat
- 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.

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 works.

Tell 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
- 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 Surmontil 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.

Taking Trimipramine with food and drink

You should avoid drinking alcohol while taking Trimipramine.

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.

Driving and using machines

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

Important information about some of the ingredients of Trimipramine

Trimipramine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Trimipramine

Always take Trimipramine 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 tablets 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 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 50mg to 75mg 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 10mg to 25mg 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 35mg to 75mg 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 tablets 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 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

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

Keep out of the sight and reach of children.

Do not use after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

Store in the original container to protect from light.

Do not store above 25°C.

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 your medicine becomes discoloured or show any signs of deterioration, seek the advice of your pharmacist.

6. Further information

What Trimipramine contains

The active ingredient in Trimipramine is trimipramine.

Each tablet contains 10mg trimipramine (as maleate).

Other ingredients are: potato starch, calcium hydrogen phosphate dihydrate, talc, magnesium stearate, lactose monohydrate, hypromellose, titanium dioxide (E171) and macrogol.

What Trimipramine looks like and contents of the pack

Trimipramine are white to off-yellow, circular, biconvex film-coated tablet, one faced impressed 'SURMONTIL' just inside the perimeter around a centrally impressed '10', reverse face has an incomplete score line.

The tablets are available as blister packs of 100 tablets.

Manufactured by: Famar Health Care Services Madrid S.A.U., Alcorcon, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Trimipramine 10mg tablets; PL 18799/2856

Leaflet date: 23.12.2022

POM

Blind or partially sighted?

Is this leaflet hard to see or read? Call **0208 515 3763** to obtain the leaflet in a format suitable for you.