

Package leaflet: Information for the user

Tianeptine 12.5 mg Film Coated Tablets (Tianeptine Sodium)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tianeptine 12.5 mg Tablets are and what they are used for.
2. What you need to know before you take Tianeptine 12.5 mg Tablets
3. How to take Tianeptine 12.5 mg Tablets
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1. What Tianeptine 12.5 mg tablets are and what they are used for

Tianeptine is an antidepressant and is used in the treatment of mild, moderate or severe depression.

2. What you need to know before you take Tianeptine 12.5 mg tablets

Do not take Tianeptine 12.5 mg Tablets:

- If you are allergic to tianeptine or any of the other ingredients of this medicine (listed in section 6).
- currently taking or have taken within the last two weeks, any monoamine oxidase inhibitors (MAOIs), i.e. medication containing the following active ingredients: phenelzine, tranylcypromine or isocarboxazid.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tianeptine 12.5 mg Tablets.

If you are depressed and/or have episodes of anxiety, you may sometimes think of doing harm to yourself or even committing suicide. These thoughts can increase at the beginning of treatment with antidepressants because these medicines take time to act. It usually takes about two weeks, sometimes even longer, for their therapeutic effects to be felt.

You may be more inclined to have these kinds of thoughts in the following situations: if you:

- have a history of having thoughts about harming yourself or committing suicide.
- are a young adult. Clinical studies have shown that the risk of suicidal behaviour is greater in adults under 25 years of age with psychiatric problems being treated with antidepressants.

If at any time you have thoughts of harming yourself or committing suicide, you should immediately contact your doctor or go to hospital.

It may be useful for you to tell a family member or someone who is close to you that you are depressed or have episodes of anxiety. Give them this leaflet to read. You might also ask them to let you know if they notice that your depression or anxiety is getting worse or if they are concerned about changes in your behaviour.

If you are required to undergo a medical procedure that requires the use of a general anaesthetic, tell the doctor and/or anaesthetist in advance that you are taking Tianeptine 12.5 mg tablets, as the treatment should be suspended 24 to 48 hours prior to the procedure.

Tell your doctor if you have a history of drug dependence or alcohol dependence.

Other medicines and Tianeptine 12.5 mg Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take if you are currently being treated, or have been treated within the last two weeks with any monoamine oxidase inhibitor (MAOIs), i.e. medication containing the following active ingredients: phenelzine, tranylcypromine or isocarboxazid.

If you are using cannabis or taking cannabis based medication please consult your doctor, as several cases have been reported of an increase in heart rate and a state of confusion developing when cannabis was combined with tricyclic antidepressants.

Tianeptine 12.5 mg Tablets with food and drink and alcohol

Tianeptine 12.5 mg tablets should be taken before or during main meals

You should not consume alcohol during treatment with tianeptine

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 or pharmacist for advice before taking this medicine.

Treatment with tianeptine is not recommended during pregnancy or while breast-feeding.

Driving and using machines

Some patients may experience reduced alertness during treatment with tianeptine. Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how tianeptine affects you.

3. How to take Tianeptine 12.5 mg tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 (one) 12.5 mg tablet three times a day (one in the morning, one at midday, and one in the evening) taken before or during main meals. Do not exceed recommended doses.

If you are over the age of 70 or suffering with kidney failure, your doctor may reduce the dose to 2 tablets a day.

Use in children and adolescents

Tianeptine is not recommended for use in children or adolescents under 18 years of age. As its safety and efficacy have not been evaluated.

If you take more Tianeptine 12.5 mg Tablets than you should

If you accidentally take too many tablets, contact your doctor, pharmacist or the nearest hospital immediately. Symptoms may include a sense of confusion, fits (seizures), drowsiness, a dry mouth and trouble breathing, especially when consumed with alcohol.

If you forget to take Tianeptine 12.5 mg Tablets

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

If you stop taking Tianeptine 12.5 mg Tablets

Do not stop taking your medicine unless your doctor tells you to.

Treatment with tianeptine should not be discontinued suddenly. As with other antidepressants the dose should be reduced gradually over a period of 7 to 14 days.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have thoughts of harming or killing yourself during tianeptine treatment or soon after stopping treatment **contact your doctor or to a hospital straight away**

Common side effects (may affect up to 1 in 10 people)

- Increased heart rate
- Irregular heart beat
- Chest pain
- Difficulty sleeping,
- Drowsiness,
- Dizziness
- Headache,
- Shivers
- Weakness
- Tremors.
- Shortness of breath
- Dry mouth
- Constipation
- Abdominal pain
- Nausea
- Vomiting
- Indigestion
- Diarrhoea
- Flatulence,
- Heart burn.
- Back pain,
- Muscle pain.
- Poor appetite.
- Hot flushes.
- Loss of strength
- Sensation of a lump in the throat
- Nightmares
- Problems with your eye sight
- Fainting or feeling faint
- Stomach pain

Uncommon side effects (may affect up to 1 in 100 people)

- Skin rash
- Itchy skin
- Drug abuse and drug dependency, especially in patients under the age of 50 years old whose medical history includes drug or alcohol dependency.

Not known (frequency cannot be estimated from the available data)

- Suicidal thoughts, and suicidal behaviour during or immediately following the suspension of treatment.
- Acne
- Formation of blisters on the skin
- Confusional state
- Hallucination
- Involuntary movements
- Low sodium levels in blood plasma
- Increased liver enzymes
- A liver disease with symptoms such as nausea, vomiting, loss of appetite, fever, yellowing of skin and eyes and dark coloured urine (hepatitis). In exceptional cases this may be severe.

The intensity and frequency of most side effects decreases as the treatment progresses and generally does not lead to the suspension of treatment.

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 (national reporting system).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tianeptine 12.5 mg tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 25°C

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tianeptine 12.5 mg Tablets contains

The active substance is tianeptine sodium 12.5 mg.

The other ingredients are:

Tablet core:

Mannitol (E421)

Maize starch

Carmellose sodium

Povidone

Silica colloidal anhydrous

Talc (E553b)

Magnesium stearate (E470b)

Film coating:

Opadry AMB 80W68912

Which contains:

Polyvinyl alcohol

Titanium dioxide (E171)

Talc (E553b)

Lecithin (E322)

Xanthan gum (E415))

What Tianeptine 12.5 mg Tablets looks like and contents of the pack

Tianeptine 12.5 mg Tablets are white to off-white oval shaped tablets, plain on both sides.

Tablets are available in packs of 1, 15, 30, 60 and 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Lupin (Europe) Limited

Victoria Court

Bexton Road

Knutsford

Cheshire

WA16 0PF

United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Poland	Tianeptine-Lupin 12,5 mg tabletki powlekane
Portugal	Tianeptina Lupin 12.5 mg Comprimidos revestidos por película

This leaflet was last revised in: (MM/YYYY)