

STABLON® 12.5 mg

Sodium Tianeptine

Sugar Coated Tablet

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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What is STABLON 12.5 mg, sugar coated tablet and what it is used for?
2. Necessary information before you take STABLON 12.5 mg, sugar coated tablet.
3. How to take STABLON 12.5 mg, sugar coated tablet.
4. What are the possible side effects.
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1. WHAT IS STABLON 12.5 mg, sugar coated tablet AND WHAT IT IS USED FOR

ANTI-DEPRESSANT

This drug is recommended in depressive states of mild, moderate or severe intensity.

2. What you need to know before you take STABLON 12.5 mg, sugar coated tablet

Do not take STABLON 12.5 mg, sugar coated tablet:

- in combination with drugs for depression of the non-selective MAOI class (see: Other medicines and STABLON sugar coated tablet).
- if you are allergic to tianeptine or any of the other ingredients of this medicine (listed in section 6).
- in children under 15 years of age.

IF YOU ARE IN ANY DOUBT, YOU MUST CONSULT YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE.

Take special care with STABLON 12.5 mg sugar coated tablet:

Special warnings

Prolonged use at high doses may lead to dependency.

Do not exceed the recommended doses.

Suicidal thoughts and worsening of your depression or anxiety disorder

If you suffer from depression and/or anxiety disorder, you may sometimes have thoughts about self-harming (causing harm to yourself) or suicide. These signs can sometimes get worse during the early stages of treatment with an antidepressant, because drugs of this type do not act immediately but only after 2 weeks or more of treatment.

You are more likely to experience signs of this type in the following situations:

- if you have already had suicidal or self-harming thoughts in the past.
- if you are a young adult. Clinical trials have shown that the risk of suicidal behaviour was greater in adults under 25 years of age who had a psychiatric illness and were receiving antidepressant treatment.

If you experience suicidal or self-harming thoughts, contact your doctor immediately or go to straight to the hospital.

You can seek help from a friend or relative by explaining that you suffer from depression or anxiety disorder and asking him or her to read this leaflet. You can ask this person to tell you if he or she thinks that your depression or anxiety is getting worse, or if he or she is concerned about changes in your behaviour.

This medicinal product contains sucrose, and so it must not be used if you have fructose intolerance, glucose and galactose malabsorption syndrome, or sucrose-isomaltase deficiency (rare metabolic conditions).

Precautions for use

Do not discontinue the treatment suddenly, but reduce the dosage over a period of 7 to 14 days.

If you must undergo general anaesthesia, it is advisable to notify the anaesthetist and to discontinue the treatment 24 or 48 hours before the operation.

Notify your doctor in case of renal insufficiency.

IF YOU ARE IN ANY DOUBT, YOU MUST CONSULT YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE

Other medicines and STABLON 12.5 mg sugar coated tablet:

Taking this drug in combination with certain drugs of the MAOI class (prescribed in cases of depression) may have very serious consequences; following treatment with an MAOI, wait two weeks before starting to take this drug.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility:

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.

Taking STABLON 12.5 mg sugar coated tablet should be avoided during pregnancy and lactation.

Driving and using machines

Some patients may experience a reduction in alertness. The attention of drivers and machine operators is therefore drawn to the possibility of somnolence occurring with the use of STABLON 12.5 mg sugar coated tablet.

List of excipients with a known effect: sucrose.

3. HOW TO TAKE STABLON 12.5 mg, sugar coated tablet

Dosage

The recommended dosage is 1 tablet three times a day, morning, midday and evening, at the beginning of the main meals.

In subjects aged over 70 years, and in subjects with renal insufficiency, the dosage should be restricted to 2 tablets per day. Do not discontinue the treatment without consulting your doctor.

ALWAYS TAKE THIS MEDICINE EXACTLY AS YOUR DOCTOR HAS PRESCRIBED:

If you take more STABLON 12.5 mg sugar coated tablet than you should:

Method of administration

Oral route.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, STABLON 12.5 mg, sugar coated tablet can cause side effects, although not everybody gets them.

- stomach ache, abdominal pain, dry mouth, loss of appetite, nausea, vomiting, constipation, flatulence,
- insomnia, drowsiness, extrapyramidal symptoms (rigidity, reduced movements), involuntary movements, nightmares, confusional state, hallucinations, fatigue,
- palpitations, cardiac disorders, pain in the region in front of the heart, quickening of the heartbeat,
- dizziness, headache, malaise, tremor, hot flushes,
- difficulty in breathing, lump in the throat,
- muscle pain or lower-back pain,
- skin rash, itching, urticaria, dermatitis bullous in exceptional cases,
- increased liver enzymes, hepatitis that can, in exceptional cases, be severe,
- hypernatremia.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW SHOULD STABLON 12.5 mg, sugar coated tablet BE STORED

Keep out of the reach and sight of children.

Do not use STABLON 12.5 mg, sugar coated tablet after the expiry date which is stated on the box.

The expiry date refers to the last day of that month.

Protect from direct light, heat & moisture.

Medicines should not be disposed of via waste water or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

What Stablion 12.5 mg, sugar coated tablet contains

The drug substance is:

Tianeptine (sodium salt)..... 12.5 mg

For one sugar coated tablet.

The other ingredients are:

D-mannitol, maize starch, talc, magnesium stearate.

Coating: ethylcellulose, glycerol oleate, SEPIFILM SE 700 White (povidone, sodium carmellose, anhydrous colloidal silica, talc, sucrose, polysorbate 80, titanium dioxide, sodium hydrogen carbonate), white beeswax.

What STABLON 12.5 mg, sugar coated tablet looks like and contents of the pack?

This medicine is in the form of sugar coated tablets. Box of 30.



Manufactured by:
Servier Research & Pharmaceutics (Pakistan) (Pvt) Ltd.
9-km Sheikhpura Road, Lahore - Pakistan
Under Licence Les Laboratoires Servier-France