Package leaflet: Information for the patient

STABLON®

Tianeptine (sodium salt): 12.5 mg

سٹیبلون®

ٹایانیپٹین (سوڈیم سالٹ) 12.5 ملی گرام

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 of the 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 STABLON 12.5 MG, COATED TABLET IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group - ATC code: N06AX14
ANTIDEPRESSANT
This medicine is recommended in depressive states of mild, moderate or severe intensity.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE STABLON 12.5 mg, coated tablet

Do not take STABLON 12.5 mg, coated tablet
- if you are allergic to tianeptine or any of the other ingredients of this medicine, listed in section 6,
- in children and adolescents under 15 years of age.

IF YOU ARE IN ANY DOUBT, IT IS ESSENTIAL TO CONSULT YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE.

Warnings and precautions

Warning

Talk to your doctor or pharmacist before taking STABLON 12.5 mg, coated tablet.
Prolonged use at high doses may lead to dependency.
Do not exceed the recommended doses.
If you are currently taking an antidepressant from the MAOIs class (see also "Other medicines and STABLON 12.5 mg, coated tablet" in section 2) and you need to be treated with tianeptine, you must stop taking the MAOI for two weeks before starting STABLON treatment. If you need to replace STABLON by a MAOI, a transition period of 24 hours is sufficient.
Patients with rare hereditary diseases of fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase insufficiency should not take this medicine.

Suicidal thoughts and worsening of your depression

If you suffer from depression, 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 this type of medication does 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 straight to the hospital.
You can seek help from a friend or relative by explaining that you suffer from depression 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 is getting worse, or if he or she is concerned about changes in your behaviour.

Precautions for use

Do not discontinue the treatment suddenly, but reduce the dosage gradually over a period of 7 to 14 days. After stopping tianeptine treatment, you need to know that you may experience certain side effects. These include anxiety, muscle pain, abdominal pain, insomnia, joint pain.
If you must undergo general anaesthesia, it is advisable to notify the anaesthetist who may discontinue the treatment 24 or 48 hours before the operation.
Notify your doctor in case of renal failure.
IF YOU ARE IN ANY DOUBT, DO NOT HESITATE TO CONSULT YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE.

Children and adolescents

The use of STABLON is contraindicated in children and adolescents under 15 years old and inadvisable in adolescents aged 15 to 18 years old. It is also important to know that patients under 18 years old have a higher risk of side effects such as suicide attempts, suicidal thoughts and hostile behaviour (mainly aggressiveness, opposition behaviour and anger) when treated with this class of medicines.
However, your doctor may prescribe this medicine to patients under 18 years old, if he/she believes it is in the interest of the patient. Please contact your doctor if he/she prescribed this medicine to a patient under 18 years old and you would like to discuss it.
You must tell your doctor if one of the symptoms listed above appears or becomes worse in a patient under 18 years old treated with STABLON.
You must also be aware that the long-term safety of this medicine concerning growth, maturation and cognitive and behavioural development has not yet been established for this age group.

Other medicines and STABLON 12.5 mg, coated tablet

Taking this medicine combined with certain medicines of the MAOI class (prescribed in cases of depression) may have very serious consequences, such as: high blood pressure, very high body temperature, seizures and death. In the event of the replacement of a treatment with an MAOI, wait two weeks before starting to take this medicine.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

STABLON 12.5 mg, coated tablet with food, drink and alcohol

Avoid drinking alcoholic beverages or using medicines containing alcohol.

Pregnancy and lactation

The use of this medicine should generally be avoided during pregnancy. If you discover that you are pregnant, consult your doctor, as he/she alone can decide whether the treatment should be continued or modified.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

In certain patients a decreased level of alertness may occur. Therefore, the attention of drivers and users of machines should be drawn to the risks of drowsiness associated with the use of this medicine.

STABLON 12.5 mg, coated tablet contains sucrose.

If your doctor has informed you of an intolerance to certain sugars, please contact him/her before taking this medicine.

STABLON 12.5 mg, coated tablet contains sodium

STABLON contains less than 1 mmol sodium (23mg) per coated-tablet, i.e. is essentially 'sodium-free'.

3. HOW TO TAKE STABLON 12.5 mg, coated tablet

Posology

The recommended posology is 1 tablet three times a day, morning, midday and evening, at the beginning of the main meals.
In patients with kidney or liver failure and in elderly patients, the posology is established by the doctor.
Do not discontinue the treatment without consulting your doctor.
ALWAYS TAKE THIS MEDICINE EXACTLY AS YOUR DOCTOR HAS PRESCRIBED.

Use in children and adolescents

Tianeptine is contraindicated in children and adolescents under 15 years old. Tianeptine is not recommended in children and adolescents under 18 years old.

Method of administration

Oral route.

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

The symptoms of a possible overdose could include

alertness disorders which may lead to coma, especially in case of multiple intoxication.
If you take more STABLON than you should, contact your doctor or pharmacist immediately. The STABLON treatment must be suspended immediately in such a case.

If you forget to take STABLON 12.5 mg, film-coated tablet:
Not applicable.

If you stop taking STABLON 12.5 mg, film-coated tablet:
Not applicable.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The undesirable effects observed with tianeptine have been of moderate intensity. They consist primarily of nausea, constipation, abdominal pain, drowsiness, headaches, dry mouth and vertigo.

The frequency of the possible undesirable effects listed below is defined using the following system:
- very common (affects more than 1 user out of 10)
- common (affects 1 to 10 users out of 100)
- uncommon (affects 1 to 10 users out of 1,000)
- rare (affects 1 to 10 users out of 10,000)
- very rare (affects less than 1 user out of 10,000)
- frequency not known (cannot be estimated from the available data)

The undesirable effects are the following:

- Common undesirable effects:
- loss of appetite,
- nightmares, insomnia, drowsiness, vertigo, headache, malaise, tremors,
- stomach ache, abdominal pain, dry mouth, nausea, vomiting, constipation, flatulence,
- palpitations, pain in the region in front of the heart, quickening of the heartbeat, hot flushes, difficulty in breathing,
- muscle pain or lower-back pain,
- tiredness, lump feeling in throat.

- Uncommon undesirable effects:
- skin rash, itching, hives, dependence.

- Undesirable effects of unknown frequency:
- suicidal thoughts and behaviour,
- confusion, hallucinations,
- acne, bullous reactions (blisters) in exceptional cases,
- increased liver enzymes, hepatitis that can, in exceptional cases, be severe,
- extrapyramidal symptoms (rigidity, reduced movements), involuntary movements,
- hyponatremia.

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 to Drug Regulatory Authority of Pakistan www.dra.gov.pk or to company website www.servier.com.pk
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE STABLON 12.5 mg, coated tablet

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 box. The expiry date refers to the last day of that month.
Store at a temperature below 30°C (climate zones III and IV).
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What STABLON 12.5 mg, coated tablet contains
- The active substance is:

Tianeptine (sodium salt) ..... 12.5 mg.
For one coated tablet

- The other ingredients are:

D-mannitol, maize starch, talc, magnesium stearate.
Coating: ethylcellulose, glycerol oleate, SEPIFILM SE 700 White (polyvidone, carmellose sodium, anhydrous colloidal silica, talc, sucrose, polysorbate 80, titanium dioxide, sodium bicarbonate), white beeswax.

What STABLON 12.5 mg, coated tablet is and content of outer packaging
This medicinal product is available in the form of coated tablets. Blister of 30 tablets.

Marketing authorisation Holder & Manufacturer
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10. DATE OF REVISION OF THE TEXT

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