

STABLON 12.5mg coated tablets

Sodium tianeptine 12.5mg

What is in this leaflet

1. What STABLON 12.5mg is and what it is used for
2. How StablON 12.5mg works
3. Before you use STABLON 12.5mg
4. How to use STABLON 12.5mg
5. While you are using STABLON 12.5mg
6. Side effects of STABLON 12.5mg
7. Storage and Disposal of STABLON 12.5mg
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What STABLON 12.5mg is and what it is used for

STABLON 12.5mg is an antidepressant.

This medicine is recommended in :

- Neurotic and reactive depression
- Anxio-depressive states with psychosomatic manifestations, especially gastrointestinal
- Anxio-depressive states in alcoholic during withdrawal stage.

How STABLON 12.5mg works

The active ingredient of STABLON 12.5mg, tianeptine increases the activity of cells in the brain and increases the rate of serotonin (a type of brain chemical) reuptake by neurones in the brain. Serotonin is important for nerve cells to communicate, which controls many body activities, including regulating mood.

Before you use STABLON 12.5mg

- When you must not use it

Do not take STABLON 12.5mg

- if you are allergic (hypersensitive) to tianeptine or

- any of the other ingredients of STABLON 12.5mg,
- in children under 15 years of age,
- in combination with drugs for depression of the non-selective MAOI class (see section "Taking other medicines").

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

- Before you start to use it

Warnings and precautions

- Prolonged use at high doses may lead to dependency.
- Do not exceed the recommended doses.
- 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 kidney or liver failures.
- As with any psychotropic treatment, the administration of this medicinal product with alcoholic beverages or medicinal products containing alcohol is inadvisable.
- As with all psychotropic agents, on treatment discontinuation it is recommended to reduce the dosage over a period of 7 to 14 days.
- In case of a history of drug-dependence or alcohol-dependence, the patients must be very closely monitored in order to avoid any increase in dosage.
- A combination with MAOI (antidepressant medicine) is inadvisable. It is necessary to allow a free interval:
 - of two weeks when tianeptine is used as a replacement of MAOI,

- of 24 hours when a MAOI is used as a replacement of tianeptine.
- This medicinal product contains sucrose. Its use is inadvisable in patients with fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare hereditary diseases),
- This medicinal product contains less than 1 mmol sodium (23mg) per coated-tablet, essentially it is considered 'sodium-free'.

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 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.

Children and adolescents

STABLON 12.5mg must not be given to children and adolescents under 15 years old and should not be given to children and adolescents aged 15-18 years.

- Taking other medicines

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.

How to use STABLON 12.5mg

- When to use it

Take your tablet three times a day, at the beginning of the main meals; morning, midday and evening.

- How much to use

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

In patients aged over 70 years, and in subjects with kidney or liver failures, 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.

- Use in children and adolescent

STABLON 12.5mg must not be given to children and adolescents under 15 years old and should not be given to children and adolescents aged 15-18 years.

- How long to use it

Do not discontinue the treatment without consulting your doctor.

ALWAYS TAKE THIS MEDICINE EXACTLY AS YOUR DOCTOR HAS PRESCRIBED.

- If you forget to use it

It is important to take your medicine every day as regular treatment is more effective. However, if you forget to take a dose of STABLON 12.5mg, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose):

If you take too many tablets or experience sudden tianeptine intoxication (maximum quantity: 2250mg, taken in a single dose), contact your doctor or nearest hospital casualty immediately. The most likely effect in case of overdose is alertness problems which may lead to coma, especially in patients who has experienced multiple intoxications.

- If you stop taking

Do not discontinue the treatment without consulting your doctor.

After stopping the treatment, you may experience certain side effects such as anxiety, muscle pain, abdominal pain, insomnia and joint pain.

ALWAYS TAKE THIS MEDICINE EXACTLY AS YOUR DOCTOR HAS PRESCRIBED.

While you are using STABLON 12.5mg

- Things you must do

Pregnancy and breast-feeding

The use of this drug should generally be avoided during pregnancy. If you discover that you are pregnant consult your doctor, he alone can decide whether the treatment should be continued or modified.

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

STABLON 12.5mg is not recommended for use in pregnancy, irrespective of the term.

If STABLON 12.5mg is required to maintain the mother's psychic state, this medicine must be started or continued at the effective dose advised by your doctor and if possible, not taken with any other medicines and the laboratory data must be considered when monitoring the newborn baby.

Breast-feeding

STABLON 12.5mg is excreted into the breast milk. Hence, it is not recommended to breastfeed during the duration of the treatment. See your doctor immediately.

- Things to be careful of

Driving and using machines

In certain patients a decreased level of alertness may occur. Attention is thus drawn to the risks of drowsiness associated with the use of this drug, especially in the case of vehicle drivers and machine operators.

Important information about some of the ingredients of STABLON 12.5mg

STABLON 12.5mg contains sucrose, and so it must not be used if you have fructose intolerance, glucose and galactose malabsorption syndrome, or sucrase-isomaltase deficiency (rare metabolic conditions).

Consult your doctor before taking this medicine.

Side effects of STABLON 12.5mg

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

Stop taking the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:

- stomach ache, abdominal pain, dry mouth, loss of appetite, nausea, vomiting, constipation, flatulence,
- insomnia, drowsiness, extrapyramidal symptoms (rigidity, reduced movements), involuntary movements, nightmares, confused 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, urticarial/hives, dermatitis bullous in exceptional cases, acne
- increased liver enzymes, hepatitis that can, in exceptional cases, be severe,
- hyponatremia (low sodium content in blood).

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))].

Storage and Disposal of STABLON 12.5mg

Storage

Keep this medicine out of the sight and reach of children.
Do not use STABLON 12.5mg 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.

Disposal

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.

Product description

What it looks like

STABLON 12.5 mg is in the form of coated tablets. It is available in box of 30 tablets.

Ingredients

Active ingredient(s)

- The active substance is tianeptine (sodium salt). One tablet contains 12.5 mg tianeptine (sodium salt).

Inactive ingredients

- The other ingredients in the tablet core are: D-mannitol, maize starch, talc, magnesium stearate, ethylcellulose, glycerol oleate, SEPIFILM SE 700 White (povidone, sodium carmellose, anhydrous colloidal silica, talc, sucrose, polysorbate 80, titanium dioxide, sodium hydrogen carbonate), white beeswax.

Registration number

MAL19992995AZ

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Product Registration Holder

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