ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

STABLON 12.5 mg, coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For one coated tablet.

Excipient: sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Major depressive episodes (i.e. typical).

4.2 Posology and method of administration

The recommended dosage is one 12.5 mg tablet three times a day (morning, midday and evening) at the beginning of the main meals.

In chronic alcoholics, whether cirrhotic or not, no alteration of the dosage is necessary.

In subjects aged over 70 years, and in subjects with renal insufficiency, the dosage should be restricted to 2 tablets per day.

4.3 Contraindications

- Hypersensitivity to tianeptine or to any of the excipients listed in section 6.1.
- Children and adolescents under 15 years old.
- Association with MAOIs (see section 4.5).
- A wash-out period of two weeks is necessary between treatment with MAOIs and treatment with tianeptine. A wash-out period of only 24 hours is required when replacing tianeptine with an MAOI.

4.4 Special warnings and precautions for use

Suicide/suicidal thoughts or clinical worsening

Depression is associated with an increased risk of suicidal thoughts, self-harming and suicidality (suicidal behaviour). This risk persists until a significant remission has been obtained. Clinical improvement may not be obtained until after several weeks of treatment, and so patients must be closely monitored until this improvement has been achieved. Clinical experience shows that the risk of suicide can increase during the very early stages of recovery.

Patients with a history of suicidal behaviour or those expressing significant suicidal thoughts before starting the treatment face a higher risk of the onset of suicidal thoughts or suicidal behaviour, and must be closely monitored during treatment. A meta-analysis of placebo-controlled clinical trials of the use of antidepressants in adults displaying psychiatric disorders has revealed an increase in the risk of suicidal behaviour in patients under 25 years of age who were being treated with antidepressants compared to those receiving a placebo. Careful monitoring of patients, and particularly of high-risk patients, must accompany use of this medication, particularly at the beginning of treatment and at times of dose changes.

The patients (and their family and friends) must be alerted to the need to monitor for the onset of clinical worsening, the appearance of suicidal thoughts/behaviour and any abnormal change of behaviour, and to seek medical advice immediately if such symptoms present.

If general anaesthesia is necessary, the anaesthetist should be informed of the treatment, and the drug discontinued 24 or 48 hours prior to surgery.

In an emergency, surgery may be performed without an intervening wash-out period; peroperative monitoring should be performed.

As with any psychotropic drug, this medicinal product should not be taken with alcoholic beverages or medicines containing alcohol.

As with all psychotropic agents, if the treatment is to be interrupted, the dosage should be gradually reduced over a period of 7 to 14 days.

If there is a history of drug dependence or alcohol dependence, the patients must be kept under very close surveillance in order to avoid any increase in dosage.

Do not exceed the recommended doses.

This medicinal product contains sucrose. Its use is contraindicated in patients with fructose intolerance, glucose and galatose malabsorption syndrome or sucrase-isomaltase deficiency (rare inherited diseases).

Paediatric population:

Stablon is contraindicated in children and adolescents under 15 years old (see section 4.3) and should not be used in adolescents aged 15 to 18 years old. Suicidal type (suicide attempts and suicidal thoughts) and hostile type (mainly aggressiveness, opposition behaviour and anger) behaviour has been observed more frequently during clinical studies in children and adolescents treated with antidepressants compared to those treated with placebo. However, if treatment is clinically required, the patient must be closely monitored to detect the appearance of suicidal symptoms. Furthermore, there is no long term safety data in children and adolescents concerning the effects on growth, sexual maturation and cognitive and behavioural development.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations that are inadvisable

+ **irreversible MAOIs (iproniazide):** because of the risk of cardiovascular collapse or paroxysmal hypertension, hyperthermia, convulsions, death.

4.6 Fertility, pregnancy and lactation

Pregnancy

It is preferable to maintain a balanced maternal psychic equilibrium throughout pregnancy. If medical treatment is necessary to ensure this balance, treatment should be initiated or continued at the necessary dose throughout pregnancy and if possible as monotherapy.

Animal data is reassuring but clinical data is still insufficient.

In consideration of this data, it is preferable not to use tianeptine during pregnancy whatever the term. If initiation or continuation of treatment by tianeptine proves to be vital during pregnancy, the pharmacological profile of the molecule should be taken into account when monitoring the newborn baby.

Breast-feeding

Tricyclic antidepressants are excreted into breast milk, and thus breast feeding is not recommended during treatment.

Fertility

A study demonstrated in rats a decrease in reproductive performance in females (increase in pre-implantation losses) at a maternotoxic dose.
The clinical impact is unknown.

4.7 Effects on ability to drive and use machines

Some patients may experience diminished alertness. The attention of drivers and machine-operators in particular should thus be drawn to the risk of somnolence with this product.

4.8 Undesirable effects

Summary of safety profile:

Side effects reported with tianeptine in clinical trials are of mild intensity. They consist mainly in nausea, constipation, abdominal pain, somnolence, headache, dry mouth and dizziness.

Tabulated list of undesirable effects

The following undesirable effects have been reported during clinical trials and/or post marketing use with tianeptine and are ranked using the following frequency:

Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10,000, <1/1000); very rare (<1/10,000), and not known (cannot be estimated from the available data).

System Organ Class (SOC)	Frequency	Undesirable effects
Metabolism and nutrition disorders	Common	Anorexia
	Not known*	Hyponatremia
Psychiatric disorders	Common	Nightmare
	Uncommon	Drug abuse and dependence, in particular in subjects less than 50 years old with a history ofdrug or alcohol dependence
	Not known*	Cases of suicidal thought or behaviour have been reported during treatment with tianeptine or shortly after discontinuation (see section 4.4)
		Confusional state, hallucination
Nervous system disorders	Common	Insomnia
		Somnolence

System Organ Class (SOC)	Frequency	Undesirable effects
		Dizziness
		Headache
		Lipothymia
		Tremor
	Not known*	Extrapyramidal disorder
		Dyskinesia
Cardiac disorders	Common	Tachycardia
		Extrasystoles
		Chest pain
Vascular disorders	Common	Hot flush
Respiratory, thoracic and mediastinal disorders	Common	Dyspnoea
Gastrointestinal disorders	Common	Gastralgia
		Abdominal pain
		Dry mouth
		Nausea
		Vomiting
		Constipation
		Flatulence
Skin and subcutaneous tissue disorders	Uncommon	Maculopapular or erythematous rash
		Pruritus
		Urticaria
	Not known*	Acne
		Dermatitis bullous in exceptional cases
Musculoskeletal and connective tissue disorders	Common	Myalgia
		Lumbar pain
General disorders and administration site conditions	Common	Asthenia
		Lump feeling in throat
Hepatobiliary disorders	Not known*	Increased liver enzymes
		Hepatitis that can, in exceptional cases, be severe

*Post-marketing data

<u>Reporting of suspected adverse reactions</u>

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

French National Agency for Medicines and Health Products Safety (ANSM) and the Regional Pharmacovigilance Centres network.

www.ansm.sante.fr

4.9 Overdose

Symptoms

The experience concerning acute tianeptine intoxication cases (maximum quantity: 2250 mg, ingested in a single administration) have mainly revealed alertness disorders that may even cause coma, especially in case of multiple intoxication.

Treatment

There is no known specific tianeptine antidote. In case of acute intoxication, a symptomatic treatment and routine monitoring must be implemented. Medical monitoring in a specialised setting is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: OTHER ANTIDEPRESSANTS

ATC code: N06AX14

Tianeptine is an antidepressant.

In animals, tianeptine has the following properties:

- Tianeptine increases the spontaneous activity of pyramidal cells in the hippocampus and accelerates their recovery after functional inhibition,
- Tianeptine increases the rate of serotonin re-uptake by neurons in the cortex and hippocampus.

In man, tianeptine is characterised by:

- marked action on somatic complaints, especially gastrointestinal complaints related to anxiety and mood disturbances.

Moreover, Tianeptine has no effect on:

- sleep and alertness,
- the cholinergic system (no anticholinergic symptoms).

5.2 Pharmacokinetic properties

Gastrointestinal absorption is rapid and complete.

Distribution is rapid, and is associated with a high level of protein binding (approximately 94%).

The molecule is extensively metabolised in the liver by the processes of beta-oxidation and N-demethylation.

The elimination of tianeptine is characterised by a short terminal half-life of 2½h and by essentially renal excretion of the metabolites.

In elderly subjects: pharmacokinetics studies performed in chronically treated elderly patients (aged over 70 years) demonstrated an increase of one hour in the elimination half-life.

In subjects with hepatic insufficiency: studies have shown that the effects of chronic alcoholism on the pharmacokinetic parameters are negligible, even when the alcoholism is associated with cirrhosis of the liver.

In subjects with renal insufficiency: studies have shown an increase of one hour in the elimination half-life.

5.3 Preclinical safety data

A study demonstrated in rats a decrease in reproductive performance in females (increase in pre-implantation losses) at a maternotoxic dose of 45 mg/kg/day.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions (climatic zones I and II).

To be stored at a temperature below 30 °C (climatic zones III and IV).

6.5 Nature and contents of container

10, 20, 28, 30, 40, 60, 90 or 100 tablets in blisters (Aluminium/PVC) (climatic zones I and II).

10, 20, 28, 30, 40, 60, 90 or 100 tablets in blisters (Aluminium/PVC) overwrapped in sachet (climatic zones III and IV).

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- 329 337.9 or 34009 329 337.9 2: 10 tablets in blisters (Aluminium/PVC).

- 329 338.5 or 34009 329 338.5 3: 20 tablets in blisters (Aluminium/PVC).
- 267 223-5 or 34009 267 223 5 7: 28 tablets in blisters (Aluminium/PVC).
- 329 339.1 or 34009 329 339.1 4: 30 tablets in blisters (Aluminium/PVC).
- 329 341.6 or 34009 329 341.6 4: 40 tablets in blisters (Aluminium/PVC).
- 329 342.2 or 34009 329 342.2 5: 60 tablets in blisters (Aluminium/PVC).
- 329 343.9 or 34009 329 343.9 3: 90 tablets in blisters (Aluminium/PVC).
- 558 336.0 or 34009 558 336.0 4: 100 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 417 228 7 or 34009 417 228 7 5: 10 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 417 229 3 or 34009 417 229 3 6: 20 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 267 224-1 or 34009 267 224 1 8: 28 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 417 230 1 or 34009 417 230 1 8: 30 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 417 231 8 or 34009 417 231 8 6: 40 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 417 232 4 or 34009 417 232 4 7: 60 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 417 233 0 or 34009 417 233 0 8: 90 tablets in blisters (Aluminium/PVC) overwrapped in sachet.
- 579 827 3 or 34009 579 827 3 7: 100 tablets in blisters (Aluminium/PVC) overwrapped in sachet.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[to be completed by the holder]

10. DATE OF REVISION OF THE TEXT

[to be completed by the holder]

11. DOSIMETRY

Not applicable

12. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable

PRESCRIBING AND DISPENSING CONDITIONS

List I.

Prescription limited to 28 days.

Prescription to be stated in full on secure prescription paper.

Overlapping forbidden unless explicitly stated on the prescription by the prescriber.

A copy of the prescription is to be kept by the pharmacist for a period of 3 years.

APPENDIX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING LICENCE HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

A.1. Name and address of the manufacturer(s) of the biological active substance(s)

LES LABORATOIRES SERVIER Industrie
905, route de Saran
45520 – GIDY
France

A.2. Name and address of the manufacturer(s) responsible for batch release

Not applicable.

B. CONDITIONS RELATIVE TO THE MARKETING AUTHORISATION

B.1. Prescribing and dispensing conditions or restrictions placed on the marketing authorisation holder

List I.

Prescription limited to 28 days.

Prescription to be stated in full on secure prescription paper.

Overlapping forbidden unless explicitly stated on the prescription by the prescriber.

A copy of the prescription is to be kept by the pharmacist for a period of 3 years.

B.2. Conditions or restrictions for a safe and efficient use of the drug

Not applicable.

B.3. Other conditions

Not applicable.

C. COMMITMENTS OF THE MARKETING AUTHORISATION HOLDER

Not applicable.

D. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE EXCIPIENTS

D-mannitol	101.000 mg
Maize starch	2.500 mg
Talc	6.500 mg
Magnesium stearate	2.500 mg

For one core tablet of 125 mg.

Ethylcellulose	0.247 mg
Glycerol oleate	0.123 mg
Povidone *	0.228 mg
Sodium carboxymethylcellulose *	0.158 mg
Anhydrous colloidal silica *	0.108 mg
Talc*	13.656 mg
Sucrose *	23.946 mg
Polysorbate 80*	0.135 mg

Titanium dioxide *	6.208 mg
Sodium bicarbonate *	0.077 mg
White beeswax	0.114 mg

* In the form of SEPIFILM SE 700 White premix

For one coated tablet of 170 mg.

APPENDIX IIIA

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND ON THE IMMEDIATE PACKAGING

NATURE / TYPE Outer packaging or immediate packaging

Outer packaging.

1. NAME OF THE MEDICINAL PRODUCT

STABLON® 12.5 mg, coated tablet

Sodium tianeptine

2. STATEMENT OF ACTIVE SUBSTANCES

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

For one coated tablet.

3. LIST OF EXCIPIENTS

Excipient with a known effect: sucrose.

4. PHARMACEUTICAL FORM AND CONTENTS

Coated tablet.

Box of 10, 20, 28, 30, 40, 60, 90 or 100.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

No special precautions for storage (climatic zones I and II).

To be stored at a temperature below 30 °C (climatic zones III and IV).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Holder

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
France

Distributor

LES LABORATOIRES SERVIER
50, RUE CARNOT
92284 SURESNES CEDEX

France

Manufacturer

LES LABORATOIRES SERVIER INDUSTRIE
905, ROUTE DE SARAN
45520 – GIDY
FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

Drug authorisation no.:

13. BATCH NUMBER

Lot {numéro}

14. PRESCRIBING AND DISPENSING CONDITIONS

List I.

Prescription limited to 28 days.

Prescription to be stated in full on secure prescription paper.

Overlapping forbidden unless explicitly stated on the prescription by the prescriber.

A copy of the prescription is to be kept by the pharmacist for a period of 3 years.

15. INSTRUCTIONS FOR USE

Not applicable.

16. INFORMATIONS IN BRAILLE

Not applicable.

PICTOGRAM WHICH MUST APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

The pictogram must comply with the order of 8th August 2008 following application of article R.5121-139 of the public health code and relating to the affixing of a pictogram on the outer packaging of certain medicines and products.

MINIMUM PARTICULARS TO APPEAR ON THE HEAT-SEALED BLISTERS OR HEAT-SEALED STRIPS

NATURE/TYPE Blisters / films

Heat sealed blister (Aluminium/PVC)

1. NAME OF THE MEDICINAL PRODUCT

STABLON 12.5 mg, coated tablet

Sodium tianeptine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Holder

LES LABORATOIRES SERVIER

Distributor

LES LABORATOIRES SERVIER

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. OTHERS

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE Small immediate packaging

Not applicable.

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Not applicable.

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

Not applicable.

4. BATCH NUMBER

Not applicable.

5. CONTENTS BY WEIGHT, VOLUME OR UNITS

Not applicable.

6. OTHERS

Not applicable.

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

STABLON 12.5 mg, coated tablet

Boxed text

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 signs of illness 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.

Leaflet contents

In this leaflet:

1. WHAT STABLON 12.5 mg, coated tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class

ANTIDEPRESSANT.

Therapeutic indications

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, coated tablet

List of information necessary before taking this medicine

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

Contraindications

Do not take STABLON 12.5 mg, coated tablet:

- if you are allergic (hypersensitive) to tianeptine or any of the other ingredients of STABLON,
- in children and adolescents under 15 years of age,
- in combination with antidepressants of the irreversible MAOI class (see section “Taking or using other medicines”). If you must change your treatment from MAOIs to STABLON, you must stop taking the MAOI for two weeks before starting the STABLON treatment. If you must replace a STABLON treatment by a MAOI treatment, a transition period of 24 hours is sufficient.

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

Precautions for use, special warnings

Take special care with STABLON 12.5 mg, coated tablet:

Special warnings

Prolonged use at high doses may lead to dependency.
Do not exceed the recommended doses.

Patients with fructose intolerance, glucose-galactose malabsorption or sucrase/isomaltase deficiency (rare inherited diseases) should not take this medicine.

Avoid drinking alcoholic beverages or medicines that contain alcohol.

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 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 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.

Use in children and adolescents under 18 years old

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 medicinal product concerning growth, sexual maturation and cognitive and behavioural development has not yet been established for this age group.

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

Interactions with other medicines

Taking or using other medicines:

Taking this drug in combination with certain drugs 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 drug.

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

Interactions with food and drinks

Not applicable.

Interactions with herbal medicines or alternative therapy products

Not applicable.

Use during pregnancy and breastfeeding

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.

Sportsmen

Not applicable.

Effects on the ability to drive or operate machinery

Driving and operating machinery

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

List of excipients with a known effect

List of excipients with a known effect: sucrose.

3. HOW TO TAKE STABLON 12.5 mg, coated tablet

Instructions for a correct use

Not applicable.

Dosage, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

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.

Method of administration

Oral route.

Symptoms and instructions in the case of overdose

If you took more Stablon 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 took more Stablon than you should, contact your doctor or pharmacist immediately. The Stablon treatment must be suspended immediately in such a case.

Instructions for the omission of one or several doses

Not applicable.

Risk of withdrawal syndrome

Not applicable.

4. POSSIBLE SIDE EFFECTS

Description of 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, headache, 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 1000)
- 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, somnolence , dizziness, 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, urticaria, dependence.
- Undesirable effects of unknown frequency:
  - suicidal thoughts and behaviour,
  - confusion, hallucinations,
  - acne, dermatitis bullous 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 via the national reporting system French National Agency

for Medicines and Health Products Safety (ANSM) and the Regional Pharmacovigilance Centres network. www.ansm.sante.fr. 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 reach and sight of children.

Expiry date

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

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

Storage conditions

No special precautions for storage (climatic zones I and II).

To be stored at a temperature below 30 °C (climatic zones III and IV).

If necessary, warnings against visible signs of deterioration

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. ADDITIONAL INFORMATION

Complete list of the active ingredients and the excipients

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 (povidone, sodium carmellose, anhydrous colloidal silica, talc, sucrose, polysorbate 80, titanium dioxide, sodium hydrogen carbonate), white beeswax.

Pharmaceutical form and content

What STABLON 12.5 mg, coated tablet is and contents of the pack

This medicinal product is presented in coated tablet form. Box of 10, 20, 28, 30, 40, 60, 90 or 100.

Name and address of the marketing authorisation holder and the manufacturing licence holder responsible for batch release, if different

Holder

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex

Distributor

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES CEDEX

Manufacturer

LES LABORATOIRES SERVIER INDUSTRIE
905, route de Saran
45520 GIDY

Names of the drug in the Member states of the European Economic Area

Austria	STABLON
Bulgaria	COAXIL
Estonia	COAXIL
France	STABLON 12,5 mg
Hungary	COAXIL
Latvia	COAXIL
Lithuania	COAXIL
Luxembourg	STABLON
Malta	STABLON 12,5 mg
Poland	COAXIL
Portugal	STABLON
Czech Republic	COAXIL
Romania	COAXIL
Slovakia	COAXIL
Slovenia	COAXIL

Approval date of the leaflet

This leaflet was last approved in {date}.

MA under exceptional circumstances

Not applicable.

On-line information

Detailed information on this medicine is available on the Ansm (France) web site.

Information reserved for healthcare professionals

Not applicable.

Other

Not applicable.