

TRIVASTAL® Retard 50

Piribedil, 50 mg

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What TRIVASTAL® Retard 50 is and what it is used for

Pharmacotherapeutic group -
ATC Code: N04BC08

TRIVASTAL® Retard 50 is a dopamine agonist (that acts in the brain to stimulate the receptors of a substance called dopamine).

This medicine is indicated:

For the treatment of Parkinson's disease alone or in combination with dopatherapy from the outset or secondarily.

How TRIVASTAL® Retard 50 works

Piribedil: dopaminergic agonist (stimulates dopamine receptors and the cerebral dopaminergic pathways).

In humans, the mechanism of action is demonstrated by the clinical pharmacology studies:

- stimulation of cortical electrogenesis of the "dopaminergic" type both while awake and during sleep,
- clinical activity on the different functions controlled

by dopamine, with this activity being demonstrated via the use of behavioural or psychometric scales.

In addition, piribedil results in an increase in femoral blood flow (the existence of dopaminergic receptors in the femoral vascular bed explains the action of piribedil on peripheral circulation).

Before you use TRIVASTAL® Retard 50

- When you must not use it

Do not use TRIVASTAL® Retard 50 in the following situations:

- a history of allergy to piribedil or any of the other ingredients in this medicine listed in section 8.
- myocardial infarction or any other serious cardiovascular disease,
- in combination with antiemetic neuroleptics (see Taking other medicines).

If you are in any doubt, you must ask your doctor or pharmacist for advice.

Pregnancy and breast-feeding

In the absence of relevant data, the use of this drug during pregnancy and breastfeeding is not recommended.

If you are pregnant or breastfeeding, if you think you are pregnant or are planning a pregnancy, ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Ask your doctor before taking TRIVASTAL® Retard 50

- if you have (have had) or develop a medical condition or symptoms, in particular kidney disease, liver disease, swelling of legs, feet or fingers.
- If you or someone close to you notices that you get confused/disorientated, agitated, aggressive, or that you develop mental problems such as delirium, delusions, or hallucinations. Your doctor may need to adjust the dose or discontinue the treatment
- If you or someone close to you has noticed that you present unusual urges or compulsive behaviour and that you cannot resist the impulse, the need or the temptation to perform certain activities which could harm you or those around you, talk to your doctor. These are impulse control disorders that can include gambling addiction, uncontrollable and excessive eating or spending, abnormally high libido or an increase in ideas and desires with a sexual connotation. Your treatment may be modified or stopped if your doctor deems it necessary.

In the event of excessive drowsiness or sudden onset of sleep during your treatment with TRIVASTAL® Retard 50, you must contact your doctor.

Your blood pressure should be checked regularly particularly at the start of treatment in order to avoid orthostatic hypotension (a drop in pressure while standing up).

In elderly subjects, the risk of falls, whether related to hypotension, sudden sleep onset or delirium, must be taken into account.

It is preferable to take the tablets after meals.

Children and adolescents

TRIVASTAL® Retard 50 is not recommended in children and adolescents under 18 years of age.

Check with your doctor or pharmacist if you are not sure.

- Taking other medicines

This medicine must not be used in combination with certain other medicines (see TRIVASTAL® Retard 50 must not be used in the following situations).

In order to avoid possible interactions between several medicines, particularly neuroleptics (excluding clozapine), tetrabenazine, some medicines used for the prevention of nausea and vomiting, and sedatives, you should always tell your doctor or pharmacist about any other treatment you are taking.

How to use TRIVASTAL® Retard 50

Oral route.

- How much to use

The dosage is strictly individual and is established by your doctor. To avoid the risk of impulse control disorders (explained in section 3), your doctor may need to adjust the dose or discontinue the treatment, if you experience any symptoms.

Always take the medication exactly as your doctor has told you.

- When to use it

The tablets should be swallowed, without chewing, with half a glass of water at the end of the meal.

- How long to use it

Comply with your doctor's prescription.

Do not stop taking the treatment without medical advice.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Consult your doctor or pharmacist immediately.

Inform your doctor immediately in case of massive ingestion.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking TRIVASTAL® Retard 50.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not discontinue your treatment with TRIVASTAL without speaking to your doctor beforehand. If you need to stop taking this medicine, your doctor will reduce the doses gradually in order to reduce the risk of worsening the symptoms. You must not discontinue TRIVASTAL suddenly. Sudden discontinuation may result in the onset of a condition known as neuroleptic malignant syndrome which may represent a major risk for your health. The symptoms include:

- akinesia (difficulty in performing movements);
- muscle stiffness;
- fever;
- unstable blood pressure;
- tachycardia (increased heart rate), see section 3;
- confusion;
- decreased level of consciousness (e.g, coma).

Do not take any new medicines without consulting your doctor.

Do not give TRIVASTAL® Retard 50 to anyone else, even if they have the same symptoms or condition as you.

TRIVASTAL® Retard 50 contains sucrose, cochineal red A (E124) and sodium.

Due to the presence of sucrose, this medicine must not be used in case of fructose intolerance, glucose and galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare metabolic disorders).

Due to the presence of cochineal red A (E124), there is a risk of allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

- Things to be careful of

Driving and using machines

TRIVASTAL® Retard 50 may induce drowsiness and sudden sleeping fits.

If this happens, you must not drive or do anything where any impairment of your alertness could expose you or other people to the risk of a serious accident or death (for example operating machinery) until the disappearance of such effects.

TRIVASTAL® Retard 50 with food, drinks and alcohol

The consumption of alcohol or alcoholic beverages is inadvisable if you take this medicine. The effects could be increased.

Side Effects

Like all medicines, TRIVASTAL® Retard 50 can cause side effects, although not everybody gets them:

The frequency of the possible side effects listed below is defined using the following system:

- Very common (affects more than 1 in 10 users)
- Common (affects 1 to 10 in 100 users)
- Uncommon (affects 1 to 10 in 1000 users)
- Rare (affects 1 to 10 in 10,000 users)
- Very rare (affects fewer than 1 in 10,000 users)
- Not known (frequency cannot be estimated from the available data)

Common side effects:

- Minor digestive disorders (nausea, vomiting, flatulence) which may be reduced by progressively increasing the dosage,
- confusion, hallucination (visual, auditory, mixed) or agitation that disappear when treatment is stopped,
- dizzy sensation that disappears when treatment is stopped,
- drowsiness.

Uncommon side effects:

- hypotension, orthostatic hypotension (decrease in blood pressure when you stand up), blood pressure instability, which may be accompanied by dizziness or malaise.

Very rare side effects:

- Excessive drowsiness during the day, sudden sleep fits.

- Incapacity to resist the impulse, need or temptation to carry out an action which could be harmful for you or those around you that may include:
 - A strong compulsion to gamble (money) in an excessive manner in spite of serious personal or familial consequences,
 - An increase or change that is worrying for you or those around you in the interest in sex or sexual behaviour, for example an increase in sex drive.
 - Excessive and compulsive spending or shopping.
 - Eating in an excessive manner (eating large amounts of food over a short period) or eating compulsively (eating more food than usual and beyond the hunger sensation).

You may also encounter the following side effects:

- Aggression
- Psychiatric disorders (delusion, delirium),
- Swelling of the legs, feet or fingers
- Dyskinesia (abnormal movements)

If you experience any side effects, contact your doctor.

Risk of allergic reactions due to the presence of Cochineal red A (E124).

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 [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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

Storage and Disposal of TRIVASTAL® Retard 50

- Storage

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.

Store below 25°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:

TRIVASTAL® Retard 50, is in the form of a prolonged-release coated tablet available in a box 30 tablets.

- Ingredients

- Active ingredient: Piribedil. One prolonged-release coated tablet contains 50 mg of Piribedil.
- Inactive ingredients: Povidone, magnesium stearate, talc, sodium hydrogen carbonate, carmellose sodium, white beeswax, titanium dioxide (E171), cochineal red A aluminium lake (E124), polysorbate 80, sucrose, anhydrous colloidal silica

- MAL number:

MAL19961025AZ

Manufacturer

Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy
France

Product registration holder

Servier Malaysia Sdn Bhd
Unit No.25-02, Level 25,
Imazium
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47400 Petaling Jaya,
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