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Package leaflet: Information for the patient

TRIVASTAL[®] RETARD 50

Piribedil 50mg
sustained-release coated tablets

ٹریووسٹال[®] ریٹارڈ ۵۰
پیریبیل ۵۰ گرام
سستہ ریٹارڈ کوئید ٹیبلٹس

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 experience any 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 TRIVASTAL 50 mg , prolonged-release coated tablet is and what it is used for
2. What you need to know before you take TRIVASTAL 50 mg , prolonged-release coated tablet
3. How to take TRIVASTAL 50 mg , prolonged-release coated tablet
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1. WHAT TRIVASTAL 50 mg , prolonged-release coated tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group - ATC Code: N04BC08

TRIVASTAL 50 mg , prolonged-release coated tablet 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 levodopa.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIVASTAL 50 mg , prolonged-release coated tablet

Do not take TRIVASTAL 50 mg , prolonged-release coated tablet in the following cases:

- If you are allergic to piribedil, or any of the other ingredients in this medicine (listed in section 6).
 - myocardial infarction or other serious cardiovascular disease,
 - in combination with anti-emetic neuroleptics (see Other medicinal products and TRIVASTAL 50 mg , prolonged-release coated tablet),
- If you are in any doubt, you must ask your doctor or pharmacist for advice.

Warnings and precautions

Ask your doctor before taking TRIVASTAL 50 mg , prolonged-release coated tablet:

- 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 notice 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, have 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, 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 confusional state, must be taken into account.

It is preferable to take the tablets after meals.

Children and adolescents

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

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

Other medicinal products and TRIVASTAL 50 mg , prolonged-release coated tablet

This medicine must not be used in combination with certain medicines (see Do not take TRIVASTAL 50 mg , prolonged-release coated tablet).

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.

TRIVASTAL 50 mg , prolonged-release coated tablet with food, drinks and alcohol

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

Pregnancy and breast-feeding

In the absence of relevant data, the use of this medicine 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.

Driving and using machines

TRIVASTAL 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 50 mg , prolonged-release coated tablet contains sucrose, red cochineal red A (E124) and sodium.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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'.

3. HOW TO TAKE TRIVASTAL 50 mg , prolonged-release coated tablet

Posology

The dose is strictly individual and is established by your doctor.

To avoid the risk of impulse control disorders (explained in section 2), your doctor may need to adjust the dose or discontinue the treatment, if you experience any symptoms. Always take the medicine exactly as your doctor has told you.

Method of administration

Oral route.

Frequency of administration

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

Duration of treatment

Comply with your doctor's prescription.

Do not stop taking the treatment without medical advice.

If you take more TRIVASTAL 50 mg , prolonged-release coated tablet than you should

Consult your doctor or pharmacist immediately.

Inform your doctor immediately in case of massive ingestion.

If you forget to take TRIVASTAL 50 mg , prolonged-release coated tablet

Not applicable.

If you stop taking TRIVASTAL 50 mg , prolonged-release coated tablet

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).

4. POSSIBLE SIDE EFFECTS

Like all medicines, TRIVASTAL 50 mg , prolonged-release coated tablet 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 dose,
 - Confusion, agitation or hallucination (visual, auditory, mixed) that disappear when treatment is stopped,
 - Dizziness 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 vertigo 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:

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

If you experience any of these side effects, contact your doctor.

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

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 company website [https:// www.servier.com.pk/or](https://www.servier.com.pk/or) Drug Regulatory Authority of Pakistan <http://dra.gov.pk/>

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

5. HOW TO STORE TRIVASTAL 50 mg , prolonged-release 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.

Do not store above 25°C.

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 FURTHER INFORMATION

What TRIVASTAL 50 mg , prolonged-release coated tablet contains

- The active substance is: Piribedil 50.00 mg
- For one prolonged-release coated tablet.

• The other ingredients are:

- Povidone, magnesium stearate, talc, sodium hydrogencarbonate, carmellose sodium, white beeswax, titanium dioxide (E171), cochineal red A aluminium lake (E124), polysorbate 80, sucrose, anhydrous colloidal silica.

What TRIVASTAL 50 mg , prolonged-release coated tablet looks like and content of the pack

This medicinal product is available in the form of prolonged-release coated tablets. Box of 30 Tablets.

7. MARKETING AUTHORISATION HOLDER

PLANT:

SERVIER RESEARCH & PHARMACEUTICALS [PAKISTAN] (PVT) LTD.
9 KM SHEIKHUPURA ROAD LAHORE PAKISTAN.

8. MARKETING AUTHORISATION NUMBER(S)

014942

9. DATE OF REVISION OF THE TEXT

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Manufactured by:
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