

PACKAGE LEAFLET

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Tasmar is and what it is used for
2. Before you take Tasmar
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Tasmar 100 mg film-coated tablet
Tolcapone

- The active substance is tolcapone (100 mg in each film-coated tablet)
- The other ingredients are:
Tablet core: Calcium hydrogen phosphate (anhydrous), Microcrystalline cellulose, Polyvidone K30, Sodium starch glycolate, Lactose monohydrate, Talc, Magnesium stearate.
Film-coat: Methylhydroxypropylcellulose, Talc, Yellow iron oxide (E 172), Ethylcellulose, Titanium dioxide (E 171), Triacetin, Sodium lauryl sulfate.

The marketing authorisation holder is:

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The manufacturer responsible for batch release is:

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1. WHAT TASMAR IS AND WHAT IT IS USED FOR

Tasmar is a pale to light yellow, oval shaped, film-coated tablet. "TASMAR" and "100" is engraved on one side. Tasmar is supplied as film coated tablets containing 100 mg tolcapone. It is available in blisters in pack sizes of 30 and 60 tablets and in glass bottles in pack sizes of 30, 60 and 100 tablets.

Tasmar is used together with levodopa/benserazide or levodopa/carbidopa when all other alternative medications cannot stabilise your Parkinson's disease.

Tasmar therapy should only be initiated by physicians experienced in the treatment of Parkinson's disease to ensure an appropriate risk-benefit assessment.

Catechol-O-methyltransferase (COMT) is a natural enzyme in your body that breaks down the levodopa medication used to treat your Parkinson's disease. Tasmar blocks COMT and slows the breakdown of levodopa. This means when it is taken together with levodopa (as levodopa/benserazide or levodopa/carbidopa) you should have an improvement in your symptoms of Parkinson's disease.

2. BEFORE YOU TAKE TASMAR

You should not start taking Tasmar until your doctor has described the risks of treatment with Tasmar and measures necessary to minimise those risks, and answered any questions you may have.

You should only receive Tasmar if your Parkinson's disease is not adequately controlled by the use of other therapies. In addition, your doctor will stop Tasmar treatment if after 3 weeks you do not improve enough to justify the risks of continuing treatment.

Liver Injury:

Tasmar may cause rare but potentially fatal liver injury. Liver injury has occurred most often after 1 month and before 6 months. Injury occurring earlier or later is also possible. It should also be noted that female patients may have a higher risk of liver injury.

***Before beginning treatment:* To reduce the risk of liver injury you should not use Tasmar if 1) you have liver disease or 2) blood tests done before starting treatment show any liver abnormality (tests of ALT, alanine amino transferase and AST, aspartate amino transferase).**

***While receiving treatment:* Blood tests will be done every 2 weeks for the first year of therapy, every 4 weeks for the next 6 months and every 8 weeks thereafter and treatment will be stopped if they become abnormal. The following symptoms may indicate liver injury and you should report them to your doctor immediately: jaundice (yellowing of the skin or eyes), darkening of your urine, pain in your stomach (particularly over the liver in the right upper area), worsening of nausea or vomiting, loss of appetite, if you tire more easily than usual or feel weak.**

NMS (Neuroleptic Malignant Syndrome):

NMS (Neuroleptic Malignant Syndrome) consists of some or all of the following: severe muscle stiffness, jerking movements of muscles, arms or legs, and soreness of muscles. Muscle injury can sometimes cause dark urine. Other important symptoms are high fever and mental confusion. Very rarely, after abruptly reducing or stopping Tasmar or other antiparkinsonian drugs, you may experience severe symptoms of muscle stiffening, fever or mental confusion. If this happens notify your doctor. Symptoms may also occur during Tasmar treatment.

***Before beginning treatment:* To reduce the risk of NMS you should not use Tasmar if your doctor says you have severe dyskinesia (involuntary movement) or a previous illness that may have been NMS. Inform your doctor of all prescription and non-prescription medications as the risk of NMS may be increased if you are taking medications that may alter the effects of the brain messenger molecules of dopamine and serotonin.**

***While receiving treatment:* If you develop symptoms as described above, that you think may be NMS, you should report them to your doctor immediately. Do not stop Tasmar or any other Parkinson's medications without telling your doctor as this may increase the risk of NMS.**

Do not take Tasmar:

- if you have liver disease or increased liver enzymes
- if you have severe dyskinesia (involuntary movement)
- if you have a previous history of Neuroleptic Malignant Syndrome Symptom Complex (NMS) and /or if you have non-traumatic Rhabdomyolysis or Hyperthermia.

- if you are hypersensitive (allergic) to tolcapone or to any of the other ingredients of Tasmar.
- if you have Phaeochromocytoma

Take special care with Tasmar:

- if during the treatment you suffer from a liver condition. The treatment with Tasmar may sometimes lead to disturbances in the way the liver works. Therefore, if you experience symptoms such as nausea, vomiting, abdominal pain, loss of appetite, weakness, fever, darkening of urine or jaundice you should contact your doctor immediately
- if you have any illnesses other than Parkinson's disease.
- if you are allergic to other medicines, foods and dyes.
- if you are taking other medicines, including those you can obtain without a prescription.
- If you have taken already Tasmar and developed acute liver injury while on Tasmar, it should not be re-introduced again.

Taking Tasmar with food and drink:

Swallow Tasmar with water. Tasmar can be taken with or without food.

Pregnancy

You must tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking Tasmar during pregnancy.

Breast-feeding

The effects of Tasmar have not been studied in infants. You should not breast-feed your infant during treatment with Tasmar.

Driving and using machines:

Tasmar has an effect on your symptoms of Parkinson's disease. Since your ability to drive a car or operate machinery may be affected by Parkinson's disease, you should discuss this with your doctor.

Tasmar used with your other Parkinson medication can cause somnolence (excessive drowsiness) and sudden sleep onset episodes. Therefore you must refrain from driving or engaging in activities where impaired alertness may put yourself or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved.

Important information about some of the unwanted effects of Tasmar:

Soon after beginning and during your treatment with Tasmar, you may have symptoms caused by levodopa such as dyskinesia (involuntary movement) and nausea. If you feel unwell, you should contact your doctor because you may need to take less levodopa.

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

Taking other medicines:

Please inform your doctor about all other medicines you are taking especially antidepressants, *alpha*-methyldopa (antihypertensive), apomorphine (used for Parkinson's disease), dobutamine (used in the management of congestive heart failure), adrenaline (used for heart attacks) and isoprenaline (used for heart attacks).

When you are taking Tasmar with anticoagulants (that prevent blood clotting) of the warfarin type, your doctor may perform regular blood tests to monitor how easily the blood clots.

If you go to hospital or if you are prescribed a new medicine, you must tell your doctor that you are taking Tasmar.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed (non-prescription medications and herbals).

3. HOW TO TAKE TASMAR

Always take Tasmar exactly as your doctor has instructed you. You should check with your doctor if you are unsure. Do not break or crush tablets.

Dosage and Frequency of administration

When beginning and during treatment with Tasmar, your dose of levodopa may need to be changed. Your doctor will advise you what to do.

Your doctor should always begin your treatment with the standard dose (100 mg three times a day). If benefits are not seen within 3 weeks of the initiation of the treatment, Tasmar should be discontinued. The dose should only be increased to the higher dose (200 mg three times a day) if the increase in how your Parkinson's disease symptoms are controlled outweighs the expected increase in side effects. The side effects at the higher dose can often be severe and affect your liver. If you do not get better at the higher dose after a total of 3 weeks, your doctor should stop your treatment with Tasmar.

Your doctor should perform a blood test to monitor your liver function before starting the treatment and regularly every 2 weeks thereafter for the first year of therapy, every 4 weeks for the next 6 months and every 8 weeks thereafter. If your doctor increases your dose, the liver tests will have to be repeated before increasing the dose and regularly afterwards.

The first dose of Tasmar is taken with the first dose of the day of levodopa and the other doses of Tasmar are taken about 6 and 12 hours later. Take one tablet in the morning, one tablet in the middle of the day and one tablet in the evening.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective or well tolerated and may change your treatment unnecessarily.

If you take more Tasmar than you should:

Contact a doctor, pharmacist or hospital immediately as you may need urgent medical attention. If another person accidentally takes your medicine, contact a doctor or hospital immediately as he or she may need urgent medical attention.

Symptoms of overdose may include nausea, vomiting, dizziness and breathing difficulties.

If you forget to take Tasmar:

Take it as soon as you remember, then continue to take it at the usual times. If you have missed several doses, please inform your doctor and follow the advice given to you. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with Tasmar is stopped:

Do not reduce or stop taking your medicine unless your doctor tells you to. Always follow the instructions of your doctor about the duration of the treatment with Tasmar.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tasmar can have side effects.

Tell your doctor or a pharmacist as soon as possible if you do not feel well while you are taking Tasmar.

The unwanted effects that are most likely to occur are: dyskinesia (involuntary movement), nausea, sleeping problems, decreased appetite, diarrhoea, fainting, feeling lightheaded when you stand, constipation and hallucination.

Disturbances in the way the liver works, sometimes severe hepatitis, have been observed. Therefore, if you experience symptoms such as nausea, vomiting, abdominal pain, loss of appetite, weakness, fever, darkening of urine or jaundice you should contact your doctor immediately.

Soon after beginning and during your treatment with Tasmar, you may have symptoms caused by levodopa such as dyskinesia (involuntary movement) and nausea. Therefore, if you feel unwell, you should contact your doctor since you may need to have your levodopa dose changed.

Contact your doctor if you develop persistent or severe diarrhoea.

This medicine can cause a harmless yellow urine discoloration. However if you notice a darkening of your urine this could be a sign of muscle injury or liver injury, please inform your doctor.

Very rarely, patients develop Neuroleptic Malignant Syndrome (severe symptoms of muscle stiffening, fever or mental confusion) when antiparkinsonian treatments are abruptly reduced or withdrawn.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING TASMAR

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions

Do not use after the expiry date stated on the pack.

Do not use Tasmar if you notice that the tablets are damaged.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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