Package leaflet: Information for the user

Tasmar 100 mg film-coated tablets
tolcapone

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 further questions, please ask your doctor or your 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 you get 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 Tasmar is and what it is used for

For the treatment of Parkinson's disease, Tasmar is used together with the medicinal product levodopa (as levodopa/benserazide or levodopa/carbidopa).
Tasmar is used when all other alternative medicines cannot stabilise your Parkinson's disease.

For the treatment of your Parkinson's disease you already take levodopa.
A natural protein (enzyme) in your body, the (COMT) Catechol-*O*-methyltransferase breaks down the levodopa. Tasmar blocks this enzyme and thus 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 the symptoms of your Parkinson's disease.

2. What you need to know before you take Tasmar

Do not take Tasmar:
- if you have liver disease or increased liver enzymes
- if you have severe involuntary movement (dyskinesia)
- if you have a previous history of severe symptoms of muscle stiffening, fever or mental confusion (Neuroleptic Malignant Syndrome (NMS) Symptom Complex) and/or if you have damage of skeletal muscle tissue (non-traumatic rhabdomyolysis) or fever (hyperthermia)
- if you are hypersensitive (allergic) to the active substance tolcapone or to any of the other ingredients of Tasmar
- if you have a special type of tumour in the adrenal medulla (Phaeochromocytoma)
- if you take a certain medication to treat depression and anxiety, called non-selective mono amino oxidase (MAO) inhibitors

Warnings and precautions
Talk to your doctor or pharmacist before taking Tasmar.
You should not start taking Tasmar until your doctor
- has described the risks of treatment with Tasmar
- has explained the measures necessary to minimise those risks

- has answered any questions you may have
- if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking Tasmar during pregnancy. The effects of Tasmar have not been studied in infants. You should not breast-feed your infant during treatment with Tasmar.

Tell your doctor if you or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or a preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

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. It should also be noted that female patients may have a higher risk of liver injury. Therefore, the following preventive measures have to be considered.

Before beginning treatment:
To reduce the risk of liver injury you should not use Tasmar if
- you have a liver disease
- in case of elevated liver function tests in the blood test done before starting treatment (tests of alanine amino transferase (ALT) and aspartate amino transferase (AST)).

While receiving treatment:
During treatment, blood tests will be done in the following time intervals:
- every 2 weeks during the first 12 months of therapy,
- every 4 weeks during the following 6 months of therapy,
- every 8 weeks during further treatment.

The treatment will be stopped, if these blood tests become abnormal.

The treatment with Tasmar may sometimes lead to disturbances in the way the liver works. Therefore, you should contact your doctor immediately if you experience symptoms such as nausea, vomiting, pain in your stomach (particularly over the liver in the right upper area), loss of appetite, weakness, fever, darkening of urine, jaundice (yellow skin or eyes) or if you tire more easily.
If you have been already treated with Tasmar and developed acute liver injury during treatment, Tasmar should not be re-introduced again.

NMS (Neuroleptic Malignant Syndrome)
Symptoms of Neuroleptic Malignant Syndrome (NMS) may occur during Tasmar treatment.
The NMS 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.

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.

The following preventive measures have to be considered.

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

While receiving treatment:
If you develop any 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.

Inform your doctor also:
- if you have any illnesses other than Parkinson's disease
- if you are allergic to other medicines, food and dyes
- if soon after beginning and during treatment with Tasmar you have symptoms which may be caused by levodopa such as involuntary movement (dyskinesia) and nausea.

If you feel unwell, you should contact your doctor because you may need to take less levodopa.

Children and adolescents
Tasmar is not recommended for use in children below the age of 18 due to insufficient data on safety or efficacy. There is no relevant indication for use in children and adolescents.

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

Please inform your doctor about all other medicines you are taking especially:
- antidepressants
- *alpha*-methyldopa (used to treat increased blood pressure)
- apomorphine (used for Parkinson's disease)
- dobutamine (used for the chronic heart disease)
- adrenaline and isoprenaline (both used for heart attacks)
- anticoagulants of the warfarin type (that prevent blood clotting). In this case your doctor may perform regular blood tests to monitor how easily your 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.

Tasmar with food and drink and alcohol
Tasmar can be taken with or without food.
Tasmar should be taken with 1 glass of water.

Pregnancy and breast-feeding and fertility
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.

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
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 has an effect on the symptoms of your Parkinson's disease.
Tasmar used with your other Parkinson medicines can cause excessive drowsiness (somnolence) and sudden sleep onset episodes (you may suddenly fall asleep). Therefore you must refrain from driving or operating machines until such recurrent episodes and excessive drowsiness have resolved.

Tasmar contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tasmar

Always take Tasmar exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Dose and frequency of administration
Your doctor should always begin your treatment with the standard dose of 3 times daily 1 tablet (100 mg (1 tablet)).
If benefits are not seen within 3 weeks of the initiation of the treatment, Tasmar should be discontinued.
To improve efficacy your doctor should only increase the dose to 3 times daily 2 tablets (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.

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

How to take the medication:
Swallow Tasmar with 1 glass of water.
Do not break or crush the tablets.
The first tablet Tasmar is to be taken in the morning together with your other parkinsonian medicine 'levodopa'.
The following doses of Tasmar should be taken 6 and 12 hours later.

Time of day	Dose	Note
Morning	1 film-coated tablet Tasmar	Together with the first daily dose of levodopa
During the day	1 film-coated tablet Tasmar	
Evening	1 film-coated tablet Tasmar	

If you take more Tasmar than you should
Contact your 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. However, if taking the next dose should be directly ahead, do not make up for the forgotten dose. Do not take a double dose

to make up for forgotten individual doses. If you have forgotten several doses, please inform your doctor and follow the advice given to you.

If you stop taking Tasmar
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, this medicine can have side effects, although not everybody gets them.

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

Very common	may affect more than 1 in 10 people
Common	may affect up to 1 in 10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1,000 people
Very rare	may affect up to 1 in 10,000 people
Not known	frequency cannot be estimated from the available data

Tell your doctor or a pharmacist as soon as possible:
- if you **do not feel well** while you are taking Tasmar
- if you experience symptoms such as **nausea, vomiting, abdominal pain, loss of appetite, weakness, fever, darkening of urine or jaundice** since uncommonly disturbances in the way the liver works, sometimes severe hepatitis was observed,
- if you notice a **darkening of your urine** since this could be a sign of a muscular or liver injury.
  Any other yellow urine discolouring is usually harmless.
- if you develop **persistent or severe diarrhoea**

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

Other possible side effects:

Very common:
- involuntary movement (dyskinesia)
- nausea, decreased appetite, diarrhoea
- headache, dizziness
- sleep problems, somnolence
- feeling lightheaded while you stand (orthostatic complaints)
- mental confusion and hallucinations
- movement disorder with involuntary muscle spasms or malpositions (dystonia)
- dreaming excessive

Common:
- chest pain
- constipation, dyspepsia, stomach ache, vomiting, dry mouth
- fainting
- increased sweating
- influenza-like symptoms

- reduced voluntary and involuntary movement (hypokinesia)
- upper respiratory tract infection
- increase of specific liver enzymes
- urine discoloration

Uncommon:
- liver injury, in rare cases with fatal outcome

Rare:
- severe symptoms of muscle stiffening, fever or mental confusion (Neuroleptic Malignant Syndrome) when antiparkinsonian treatments are abruptly reduced or withdrawn
- impulse control disorders (inability to resist the impulse of an action that could be harmful) This may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.
  - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
  - Uncontrolled excessive shopping or spending.
  - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than needed to satisfy your hunger).

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Tasmar

Keep this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Tasmar contains
- The active substance is tolcapone (100 mg in each film-coated tablet).
- The other ingredients are:
  Tablet core*:* calcium hydrogen phosphate, microcrystalline cellulose, povidone K30, sodium starch glycolate, lactose monohydrate (see Section 2 'Tasmar contains lactose'), talc, magnesium stearate.
  Film-coat*:* hydroxypropyl methylcellulose, talc, yellow iron oxide, ethyl cellulose, titanium dioxide (E171), triacetin, sodium lauril sulfate.

What Tasmar looks like and contents of the pack
Tasmar is a pale to light yellow, oval shaped, film-coated tablet. “TASMAR” and “100” are 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 or 60 tablets and in glass bottles in pack sizes of 30, 60, 100 or 200 film-coated tablets.

Not all pack sizes may be marketed.

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This leaflet was last revised in October 2022

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.