TASMAR® (tolcapone) tablets 100mg and 200mg

patient diary

To help you keep track of your appointments for liver function tests during the **first year of treatment** **and** to minimize the risk of hepatic reactions and NMS-like reactions

PATIENT INFORMATION

Name: _____

Address: _____

Telephone: _____

Specialist: _____

Specialist tel. no.: _____

PD Nurse: _____

PD Nurse tel. no.: _____

Treated with TASMAR® since: _____

In an emergency contact: _____

Name: _____

Tel. no.: _____

PLEASE READ THIS BEFORE TAKING TASMAR®

This booklet will help you to be aware of some of the main risks of your treatment and to keep track of the blood tests which must be carried out to check that your liver is functioning correctly.

You should also read the patient leaflet which comes with each pack, as this has more detailed information. If you have any questions or concerns about your treatment at any time you should ask your specialist nurse, doctor or pharmacist.

IMPORTANT PATIENT INFORMATION

LIVER INJURY

Tolcapone may cause rare but potentially fatal liver injury. Because of this, you should only receive Tolcapone if your Parkinson's disease is not adequately controlled by the use of other lower risk therapies. In addition, your doctor will stop Tolcapone treatment if after 3 weeks you do not improve enough to justify the risks of continuing treatment.

Liver injury has occurred most often after 1 month and before 6 months of starting treatment. Injury occurring earlier or later is also possible. Therefore, the following precautions have to be taken.

Before beginning treatment:

To reduce the risk of liver injury you should not use Tolcapone if

- you have liver disease or
- blood tests done before starting treatment show abnormal results (test of ALT / and AST).

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.

If dose is increased monitoring follows the frequencies as described for start of therapy, Treatment will be stopped if liver test results become abnormal.

You should contact your doctor or pharmacist if you experience one of the following effects:

- Nausea
- Vomiting
- Abdominal pain (especially located around the liver in the right upper area)
- Loss of appetite
- Weakness
- Fever
- Darkening of urine
- Jaundice (yellowing of the white skin of the eyes)
- Tiredness

These effects may be caused by liver injury and thus need to be investigated as soon as possible. If you have been already treated with tolcapone and developed acute liver injury during treatment, tolcapone should not be re-introduced.

IMPORTANT PATIENT INFORMATION

NMS

NMS (Neuroleptic Malignant Syndrome) may occur while receiving Tolcapone or it may occur within days after stopping Tolcapone. NMS has muscle-related symptoms of 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.

Before beginning treatment: To reduce the risk of NMS you should not use Tolcapone if you have severe dyskínesia (abnormal involuntary movements) or a previous illness that may have been NMS and/or non-traumatic muscle damage (non-traumatic rhabdomyolysis), or a special form of fever (malignant hyperthermia). Inform your doctor of all prescription and non-prescription medications because the risk of NMS may be increased if you are taking some specific medications.

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

USING THIS DIARY

You must have a blood test every two weeks during the first year of tolcapone treatment to check that there is no effect on your liver. This diary is designed to help you make sure that these tests are carried out and to keep track of the results.

You should take this diary each time you visit your nurse or doctor and get them to write down your last test result and sign it. You can then use it to arrange a day and time for your next appointment.

If you have any questions about your treatment or the use of this diary, please ask your specialist nurse, doctor or pharmacist.

PATIENT DIARY

At each visit enter the results of the previous liver function test and note the date and time of the next test.

Week	Date/ Time	ALT Result	AST Result	Signature	Comment
0 (before starting treatment)					
2					
4*					
6					
8					

Tolcapone dose _____ If this dose is increased, then monitoring should start again from week 0 in a new diary

*If there is no improvement in Parkinson's disease by week 3 then Tolcapone should be discontinued

At each visit enter the results of the previous liver function test and note the date and time of the next test.

Week	Date/ Time	ALT Result	AST Result	Signature	Comment
10					
12					
14					
16					
18					

Tolcapone dose _____ If this dose is increased, then monitoring should start again from week 0 in a new diary

PATIENT DIARY

At each visit enter the results of the previous liver function test and note the date and time of the next test.

Week	Date/ Time	ALT Result	AST Result	Signature	Comment
20					
22					
24					
26					
28					

Tolcapone dose _____ If this dose is increased, then monitoring should start again from week 0 in a new diary

At each visit enter the results of the previous liver function test and note the date and time of the next test.

Week	Date/ Time	ALT Result	AST Result	Signature	Comment
30					
32					
34					
36					
38					

Tolcapone dose _____ If this dose is increased, then monitoring should start again from week 0 in a new diary

PATIENT DIARY

At each visit enter the results of the previous liver function test and note the date and time of the next test.

Week	Date/ Time	ALT Result	AST Result	Signature	Comment
40					
42					
44					
46					
48					

Tolcapone dose _____ If this dose is increased, then monitoring should start again from week 0 in a new diary

At each visit enter the results of the previous liver function test and note the date and time of the next test.

Week	Date/ Time	ALT Result	AST Result	Signature	Comment
50					
52					

Tolcapone dose _____ If this dose is increased, then monitoring should start again from week 0 in a new diary

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If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

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

Marketing Authorisation Holder
Meda Health Sales Ireland Ltd,
34/35 Block A, Dunboyne Business Park,
Dunboyne, Co Meath.

Tel: +353 1 802 6624
Fax: +353 1 676 2517
Website: www.meda.ie
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