patient diary

To help you keep track of your appointments for liver function tests during the first year

This diary is for patients who have been prescribed Tasmar®.
This dairy has been provided as a service to medicine by Meda Pharmaceuticals Ltd.

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 has important information that will help you to get the most from your treatment. It will help you to understand 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 leaflet which comes with each TASMAR® pack, as this contains more detailed information. If you have any questions or concerns about your treatment at any time you should ask your specialist nurse or doctor.

Why have you been prescribed TASMAR®?

You will have been given TASMAR® by your doctor because your Parkinson's disease is no longer controlled as well as it should be by your existing therapy. For example you may find that each dose of levodopa 'wears off' earlier, so you start to have symptoms before the next dose is due.

TASMAR® works by making each dose of levodopa last longer, so you are less likely to experience these 'wearing off' symptoms. Your doctor has probably already added other treatments to your levodopa to try and reduce these symptoms.

HOW SAFE IS TASMAR®?

Like all medicines, TASMAR® can have unwanted effects in some people. Many of these effects are mild and will go away during the first few months. In a very small number of people, TASMAR® may cause serious liver problems. It is for this reason that you must have a blood test every two weeks to make sure that your liver function is normal.

Your doctor will have considered the risks and benefits of TASMAR® treatment based on your medical history and will be happy to explain these to you.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. You can also report side effects directly to the MHRA via the Yellow Card Scheme at: www.mhra.gov.uk/yellow-card.

Side effects should also be reported to Meda's Medical Information line on 01748 828810. By reporting side effects, you can help provide more information on the safety of this medicine.

WHAT ARE THE POSSIBLE SIDE-EFFECTS?

The effects that are very common are:

- Dyskinesia (involuntary movement)
- Nausea
- Sleeping problems
- Decreased appetite
- Diarrhoea
- Feeling light headed when you stand
- Hallucinations
- Headache
- Dizziness
- Somnolence
- Mental confusion
- Excessive dreaming
- Dystonia (involuntary muscle spasms or malpositions)

You should tell your doctor about any unwanted effects that you experience. Some of these effects may occur soon after you start treatment and may mean that your dose of levodopa can be reduced.

IF YOU EXPERIENCE ANY OF THE FOLLOWING EFFECTS, YOU SHOULD CONTACT YOUR DOCTOR

- Nausea
- Vomiting
- Abdominal pain
- Loss of appetite
- Weakness
- Fever
- Darkening of the urine
- Jaundice
- Tiredness

These effects may be caused by disturbances in the way the liver works and thus need to be investigated as soon as possible.

If TASMAR® does not produce an improvement in your Parkinson's disease after three weeks, then it will be discontinued.

USING THIS DIARY

You must have a blood test every two weeks during the first year of TASMAR® 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 or doctor.

TASMAR®
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					

TASMAR® 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 TASMAR® 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					

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

TASMAR®
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					

TASMAR® 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					

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

TASMAR®
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					

TASMAR® 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					

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

TASMAR®
IMPORTANT PATIENT INFORMATION

THIS FORM DESCRIBES THE RISKS OF TREATMENT WITH TASMAR® AND THE MEASURES NECESSARY TO MINIMIZE THESE RISKS. YOU SHOULD NOT START TAKING TASMAR UNTIL YOU HAVE READ THIS FORM AND YOUR DOCTOR HAS ANSWERED ANY QUESTIONS YOU MAY HAVE. IF YOU DEVELOP ANY OF THE SYMPTOMS MENTIONED BELOW DO NOT STOP THE TASMAR® TREATMENT ON YOUR OWN, BUT ASK FOR PHYSICIAN'S ADVICE IMMEDIATELY.

LIVER INJURY

Tasmar® may cause rare but potentially fatal liver injury. Because of this, you should only receive Tasmar® if your Parkinson's disease is not adequately controlled by the use of other lower risk 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 has occurred most often after 1 month and before 6 months of starting treatment. Injury occurring earlier or later is also possible. If detected early by blood tests or symptoms, and treatment is stopped, permanent liver injury is unlikely.

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 within 2 days of starting treatment show any liver abnormality (test of ALT / and AST).

While receiving treatment: Remember to inform your doctor immediately if you notice any of the following: Nausea, vomiting, abdominal pain, loss of appetite, weakness, fever, darkening of urine, jaundice (itching or yellow skin or eyes), or tiredness. These symptoms may indicate liver injury. 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.

NMS

NMS (Neuroleptic Malignant Syndrome) may occur while receiving Tasmar® or it may occur within days after stopping Tasmar®. 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 Tasmar® 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 immediately. Do not stop Tasmar® or any other Parkinson's medication without telling your doctor as this may increase the risk of NMS.

OTHER SIDE EFFECTS

Tasmar®, like most medications used to treat Parkinson's disease may cause side effects when first started. With Tasmar® this may be due to an increase in the effectiveness of your medications containing levodopa. These can occur as early as after the first dose and generally develop within a few days. Most commonly these are dyskinesia (involuntary movement), nausea, decreased appetite, diarrhoea, headache, dizziness, sleep problems, somnolence, feeling lightheaded while you stand (orthostatic complaints), mental confusion, hallucinations, dystonia (involuntary muscle spasms or malpositions), excessive dreaming.

If this happens, your doctor may need to adjust some of your other medications for you to have your best response to Tasmar®. These adjustments can generally be completed within 2-3 weeks. Your doctor will stop Tasmar® treatment if after 3 weeks you do not improve enough to justify the risks of continuing treatment.

PATIENT PASSPORT/DIARY

To help you keep track of the blood testing and to have important information about Tasmar® with you in case it may be needed, you may wish to use a specially designed pocket sized folder that will be provided by your doctor.

ADDRESS
Meda Pharmaceuticals Ltd
Skyway House
Parsonage Road
Takeley
Bishops Stortford
CM22 6PU
tel: +44 (0) 845 460 0000
email: info@medapharma.co.uk

VISIT US
www.medapharma.co.uk

MEDA

UK/TAS/14/0001(1) Date of preparation: August 2016