
New Zealand Consumer Medicine Information

TASMAR[®]

Tolcapone

100mg tablet

What is in this leaflet

This leaflet answers some common questions about TASMAR tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TASMAR tablets against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TASMAR is used for

TASMAR contains the active ingredient tolcapone.

TASMAR is used in the treatment of Parkinson's disease.

TASMAR belongs to a group of medicines called catechol-O-methyltransferase (COMT) inhibitors.

COMT inhibitors work together with levodopa/benserazide (Madopar[®]) or levodopa/carbidopa (Sinemet[®], Sindopa[®]). COMT is an enzyme that occurs naturally in your body and breaks down levodopa (the medication used to treat Parkinson's disease). TASMAR blocks COMT and slows the breakdown of levodopa. This means that when it is taken together with levodopa (as levodopa/benserazide or levodopa/carbidopa) the medicine you take is more effective.

You should have an improvement in your symptoms of Parkinson's disease and you may need to take less levodopa/benserazide (Madopar[®]) or levodopa/carbidopa (Sinemet[®], Sindopa[®]) when taking TASMAR. Your doctor will stop TASMAR treatment if after 3 weeks you do not improve enough to justify the risks of continuing treatment.

Your doctor however, may have prescribed TASMAR for another purpose.

Ask your doctor if you have any questions about why TASMAR has been prescribed for you.

Before you take TASMAR

When you must not take it

Do not take TASMAR if:

- 1. You have had an allergic reaction to TASMAR or any ingredients listed at the end of this leaflet.**
- 2. TASMAR contains lactose and should therefore not be taken by anyone with the rare hereditary problem of galactose intolerance.**

3. **You have liver problems or increased liver enzymes.**
4. **You have, or have had:**
 - Neuroleptic Malignant Syndrome (NMS) – a complex of symptoms including muscle rigidity and contractions, tremor, high temperature, sweating, and mental changes such as agitation, confusion, stupor and coma
 - Non-traumatic rhabdomyolysis (temporary paralysis or muscle ache, tenderness or weakness)
 - hyperthermia (extremely high body temperature)
 - severe dyskinesia (uncontrollable twitching, jerking or writhing movements associated with Parkinson's disease)
 - Pheochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney. Symptoms include bouts of anxiety and headaches. Palpitations (banging of the heart felt in the chest), dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurring vision, stomach pains and raised blood pressure).
5. **You are taking a non-selective monoamine oxidase inhibitor (MAOI) eg. phenelzine (Nardil[®]) or tranylcypromine (Parnate[®]), or you are taking both selegiline (Eldepryl[®], Apo-Selegiline[®], Selgene[®]) and moclobemide (Aurorix[®], Apo-Moclobemide[®])**
6. **The packaging is torn or shows signs of tampering**
7. **The expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking TASMAR, talk to your doctor.

Before you start to take it

Your doctor must tell you about the risk of side effects associated with TASMAR and the liver function testing programme you will need while you are on TASMAR. You must have a liver function test before treatment with TASMAR begins.

If your liver function test results are not normal it is likely that your doctor will not start you on TASMAR.

Ask your doctor if there is anything you want to know or don't understand before you start taking TASMAR.

Tell your doctor if:

1. **You are pregnant or plan to become pregnant**
It is not known whether TASMAR is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take TASMAR when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
2. **You are breast-feeding or plan to breast-feed**
The safety of TasmAR in infants is unknown, therefore breastfeeding is not recommended while taking TASMAR.
3. **You have any other health problems, especially the following:**
 - kidney disease
4. **You are allergic to any other medicines, foods, dyes or preservatives**

If you have not told your doctor about any of the above, tell them before you start taking TASMAR.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with TASMAR. These medicines include:

- some antidepressants called MAO-A inhibitors such as moclobemide (Aurorix[®], Apo-Moclobemide[®])
- non-selective MAOs used to treat depression such as phenelzine (Nardil[®]) and tranylcypromine (Parnate[®])
- methyl dopa (Prodopa[®]), an antihypertensive
- dobutamine, a medicine used in the management of congestive heart failure
- apomorphine (Apomine[®]), a medicine used for Parkinson's disease
- adrenaline (EpiPen[®])
- isoprenaline (Isuprel[®]), a medicine used for heart conditions
- warfarin (Coumadin[®], Marevan[®]), a medicine to prevent blood from clotting (an anticoagulant)
- desipramine (Pertofran[®]), maprotiline (Ludimil[®]) and venlafaxine (Efexor[®]). All are antidepressant medicines.
- benserazide (Madopar[®]) a medicine used to treat Parkinson's disease.

These medicines may be affected by TASMAR, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking TASMAR.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take TASMAR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Take TASMAR exactly as your doctor has prescribed.

Your doctor will tell you how many TASMAR tablets to take each day.

The recommended initial dose is one TASMAR 100mg tablet three times a day. The first dose is taken with the first daily dose of levodopa (an ingredient in Madopar[®], Sinemet[®] and Sindopa[®]) and the other doses are taken approximately 6 and 12 hours later. This means taking one tablet in the morning, one at midday and one in the evening.

In special circumstances your dose may need to be increased to two TASMAR 100mg tablets (200mg) three times a day. Your doctor will advise you.

Your dose of levodopa may need to be reduced when starting TASMAR and during treatment with TASMAR. Your doctor will advise you.

How to take it

Swallow the tablets whole, with water.

Do not break or crush the tablets, and do not take any tablets that are damaged, because they have a bitter taste.

The tablets can be taken with or without food.

How long to take TASMAR

TASMAR is used for long-term treatment or as instructed by your doctor.

Continue taking TASMAR until your doctor tells you to stop.

If you forget to take TASMAR

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

If you are not sure what to do, talk to your doctor or pharmacist.

Do not double a dose to make up for one you have missed.

If you have trouble remembering your dose, ask your pharmacist for some hints.

While you are taking TASMAR

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking TASMAR.

Tell your doctor if you become pregnant while taking TASMAR.

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 and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Contact your doctor if you develop persistent or severe diarrhoea. This may happen 2 to 4 months after you start taking TASMAR.

Treatment with TASMAR may sometimes lead to disturbances in the way the liver works. Your doctor will ask you to have regular blood tests to monitor your liver function. Liver function tests must be performed:

- Before starting TASMAR
- Every 2 weeks for the first year of treatment
- Then every 4 weeks for the next 6 months
- Then every 8 weeks thereafter.

If your liver function test results rise above normal during treatment with TASMAR the test will be repeated. If the result is confirmed, TASMAR may be discontinued slowly over 5 days.

Things you must not do

Do not stop taking TASMAR or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

If you stop taking TASMAR suddenly, you increase the risk of serious side effects.

Do not give TASMAR to anyone else even if they have the same condition as you.

Do not use TASMAR to treat other complaints unless your doctor says to.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how TASMAR affects you.

Since your ability to drive a car or operate machinery may be affected by Parkinson's disease, you should discuss this with your doctor.

Side effects

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

TASMAR helps most people with Parkinson's disease but it may have unwanted side effects in some people. All medicines can have side effects. You may need close monitoring and medical treatment if you experience some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

TASMAR can cause your urine to look more yellow. This is not harmful unless it is quite dark.

Tell your doctor if you notice any of the following and they worry you:

- increased dyskinesia (involuntary movement)
- nausea (feeling sick)
- vomiting
- sleeping problems
- somnolence (sleepiness)
- fainting
- hallucination
- decreased appetite
- diarrhoea
- constipation
- headache
- dizziness

Tell your doctor immediately if you notice any of the following;

- persistent nausea (feeling sick)
- fatigue or lethargy (feeling very tired)
- persistent decreased appetite
- jaundice (yellowing of skin)
- dark urine
- itchiness
- tenderness in upper right side of abdomen (near your navel)
- temporary paralysis or muscle ache, tenderness or weakness.

These may be symptoms of serious effects to your liver. You may need liver function tests immediately. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the nearest Accident and Emergency Centre if you notice the following symptoms, particularly if the dose of TASMAR has been changed, or you have stopped taking TASMAR:

- **Severe symptoms of muscle stiffening, twitching of muscles or tremor, rapid heart beat, fever or mental confusion.** This is called Neuroleptic Malignant Syndrome (NMS) and may occur when you stop taking TASMAR.

This is a serious side effect. You may need urgent medical attention. However, it is a rare side effect.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much TASMAR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdosage may include nausea, vomiting and dizziness, especially when TASMAR is taken with levodopa.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

Storage conditions

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep TASMAR in a cool dry place where the temperature stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep TASMAR where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking TASMAR, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

Availability

TASMAR comes in one tablet strength, 100mg. TASMAR is supplied in bottle packs of 100.

What TASMAR looks like

TASMAR 100mg tablets are pale to light yellow hexagonal tablets with "Tasmar 100" engraved on one side.

Ingredients

Active ingredient – tolcapone

Inactive ingredients - calcium hydrogen phosphate, microcrystalline cellulose, polyvidone K30, sodium starch glycolate, lactose, talc, magnesium stearate, methylhydroxypropylcellulose, yellow iron oxide (E 172), ethylcellulose, titanium dioxide (E 171), tricetin, purified water, sodium lauryl sulfate.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Valeant Pharmaceuticals New Zealand Ltd
C/O Supply Chain Solutions
74 Westney Road
Mangere
AUCKLAND

Telephone: 09-257-0521

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