Package leaflet: Information for patient



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 any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. 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.

Δ DAMAR tablets 250 + 25 mg

levadopa + carbidopa

What is in this leaflet

- 1. What **DAMAR** is and what it is used for
- What you need to know before you take **DAMAR** How to take **DAMAR**
- Possible side effects
- How to store DAMAR
- Contents of the pack and other information

1. What DAMAR is and what it is used for

DAMAR contains two different medicines called: levodopa and carbidopa. **DAMAR** belongs to a class of drugs used to treat Parkinson's disease. The symptoms of this disease are probably caused by a lack of dopamine, a substance that is normally produced by the brain. Dopamine plays a role in controlling muscle movement. A lack of it causes problems in muscle movement.

Levodopa is absorbed by the nerve cells in your brain and turned into dopamine. The dopamine helps to improve the signs of your Parkinson's disease. Carbidopa belongs to a group of medicines called 'aromatic amino disease. Carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body. Your doctor prescribed **DAMAR** tablets to you for treatment of:

- Parkinson's disease long-term illness where you become slow and unsteady, your muscles feel stiff and you may develop shaking or
- trembling (called 'tremor').
 Parkinson's syndrom that may develop after encephalitis (swelling of the brain), stroke in the area of the basal ganglia, long-term exposure to numerous toxic substances but not one caused by other medications.

DAMAR relieves symptoms of Parkinson's disease. If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

2. What you need to know before you take DAMAR Do not take DAMAR if:

- you are allergic (hypersensitive) to carbidopa or levodopa or any of the other ingredients of **DAMAR** (listed in Section 6) you have a condition called 'narrow-angle glaucoma' that may cause
- a sudden build up of pressure in the eye
- you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors) used for depression. You need to stop using these medicines at least two weeks before you start Sinemet (see also under 'Taking other medicines' below).
- you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor
- you have a severe mental disorder
- you are pregnant, might become pregnant, or are breast-feeding.

Do not take **DAMAR** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking DAMAR.

Take special care with **DAMAR**Check with your doctor or pharmacist before taking your medicine if:
you have a history of fits (convulsions)

- you have had an ulcer in your gut (called 'duodenal' or 'peptic ulcer') or have vomited blood
- you have had a heart attack, heart beat problems, circulation or breathing problems
- vou have had kidney, liver or hormonal problems
- you have had depression or other mental problems
- you have a condition called 'chronic wide-angle glaucoma' that may cause a build up of pressure in the eye. You will need to have regular checks on the pressure in your eye.
- you sometimes have sudden sleep attacks or sometimes feel very sleepy you are due to have surgery.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking DAMAR.

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of DAMAR and other medicines used to treat Parkinson's disease.

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 an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Taking other medicines with DAMAR tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because **DAMAR** can affect the way some medicines work. Also some other medicines can affect the way **DAMAR** works.

In particular, tell your doctor or pharmacist if you are taking the following medicines:

Antihypertensives, high blood pressure medications

Medicines for Parkinson's disease containing levodopa, you will need to wait 12 hours after your last dose before starting **DAMAR**. Tell the doctor or pharmacist even if you have only taken them in the past. Anticholinergic medicines (such as orphenadrine, trihexyphenidyl,

benzatropine and procyclidine)

- Medicines used to treat depression Medicine for depression called a 'non-selective monoamine oxidase inhibitor' (MAOI)
- · Antipsychotics, medicines for treating mental desorders
- Ferrous sulfate (used to treat low levels of iron in the blood).
- Miorelaxants
- Medicines for tuberculosis (TB) isoniazid ,
- Antiepileptics such as phenytoin which is used to treat fits (convulsions).
- Papaverine which is used to treat impotence in men.

Breastfeeding

Since levodopa (one of the ingredients of the DAMAR tablets) is excreted in the mother's milk, and because of serious possible side effects in infants, do not take DAMAR tablets if you are breast-feeding. Ask your doctor or pharmacist for advice before you start breastfeeding.

Tests while you are taking DAMAR

This medication can affect some laboratory tests that your doctor may perform on blood or urine samples. Please remind your doctor if you are taking **DAMAR** and are having any tests.

Taking DAMAR with food and drink

Try to avoid taking your tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese) DAMAR may not work as well as it should

Pregnancy and breast-feeding

Pregnancy
Do not take DAMAR if you are pregnant, might become pregnant or are breast-feeding.

Breast-feeding

Levodopa, one of the substances in DAMAR, is passed into human milk. Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines
Δ Trigonik, a drug with possible influence on your psycho-physical ability. (Caution is therefore advised when taking such a drug and driving vehicles or machines.)

DAMAR affects different people in different ways. Some people have side effects which affect their ability to drive or use tools or machines (see Section 4. Possible side effects). Do not drive or use tools or machines if you get these effects.

DAMAR can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive or use tools or machines. Your doctor will tell you if you can start driving again if these attacks stop.

3. How to take DAMAR tablets?

Take this medicine by mouth. Swallow DAMAR tablets whole with enough water (do not crush or chew them). Take them with or just after food. Try to avoid taking your tablets with a heavy meal.Take them about the same time every day. Always take **DAMAR** exactly as your doctor has told you. You should check with your doctor if you are not sure. Although your medicine can have an effect after one day it may take up to seven days to work. How much you take and when you take it is different for different people. Take them at regular time intervals according to your doctor's instructions. Do not change the times at which you take your tablets or take any other medicines for Parkinson's disease without first consulting your doctor.

If you did not take levodopa before

The usual starting dose is one half to one DAMAR tablet one or two times

If you have taken levodopa before

Your doctor will ask you to stop taking other medication for treatment Parkinson's disease before starting treatment with DAMAR tablets.

Children under 18 years of age

DAMAR is not suitable for children under the age of 18 years.

If you take more DAMAR than you should

If you take too many tablets see your doctor immediately.

If you forget to take DAMAR

Do not take a double dose to make up for a forgotten dose.

If you stop taking DAMAR

Do not stop taking DAMAR or change your dose without talking to your doctor first. When you stop taking Sinemet the following can occur: stiff muscles, high temperature (fever) and mental changes.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, DAMAR can cause side effects, although not everybody gets them.

Stop taking DAMAR and see your doctor straight away, if you notice any

- of the following side effects: allergic reaction, the signs may include hives(nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulty in breathing or swallowing
- chest pain
- uneven (irregular) heart beat or palpitations
- dizziness on standing-up quickly
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces(gastro- intestinal bleeding)
- blood problems, the signs may include pale skin(pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury stiff muscles, high fever
- mental changes including delusions, hallucinations and depression
- fits (convulsions).

The most common side effects are

· abnormal movements such as twitching or spasms (which may or may not be like your Parkinson's symptoms) nausea.

Other side effects include

fainting, anorexia, high blood pressure

- inflammation of the veins, being sick (vomiting) diarrhoea, discoloration of urine, sweat or saliva on-off phenomenon, characteristic of some people with long-standing
- Parkinson's disease. This is when you can have unpredictable changes from being mobile -"on" - to a sudden inability to move - "off". "Off" to "on can occur just as suddenly.
- dizziness; sleepiness (including excessive drowsiness or sudden sleep onset episodes), pins and needles
- dream abnormalities, confusion, feeling agitated, shortness of breath, hair loss

You may experience the following side effects:

 inability to resist the impulse to perform an action that could be harmful, which 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 uncontrollable 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 is needed to satisfy your hunger).

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

Side effects that have been reported with medicines containing levodopa These may be experienced when taking DAMAR.

Nervous system:

- loss of control over the voluntary movements of everyday life
- numbness, increased hand tremor, muscle twitching, muscle cramp, irregular movement of jaw muscles resulting in difficulty opening the
- difficulty sleeping, feeling anxious or high, falling over and abnormal walking patterns
- headache.

Eyes:

- drooping eyelid and dilated pupil
- changes in vision, irregular movement of the eye.

Digestive system:

- · indigestion, dry mouth, bitter taste
- swelling of the salivary glands, difficulty swallowing, grinding of the teeth
- hiccups, abdominal pain and distress, constipation, wind
- burning sensation of the tongue.

Sexual:

persistent abnormal erection of the penis

Urinary:

difficulty passing urine or incontinence (inability to control urine flow)

 changed patches of pigmented skin, including, irritated or irregular moles, or moles in which you have noticed changes(melanoma)

General:

- weight gain or loss, swelling in the limbs
- flushing, hot flushes, increased sweating
- feeling weak, faint or tired
- hoarseness, general feeling of being unwell
- increased energy or activity, unusual breathing pattern.

If any symptoms persist or you experience any other side effects please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting suspected adverse drug reactions

In case of any adverse reactions after administration of the drug, it is necessary to tell your doctor or pharmacist. This implies every possible undesirable reactions not listed in this leaflet, as well as those which are.

5. How to store DAMAR

Do not store above 25°C. Store in the original pack .

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What DAMAR contains?

DAMAR 250 + 25 mg

Each tablet contains 250 mg of levodopa and 25 mg of carbidopa as an active substances. Other ingridients: lactose monohydrate, partially pregelatinized corn starch, magnesium stearate, TopMill blue.

Contents of the pack

100 (10x10) tablets of 250 + 25 mg in a blister pack, in a box.

Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals d.o.o.

Donji Bistarac bb 75300 Lukavac, Bosnia and Herzegovina.

Data of first authorisation / renewal of the authorisation in BIH: DAMAR 250 + 25 mg (levadopa,carbidopa)

Date: 07.12.2015. Number: 04-07.9-1652/14

ENUP00444 V1