

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 mouth
- 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)

Skin:

- 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