

Package leaflet: information for the user

Padovel 200 mg/50 mg/200 mg film-coated tablets

Levodopa/carbidopa/entacapone

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. See section 4.

What is in this leaflet:

1. What Padovel is and what it is used for
2. What you need to know before you take Padovel
3. How to take Padovel
4. Possible side effects
5. How to store Padovel
6. Contents of the pack and other information

1. What Padovel is and what it is used for

Padovel contains three active substances (levodopa, carbidopa and entacapone) in one film-coated tablet. Padovel is used for the treatment of Parkinson's disease.

Parkinson's disease is caused by low levels of a substance called dopamine in the brain. Levodopa increases the amount of dopamine and hence reduces the symptoms of Parkinson's disease. Carbidopa and entacapone improve the antiparkinson effects of levodopa.

2. What you need to know before you take Padovel

Do not take Padovel if you

- are allergic to levodopa, carbidopa or entacapone, or any of the other ingredients of this medicine (listed in section 6);
- have narrow-angle glaucoma (an eye disorder);
- have a tumour of the adrenal gland;
- are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO-inhibitors);
- have ever had neuroleptic malignant syndrome (NMS – this is a rare reaction to medicines used to treat severe mental disorders);
- have ever had non-traumatic rhabdomyolysis (a rare muscle disorder);
- have a severe liver disease.

Warnings and precautions

Talk to your doctor or pharmacist before taking Padovel if you have or have ever had:

- a heart attack or any other diseases of the heart including cardiac arrhythmias, or of the blood vessels;
- asthma or any other disease of the lungs;
- a liver problem, because your dose may need to be adjusted;
- kidney or hormone-related diseases;
- stomach ulcers or convulsions;
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon;
- any form of severe mental disorder like psychosis;
- chronic wide-angle glaucoma, because your dose may need to be adjusted and the pressure in your eyes may need to be monitored.

Consult your doctor if you are currently taking:

- antipsychotics (medicines used to treat psychosis)
- a medicine which may cause low blood pressure when rising from a chair or bed.

You should be aware that Padovel may make these reactions worse.

Consult your doctor if during the treatment with Padovel you:

- notice that your muscles get very rigid or jerk violently, or if you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. If any of this happens, contact your doctor immediately;
- feel depressed, have suicidal thoughts, or notice unusual changes in your behaviour;
- find yourself suddenly falling asleep, or if you feel very drowsy. If this happens, you should not drive or use any tools or machines (see also section Driving and using machines);
- notice that uncontrolled movements begin or get worse after you started to take Padovel. If this happens, your doctor may need to change the dose of your antiparkinson medicine;
- experience diarrhoea: monitoring of your weight is recommended in order to avoid potentially excessive weight loss;
- experience progressive anorexia, asthenia (weakness, exhaustion) and weight decrease within a relatively short period of time. If this happens, a general medical evaluation including liver function should be considered;
- feel the need to stop using Padovel, see section If you stop taking Padovel.

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

Your doctor may take some regular laboratory tests during a long term treatment with Padovel. If you must undergo surgery, please tell your doctor that you are using Padovel.

Padovel is not recommended to be used for treatment of extrapyramidal symptoms (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions) caused by other medicines.

Children and adolescents

Experience with Padovel in patients under 18 years is limited. Therefore, the use of Padovel in children is not recommended.

Other medicines and Padovel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Padovel if you are taking certain medicines for treating depression (combinations of selective MAO-A and MAO-B inhibitors, or non-selective MAO inhibitors).

Padovel may increase the effects and side effects of certain medicines. These include:

- medicines used to treat depression such as moclobemide, amitryptiline, desipramine, maprotiline, venlafaxine and paroxetine;
- rimiterole and isoprenaline, used to treat respiratory diseases;
- adrenaline, used for severe allergic reactions;
- noradrenaline, dopamine and dobutamine, used to treat heart diseases and low blood pressure;
- alpha-methyldopa, used to treat high blood pressure;
- apomorphine, which is used to treat Parkinson's disease.

The effects of Padovel may be weakened by certain medicines. These include:

- dopamine antagonists used to treat mental disorders, nausea and vomiting;
- phenytoin used to prevent convulsions;
- papaverine used to relax the muscles.

Padovel may make it harder for you to digest iron. Therefore, do not take Padovel and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

Padovel with food and drink

Padovel may be taken with or without food. For some patients, Padovel may not be well absorbed if it is taken with, or shortly after eating protein-rich food (such as meats, fish, dairy products, seeds and nuts). Consult your doctor if you think this

applies to you.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not breast-feed during treatment with Padovel.

Driving and using machines

Padovel may lower your blood pressure, which may make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you use any tools or machines.

If you feel very drowsy, or if you sometimes find yourself suddenly falling asleep, wait until you feel fully awake again before driving or doing anything else that requires you to be alert. Otherwise, you may put yourself and others at risk of serious injury or death.

3. How to take Padovel

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For adults and elderly:

- Your doctor will tell you exactly how many tablets of Padovel to take each day.
- The tablets are not intended to be split or broken into smaller pieces.
- You should take only one tablet each time.
- Depending on how you respond to treatment, your doctor may suggest a higher or lower dose.
- If you are taking Padovel 200 mg/50 mg/200 mg, do not take more than 7 tablets of this strength per day.

Talk to your doctor or pharmacist if you think the effect of Padovel is too strong or too weak, or if you experience possible side effects.

If you take more Padovel than you should

If you have accidentally taken more Padovel tablets than you should, talk to your doctor or pharmacist immediately. In case of an overdose you may feel confused or agitated, your heart rate may be slower or faster than normal or the color of your skin, tongue, eyes or urine may change.

If you forget to take Padovel

Do not take a double dose to make up for a forgotten tablet. If it is more than 1 hour until your next dose:

Take one tablet as soon as you remember, and the next tablet at the normal time.

If it is less than 1 hour until your next dose:

Take a tablet as soon as you remember, wait 1 hour, then take another tablet. After that carry on as normal.

Always leave at least an hour between Padovel tablets, to avoid possible side effects.

If you stop taking Padovel

Do not stop taking Padovel unless your doctor tells you to. In such a case your doctor may need to adjust your other antiparkinson medicines, especially levodopa, to give sufficient control of your symptoms. If you suddenly stop taking of Padovel and other antiparkinsonian medicines it may result in unwanted side effects.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Many of the side effects can be relieved by adjusting the dose.

If you during the treatment with Padovel experience the following symptoms, contact your doctor immediately:

- Your muscles get very rigid or jerk violently, you get tremors, agitation, confusion, fever, rapid pulse, or wide fluctuations in your blood pressure. These can be symptoms of neuroleptic malignant syndrome (NMS, a rare severe reaction to medicines used to treat disorders of the central nervous system) or rhabdomyolysis (a rare severe muscle disorder).
- Allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulties in breathing or swallowing.

Very common (may affect more than 1 in 10 people)

- uncontrolled movements (dyskinesias)
- feeling sick (nausea)
- harmless reddish-brown discoloration of urine
- muscle pain
- diarrhoea

Common (may affect up to 1 in 10 people)

- light-headedness or fainting due to low blood pressure, high blood pressure
- worsening of Parkinson's symptoms, dizziness, drowsiness
- vomiting, abdominal pain and discomfort, heartburn, dry mouth, constipation
- inability to sleep, hallucinations, confusion abnormal dreams (including nightmares), tiredness
- mental changes – including problems with memory, anxiety and depression (possibly with thoughts of suicide)

- heart or artery disease events (e.g. chest pain), irregular heart rate or rhythm
- more frequent falling
- shortness of breath
- increased sweating, rashes
- muscle cramps, swelling of legs
- blurred vision
- anaemia
- decreased appetite, decreased weight
- headache, joint pain
- urinary tract infection

Uncommon (may affect up to 1 in 100 people)

- heart attack
- bleeding in the gut
- changes in the blood cell count which may result in bleeding, abnormal liver function tests
- convulsions
- feeling agitated
- psychotic symptoms
- colitis (inflammation of the colon)
- discolourations other than urine (e.g. skin, nail, hair, sweat)
- swallowing difficulties
- inability to urinate

The following side effects have also been reported:

- hepatitis (inflammation of the liver)
- itching

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 or personal 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; they will discuss ways of managing or reducing the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Padovel

Keep this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

After first opening 30 tablets´ bottle pack: 30 days.

After first opening 175 tablets´ bottle pack: 175 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Padovel contains

- The active substances of Padovel are levodopa, carbidopa and entacapone.
- Each Padovel 200 mg/50 mg/200 mg tablet contains 200 mg of levodopa, 50 mg of carbidopa and 200 mg of entacapone.
- The other ingredients in the tablet core are cellulose microcrystalline, crospovidone, povidone K-30, magnesium stearate and sodium citrate.
- The ingredients in the film-coating are hypromellose, polyethylene glycol, titanium dioxide (E171), red iron oxide (E172) and polysorbate 80.

What Padovel looks like and contents of the pack

Padovel 200 mg/50 mg/200 mg: dark brownish red colored, oval shaped, film coated tablets with debossed "200" on one side and plain on other side.

Padovel comes in bottle pack (HDPE Container) in six different pack sizes (10, 30, 100, 130, 175 or 500 tablets) and blisters Alu/Alu in five different pack sizes (10, 30, 100, 130 and 250 tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

SVUS Pharma a.s.

Smetanovo nábřeží 1238/20a, 500 02 Hradec Králové

Czech Republic