Package leaflet: Information for the user

Sastravi 50 mg/12.5 mg/200 mg film-coated tablets
Sastravi 75 mg/18.75 mg/200 mg film-coated tablets
Sastravi 100 mg/25 mg/200 mg film-coated tablets
Sastravi 125 mg/31.25 mg/200 mg film-coated tablets
Sastravi 150 mg/37.5 mg/200 mg film-coated tablets
Sastravi 175 mg/43.75 mg/200 mg film-coated tablets
Sastravi 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 Sastravi is and what it is used for

Sastravi contains three active substances (levodopa, carbidopa and entacapone) in one film-coated tablet. Sastravi 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 Sastravi

Do not take Sastravi if you

- are allergic to levodopa, carbidopa or entacapone, soya, peanut 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 Sastravi 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 Sastravi may make these reactions worse.

Consult your doctor if during the treatment with Sastravi 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 Sastravi. 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 Sastravi, see section 'If you stop taking Sastravi'.

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of Sastravi 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 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 Sastravi.

If you must undergo surgery, please tell your doctor that you are using Sastravi.

Sastravi 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.

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

Children and adolescents

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

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

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

Sastravi may increase the effects and side effects of certain medicines. These include:
- medicines used to treat depression such as moclobemide, amitriptyline, 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 Sastravi 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.

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

Sastravi with food and drink
Sastravi may be taken with or without food. For some patients, Sastravi 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 Sastravi.

Driving and using machines
Sastravi 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.

Sastravi contains lecithin (soya)
If you are allergic to peanut or soya, do not use this medicinal product.

Sastravi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Sastravi

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 Sastravi 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 Sastravi 50 mg/12.5 mg/200 mg, 75 mg/18.75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg or 150 mg/37.5 mg/200 mg tablets, do not take more than 10 tablets per day.
- If you are taking Sastravi 175 mg/43.75 mg/200 mg, do not take more than 8 tablets per day.
- If you are taking Sastravi 200 mg/50 mg/200 mg, do not take more than 7 tablets per day.

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

Use in children and adolescents
Sastravi should not be used in children and adolescents under 18 years of age.

If you take more Sastravi than you should
If you have accidentally taken more Sastravi 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 Sastravi
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 Sastravi tablets, to avoid possible side effects.

If you stop taking Sastravi
Do not stop taking Sastravi 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 Sastravi 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 Sastravi 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 discolouration 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
- feeling of weakness, fatigue
- abnormal gait
- 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
- feeling unwell

Not known (cannot be estimated from the available data)
- Craving for large doses of Sastravi in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of Sastravi.

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 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; 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 HPRA Pharmacovigilance Website: www.hpra.ie . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sastravi

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.

Do not store above 30°C.

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

6. Contents of the pack and other information

What Sastravi contains
- The active substances are levodopa, carbidopa and entacapone.
- Each film-coated tablet contains 50 mg of levodopa, 12.5 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 75 mg of levodopa, 18.75 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 100 mg of levodopa, 25 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 125 mg of levodopa, 31.25 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 150 mg of levodopa, 37.5 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 175 mg of levodopa, 43.75 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- Each film-coated tablet contains 200 mg of levodopa, 50 mg of carbidopa (as monohydrate) and 200 mg of entacapone.
- The other ingredients are *Tablet core:* croscarmellose sodium, hydroxypropylcellulose, trehalose dihydrate, powdered cellulose, anhydrous sodium sulfate, microcrystalline cellulose, magnesium stearate.
- *Film coat:* polyvinyl alcohol-part. hydrolyzed, talc, titanium dioxide (E171), macrogol, iron oxide red (172), lecitin (soya) (E322), iron oxide yellow (E172).

What Sastravi looks like and contents of the pack
Sastravi 50 mg/12.5 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 6.85 x 14.2 mm with "50" marked on one side and "LEC" on the opposite side.
Sastravi 75 mg/18.75 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 7. 04 x 14.7 mm with "75" marked on one side and "LEC" on the opposite side.
Sastravi 100 mg/25 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 7.23 x 15.3 mm with "100" marked on one side and "LEC" on the opposite side.

Sastravi 125 mg/31.25 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 7.5 x 15.8 mm with “125” marked on one side and “LEC” on the opposite side.
Sastravi 150 mg/37.5 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 7.68 x 16.2 mm with “150” marked on one side and “LEC” on the opposite side.
Sastravi 175 mg/43.75 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 7.92 x 16.6 mm with “175” marked on one side and “LEC” on the opposite side.
Sastravi 200 mg/50 mg/200 mg: Brownish red, oval, biconvex film-coated tablet 8.21 x 17.2 mm with “200” marked on one side and “LEC” on the opposite side.

Pack sizes:
Tablet container with screw cap:
10, 30, 100, 130, and 175 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Teva B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer
Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str.
Dupnitsa 2600
Bulgaria

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Sastravi Filmtabletten
Czech Republic	Sastravi
Denmark	Sastravi
Finland	Sastravi
Hungary	Sastravi filmtabletta
Iceland	Sastravi
Ireland	Sastravi
Malta	Sastravi
Romania	Sastravi comprimate filmate
Slovakia	Sastravi
Sweden	Sastravi
United Kingdom	Sastravi

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