

Package leaflet: information for the user

Entacapone Teva 200 mg film-coated tablets

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

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1. What Entacapone Teva is and what it is used for

Entacapone Teva tablets contain entacapone and are used together with levodopa to treat Parkinson's disease. Entacapone Teva aids levodopa in relieving the symptoms of Parkinson's disease. Entacapone Teva has no effect on relieving the symptoms of Parkinson's disease unless taken with levodopa.

2. What you need to know before you take Entacapone Teva

Do NOT take Entacapone Teva

- if you are allergic to entacapone or any of the other ingredients of this medicine (listed in section 6);
- if you have a tumour of the adrenal gland (known as pheochromocytoma; this may increase the risk of severe high blood pressure);
- if you are taking certain antidepressants (ask your doctor or pharmacist whether your antidepressive medicine can be taken together with Entacapone Teva);
- if you have liver disease;
- if you have ever suffered from a rare reaction to antipsychotic medicines called neuroleptic malignant syndrome (NMS). See section 4 Possible side effects for the characteristics of NMS;
- if you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury.

Warnings and precautions

Talk to your doctor or pharmacist before taking Entacapone Teva:

- if you have ever had a heart attack or any other diseases of the heart;
- if you are taking a medicine which may cause dizziness or light-headedness (low blood pressure) when rising from a chair or bed;
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon;
- if you experience diarrhoea, monitoring of your weight is recommended in order to avoid potentially excessive weight loss;
- if you experience increasing loss of appetite, weakness, exhaustion and weight loss within a relatively short period of time, a general medical evaluation including liver function should be considered.

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.

As Entacapone Teva tablets will be taken together with other levodopa medicines, please also read the package leaflets of these medicines carefully.

The dose of other medicines to treat Parkinson's disease may need to be adjusted when you start taking Entacapone Teva. Follow the instructions that your doctor has given you.

Neuroleptic Malignant Syndrome (NMS) is a serious but rare reaction to certain medicines, and may occur especially when Entacapone Teva and other medicines to treat Parkinson's disease are suddenly stopped or the dose is suddenly reduced. For the characteristics of NMS see Section 4 Possible side effects. Your doctor may advise you to slowly discontinue the treatment with Entacapone Teva and other medicines to treat Parkinson's disease.

Entacapone Teva taken with levodopa may cause drowsiness and may cause you to sometimes suddenly fall asleep. If this happens, you should not drive or use any tools or machines (see Driving and using machines).

Other medicines and Entacapone Teva

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular please tell your doctor if you are taking any of the following:

- rimeterole, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, apomorphine;
- antidepressants including desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin used to thin the blood;
- iron supplements. Entacapone Teva may make it harder for you to digest iron. Therefore, do not take Entacapone Teva and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

Pregnancy, breast-feeding and fertility

Do not use Entacapone Teva during pregnancy or if you are breast-feeding.

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.

Driving and using machines

Entacapone Teva taken together with levodopa may lower your blood pressure, which may make you feel light-headed or dizzy. Be particularly careful when you drive or when you use tools or machinery.

In addition, Entacapone Teva taken with levodopa may make you feel very drowsy, or cause you to sometimes find yourself suddenly fall asleep. Do not drive or operate machinery if you experience these side effects.

3. How to take Entacapone Teva

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

Entacapone Teva is taken together with medicines containing levodopa (either levodopa/carbidopa preparations or levodopa/benserazide preparations). You may also use other medicines to treat Parkinson's disease at the same time.

The recommended dose of Entacapone Teva is one 200 mg tablet with each levodopa dose. The maximum recommended dose is 10 tablets per day, i.e. 2,000 mg of Entacapone Teva.

If you are receiving dialysis for renal insufficiency, your doctor may tell you to increase the time between doses.

Use in children and adolescents

Experience with Entacapone Teva in patients under 18 years is limited. Therefore, the use of Entacapone Teva in children cannot be recommended.

If you take more Entacapone Teva than you should

In the event of an overdose, consult your doctor, pharmacist or the nearest hospital immediately.

If you forget to take Entacapone Teva

If you forget to take the Entacapone Teva tablet with your levodopa dose, you should continue the treatment by taking the next Entacapone Teva tablet with your next levodopa dose.

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

If you stop taking Entacapone Teva

Do not stop taking Entacapone Teva unless your doctor tells you to.

When stopping your doctor may need to re-adjust the dosage of your other medicines to treat Parkinson's disease. Suddenly stopping Entacapone Teva and other medicines to treat Parkinson's disease may result in unwanted side effects. See Section 2 Warnings and precautions.

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. Usually side effects caused by Entacapone Teva are mild to moderate.

Some of the side effects are often caused by the increased effects of levodopa therapy and are most common at the start of treatment. If you experience such effects at the start of treatment with Entacapone Teva you should contact your doctor who may decide to adjust your dosage of levodopa.

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

- Uncontrollable movements with difficulty in performing voluntary movements (dyskinesias);
- feeling sick (nausea);
- harmless reddish-brown discoloration of urine.

Common (may affect up to 1 in 10 people):

- Excessive movements (hyperkinesias), worsening of symptoms of Parkinson's disease, prolonged muscle cramps (dystonia);
- being sick (vomiting), diarrhoea, abdominal pain, constipation, dry mouth;
- dizziness, tiredness, increased sweating, fall;
- hallucinations (seeing/hearing/feeling/smelling things that are not really there), sleeplessness, vivid dreams, and confusion;
- heart or artery disease events (e.g. chest pain).

Uncommon (may affect up to 1 in 100 people):

- Heart attack.

Rare (may affect up to 1 in 1,000 people):

- Rashes;
- abnormal results in liver function test.

Very rare (may affect up to 1 in 10,000 people):

- Agitation;
- decreased appetite, weight loss;
- hives.

Not known (frequency cannot be estimated from the available data):

- Inflammation of the colon (colitis), inflammation of the liver (hepatitis) with yellowing of the skin and whites of the eyes;
- discolouration of skin, hair, beard and nails.

When Entacapone Teva is given at higher doses:

In doses of 1,400 to 2,000 mg per day, the following side effects are more common:

- Uncontrollable movements;
- nausea;
- abdominal pain.

Other important side effects which may occur:

- Entacapone Teva taken with levodopa may rarely make you feel very drowsy during the day, and cause you to suddenly fall asleep;
- Neuroleptic Malignant Syndrome (NMS) is a rare severe reaction to medicines used to treat disorders of the nervous system. It is characterised by stiffness, muscle twitching, shaking, agitation and confusion, coma, high body temperature, increased heart rate and unstable blood pressure;
- a rare severe muscle disorder (rhabdomyolysis) which causes pain, tenderness and weakness of the muscles and may lead to kidney problems.

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 the Yellow Card Scheme website:

www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Entacapone Teva

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 carton and tablet container label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Entacapone Teva contains**

- The active substance is entacapone. Each film-coated tablet contains 200 mg of entacapone.
- The other ingredients in the tablet core are cellulose microcrystalline, povidone, starch pregelatinised, magnesium stearate and in the film-coating are poly(vinyl alcohol), talc, titanium dioxide (E171), macrogol, iron oxide yellow (E172), lecithin (soya), iron oxide red (E172).

What Entacapone Teva looks like and contents of the pack

Entacapone Teva film-coated tablets are light brown, biconvex ellipse-shaped with approximately 18 mm length and 10 mm width, embossed with "E200" on one side and plain on the other side.

Entacapone Teva is available in HDPE tablet containers with polypropylene screw caps with desiccant insert containing 30, 60, 100 or 175 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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