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Package leaflet: Information for the patient

Entacapone 200 mg film-coated tablets

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 Entacapone is and what it is used for

Entacapone tablets contain entacapone and are used together with levodopa to treat Parkinson's disease. Entacapone aids levodopa in relieving the symptoms of Parkinson's disease. Entacapone 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

Do not take Entacapone:
- if you are allergic to entacapone or any of the other ingredients of this medicine (listed in Section 6). Symptoms of allergy include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin
- if you have phaeochromocytoma , a tumour of the adrenal gland (a gland which sits near the kidney) because this may increase the risk of severe high blood pressure
- if you are taking certain antidepressants known as non-selective monoamine oxidase inhibitors (MAOIs). Examples include phenelzine and tranylcypromine (ask your doctor or pharmacist whether your antidepressive medicine can be taken together with Entacapone)
- if you are taking reversible monoamine oxidase inhibitors type A (such as moclobemide) together with monoamine oxidase inhibitors type B (examples include selegiline)
- 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 of this leaflet (Possible side effects) for the symptoms of NMS
- if you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury. Rhabdomyolysis causes pain, tenderness and weakness of the muscles, sensitivity to pressure, and may lead to kidney problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Entacapone:
- 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 any unexplained muscle pain, tenderness or weakness, or sensitivity to pressure
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon (large intestine or gut)
- 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. Your doctor may consider doing a general medical evaluation including testing your liver function.

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.**

As Entacapone 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. 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 and other medicines to treat Parkinson's disease are suddenly stopped or the dose is suddenly reduced. For the symptoms of NMS see Section 4 (Possible side effects). Your doctor may advise you to slowly discontinue the treatment with Entacapone and other medicines to treat Parkinson's disease.

Entacapone 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").

Children and adolescents
Experience with Entacapone in patients under 18 years is limited. Therefore, the use of Entacapone in children is not recommended.

Other medicines and Entacapone
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription or herbal medicines.

In particular please tell your doctor if you are taking any of the following:
- rimiterole, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, apomorphine
- antidepressants: tricyclic antidepressants (such as amitriptyline, desipramine), maprotiline, venlafaxine, paroxetine, reversible monoamine oxidase inhibitors type A (such as moclobemide)
- warfarin (used to thin the blood)
- iron supplements. Entacapone may make it harder for you to digest iron. Therefore, do not take Entacapone 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 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 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 taken with levodopa may make you feel very drowsy, or cause you to sometimes suddenly fall asleep.

Do not drive or operate machinery if you experience these side effects.

Entacapone contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Entacapone

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 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 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. This medicine can be taken with or without food.

Patients with kidney problems
If you are receiving dialysis because you have kidney problems, your doctor may tell you to increase the time between doses.

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Date/Time of Creation	12/04/21 12:46	Track-Wise PR No.	2409635	Client Market	United Kingdom	Software / Ver. No.	Adobe InDesign 15.1		
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Artwork Proof No.	1	Aff. Superseded Code	1949066						
Pharma Code	NA	Barcode Information	NA	New Material Code	75079324	Actual A/w Size	Open Size - 170 x 400 mm		
Product Render ID No.	NA	MA Number	PL 04569/1188	ITF Barcode		Other Sizes (if any)	Folded size - 170 x 40 mm		
Main Font Type - 1	Myraid Pro	SAP or SPC Code	400505398, 400505399	Superseded Code	75068959	Pitch After Every	NA		
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If you take more Entacapone than you should
In the event of an overdose, consult your doctor or the nearest hospital **immediately**. Symptoms include confusion, decreased activity, feeling sleepy, decreased muscle tone, skin discolouration and urticaria (hives).

If you forget to take Entacapone
If you forget to take the Entacapone tablet with your levodopa dose, you should continue the treatment by taking the next Entacapone tablet with your next levodopa dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Entacapone
Do not stop taking Entacapone 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 and other medicines to treat Parkinson's disease may result in unwanted side effects. See Section 2 of this leaflet (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 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 the treatment. If you experience such effects at the start of treatment with Entacapone you should contact your doctor who may decide to adjust your dosage of levodopa.

Tell your doctor if you get any of the following side effects:
- Entacapone 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 and can happen when these medicines are discontinued or stopped abruptly. It is characterised by stiffness, muscle twitching, shaking, agitation, 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, sensitivity to pressure, and may lead to kidney problems,
- 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 sex 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 these symptoms.
- Heart attack (symptoms include chest pain which can feel as if it is travelling to other parts of your body such as your left arm, jaw and neck, shortness of breath, anxiety, feeling light-headed and nausea (feeling sick) or vomiting (being sick). This is an uncommon side effect (may affect up to 1 in 100 people)
- Inflammation of the colon (colitis; symptoms include prolonged or persistent diarrhoea) or inflammation of the liver (hepatitis) with yellowing of the skin and whites of the eyes. The frequency of these side effects is not known (cannot be estimated from the available data)

Other side effects:

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, falling
- 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, angina)

Rare (may affect up to 1 in 1,000 people):
- rashes characterised by redness or bumps on the skin
- abnormal results in liver function tests

Very rare (may affect up to1 in 10,000 people):
- agitation
- decreased appetite, weight loss
- hives

Not known (frequency cannot be estimated from the available data):
- discolouration of the skin, hair, beard and nails

When Entacapone 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 with difficulty in performing voluntary movements (dyskinesias)
- feeling sick (nausea)
- abdominal pain

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

5. How to store Entacapone

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 label, carton, bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

For bottle pack only: Once open use within 100 days.

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 Entacapone contains:
- The active substance is entacapone. Each tablet contains 200 mg of entacapone.
- The other ingredients in the tablet core are cellulose, microcrystalline, mannitol, hydroxypropylcellulose, low-substituted, magnesium stearate, hydrogenated vegetable oil.
- The film-coating contains hypromellose, titanium dioxide (E171), glycerin, magnesium stearate, iron oxide yellow (E172), sucrose, polysorbate 80, iron oxide red (E172).

What Entacapone looks like and contents of the pack
Entacapone 200 mg film-coated tablets are light orange, oval-shaped, biconvex, film coated tablets debossed with "EE200" on one side of the tablet and "M" on the other side. They are packed in blisters, bottles and cartons containing multiple bottles.

Blister packs comprise of clear transparent PVC/PE/PVdC film on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side containing 30, 60, 100, 200, 300 or 400 tablets, or a perforated blister unit dose pack containing 100x1 tablets.

Bottle packs comprise of white coloured high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) screw cap containing 30, 50, 60, 100, 250 or 500 tablets.

Cartons containing 200, 300, or 400 tablets as 4, 6 or 8 bottles of 50 tablets. Bottles comprise of white coloured high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) screw cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL,
United Kingdom.

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Mylan Hungary Kft., H-2900, Komárom, Mylan utca 1.Hungary.

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