

Entacapone HEC 200MG Film-Coated Tablets

Entacapone (200mg)

What is in this leaflet

1. What Entacapone HEC is used for
2. How Entacapone HEC works
3. Before you use Entacapone HEC
4. How to use Entacapone HEC
5. While you are using it
6. Side effects
7. Storage and Disposal of Entacapone HEC
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Entacapone HEC is used for

Entacapone HEC contains entacapone and is used together with levodopa to treat Parkinson's disease for those who cannot be stabilised on levodopa combinations.

How Entacapone HEC works

Entacapone HEC supports levodopa in relieving the symptoms of Parkinson's disease. Entacapone HEC has no effect on relieving the symptoms of Parkinson's disease unless taken with levodopa.

Before you use Entacapone HEC

- When you must not use it

Do not take Entacapone HEC

- if you are allergic to entacapone, peanut, soya or any of the other ingredients of this medicine;
- if you have a tumour of the adrenal gland, known as a pheochromocytoma
- if you are taking certain antidepressants. Ask your doctor or pharmacist whether your antidepressive medicine can be taken together with Entacapone HEC;
- if you have liver disease;
- if you have ever suffered from a rare reaction to antipsychotic medicines called neuroleptic malignant syndrome (NMS).
- if you have ever suffered from a rare muscle disorder (rhabdomyolysis), which was not caused by injury.

Pregnancy and breast-feeding

Do not take Entacapone HEC if you are pregnant, think you may be pregnant or are planning to have a baby.

Do not take Entacapone HEC if you are breast-feeding. Ask your doctor or pharmacist for advice before taking this medicine.

- Before you start to use it

Talk to your doctor or pharmacist before taking Entacapone HEC:

- 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 diarrhea
- if you experience excessive gambling or sexual activity
- if you experience increasing loss of appetite, weakness, exhaustion and weight loss within a relatively short period of time.

Tell your doctor if you, your family or your carer notices that you are developing urges or cravings that are unusual for you or that you are unable to 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.

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.

- Taking other medicines

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

Especially, if you are taking any of the following:

- rimeterol, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa and apomorphine;
- medicines used to treat depression including desipramine, maprotiline, venlafaxine and paroxetine;
- warfarin used to thin the blood;
- iron supplements. It 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.

How to use Entacapone HEC

- How much to use

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 HEC should only be used in combination with levodopa/benserazide or levodopa/carbidopa. The prescribing information for these levodopa preparations is applicable to their concomitant use with entacapone.

The usual dose of Entacapone is one 200 mg tablet with each levodopa dose. The maximum recommended dose is 10 tablets daily, i.e. 2,000 mg of entacapone.

If you are receiving dialysis for renal insufficiency, your doctor may tell you to increase the time between doses. Your doctor will tell you exactly how many tablets of Entacapone HEC to take.

Entacapone enhances the effects of levodopa. Hence, to reduce levodopa-related dopaminergic adverse reactions, e.g. dyskinesias (abnormal involuntary movement), nausea, vomiting and hallucinations, it is often necessary to adjust levodopa dosage within the first days to first weeks after initiating entacapone treatment. The daily dose of levodopa should be reduced by about 10 to 30% by extending the dosing intervals

and/or by reducing the amount of levodopa per dose, according to the clinical condition of the patient.

Entacapone increases the bioavailability of levodopa from standard levodopa/benserazide preparations slightly more (5 to 10%) than from standard levodopa/carbidopa preparations. Hence, patients who are taking standard levodopa/benserazide preparations may need a larger reduction of their levodopa dose when entacapone is initiated.

If entacapone treatment is discontinued, it is necessary to adjust the dosing of other antiparkinsonian treatments, especially levodopa, to achieve a sufficient level of control of the parkinsonian symptoms.

Use in elderly

No dosage adjustment of entacapone is required for elderly patients.

Use in children

Entacapone HEC is not recommended for use in children below age 18 due to lack of data on safety and efficacy.

- When to use it

Take Entacapone HEC at the same time as you take a dose of your levodopa medication. Entacapone HEC can be taken with or without food.

- How long to use it

Continue taking Entacapone HEC for as long as your doctor recommends.

- If you forget to use it

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 take more Entacapone HEC than you should (overdose)

In the event of an overdose, consult your doctor, pharmacist or the nearest hospital immediately. You may require medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Entacapone HEC.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. In such a case your doctor may need to re-adjust the dosage of the other medicines you are taking to treat Parkinson's disease. Suddenly stopping entacapone and other medicines to treat Parkinson's disease may result in unwanted side effects.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Entacapone HEC to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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 HEC contains soya

Entacapone HEC contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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 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.

Very common:

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

Common:

- excessive movements (hyperkinesia), worsening of symptoms of Parkinson's disease, prolonged muscle spasms (dystonia)
- vomiting, diarrhea, abdominal pain, constipation, dry mouth
- dizziness, tiredness, increased sweating, falls
- hallucinations (seeing, hearing, feeling or smelling things that are not really there), sleeplessness, vivid dreams, and confusion
- heart or artery disease events (e.g. chest pain).

Uncommon:

- heart attack.

Rare:

- rashes
- abnormal liver function test results.

Very rare:

- agitation
- decreased appetite, weight loss
- hives.

Not known:

- 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 is given at higher doses

In doses of 1,400 - 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 taken with levodopa may rarely make you feel very drowsy during the day and cause you to fall asleep suddenly
- Neuroleptic Malignant Syndrome 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 problem
- Behavioural changes such as the urge to gamble or increased sexual desire and urges (increased libido and hypersexuality) have been reported in patients receiving dopaminergic medicines such as entacapone with levodopa.

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).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the

website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Entacapone HEC

- Storage

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

Store at temperature below 30°C.

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

- Disposal

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.

Product Description

What it looks like

Entacapone HEC 200 mg film-coated tablets are orange brown capsular-shaped film-coated tablets, debossed "S52" on one side and blank on the other side. The tablet size is 14*6.5 mm.

Entacapone HEC is available in packs of 30 and 100 film-coated tablets in a bottle with a child-resistant cap.

Ingredients

-Active ingredient

Entacapone

- Inactive ingredients

Tablet core: microcrystalline cellulose, mannitol, sodium starch glycolate (type A), povidone (K29/32), magnesium stearate

Film-coating: polyvinyl alcohol (partly hydrolyzed), talc, titanium dioxide (E171), macrogol 3350, iron oxide yellow (E172), lecithin (soya), iron oxide red (E172).

- MAL number(s):

MAL19116034ACZ

Manufacturer

Sunshine Lake Pharma Co., Ltd.
Northern Industry Road 1#, Song Shan Lake, DongGuan, GuangDong Province, 523808, P.R. China

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor, Malaysia

Date of revision

12/09/2023

Serial Number

NPRA(R2/1)230911/1140