

Patient Leaflet According to the Pharmacists' Regulations (Preparations) -
1986

This medicine is dispensed with a doctor's prescription only

Entacapone Medochemie

Coated Tablets

The active ingredient and its content:

Each tablet contains 200 mg entacapone

Inactive ingredients:

See section 6 "additional information".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Entacapone Medochemie is used for the treatment of Parkinson's disease, in combination with levodopa/carbidopa or levodopa/benserazid.

Therapeutic group:

Catechol-O-methyl transferase inhibitor.

Entacapone Medochemie aids levodopa in relieving the symptoms of Parkinson's disease.

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

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient entacapone, or to any of the other additional ingredients this medicine contains (see section 6).
- you have a tumor of the adrenal gland (pheochromocytoma; this may increase the risk of severe high blood pressure).
- you are taking certain antidepressants (ask your doctor or pharmacist whether the antidepressant you are taking can be taken together with Entacapone Medochemie).
- you have liver disease.
- you have ever suffered from a rare reaction to antipsychotic medicines called neuroleptic malignant syndrome (NMS). See section 4 "side effects" for the characteristics of NMS.
- you have ever suffered from a rare muscle disorder called rhabdomyolysis

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| <p>which is not a result of injury.</p> <ul style="list-style-type: none">• you are pregnant or breastfeeding. |
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Special warnings regarding the use of this medicine:

Consult your doctor if one of the following conditions are relevant for you:

Before treatment with Entacapone Medochemie, tell your doctor if:

- you have ever had a heart attack or any other diseases of the heart;
- you are taking a medicine which may cause dizziness or light-headedness (low blood pressure) when rising from a chair or bed;
- you experience prolonged diarrhea, consult your doctor as it may be a sign of inflammation of the colon;
- you experience diarrhea, monitoring of your weight is recommended in order to avoid potentially excessive weight loss;
- 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 that you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviors are called impulse control disorders and can include addiction to 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.

Since Entacapone Medochemie tablets will be taken together with other levodopa medicines, carefully read the package leaflets of these medicines as well.

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

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

Entacapone Medochemie 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 Medochemie in patients under 18 years of age is limited. Accordingly, the use of Entacapone Medochemie in children and

adolescents is not recommended.

Drug interactions

Tell your doctor or pharmacist if you are taking, or have recently taken other medicines including non-prescription medicines and nutritional supplements or medicines of plant origin. Especially tell your doctor if you are taking:

- rimiterol, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, apomorphine;
- antidepressants including desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin used to thin the blood;
- iron supplements. Entacapone Medochemie may make it more difficult for you to digest iron. Accordingly, do not take Entacapone Medochemie and iron supplements at the same time. Wait at least 2-3 hours after taking one of them before taking the other.

Using this medicine and food

You can take Entacapone Medochemie with or without food.

Pregnancy, breast-feeding and fertility

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking any medicines.

Driving and using machines

Entacapone Medochemie taken together with levodopa may lower your blood pressure, which may make you feel light-headed or dizzy. Be especially careful when driving or using tools or machinery.

In addition, Entacapone Medochemie 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.

3. How to use this Medicine

Always take this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dose and how you should take this medicine.

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

Only your doctor will determine your dosage and how you should take this medicine. The recommended dose of Entacapone Medochemie is usually:

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

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 Medochemie to take.

Your doctor may suggest a higher or lower dosage, according to your reaction to treatment. If you feel that the effect of the medicine is too strong or too weak, refer to your doctor or pharmacist.

Do not exceed the recommended dose.

Method of administration

Take Entacapone Medochemie at the same time as you take a dose of levodopa. Swallow the tablet with a full glass of water. Do not split the tablet! There is no information on crushing or chewing the tablets.

If you have accidentally taken a higher dose

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you have forgotten to take Entacapone Medochemie

If you have forgotten to take Entacapone Medochemie with a dose of levodopa, continue treatment by taking the next tablet of Entacapone Medochemie with your next levodopa dose.

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

Duration of treatment

Adhere to the treatment as recommended by your doctor.

If you stop taking Entacapone Medochemie

Even if your health improves, do not stop taking this medicine without consulting your doctor.

When stopping treatment, your doctor may need to readjust the dosage of the other medicines you take for the treatment of Parkinson's disease. Suddenly stopping Entacapone Medochemie and other medicines to treat Parkinson's disease may result in unwanted side effects. See section 2 "Special warnings regarding the use of this medicine".

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

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

4. Side effects

Like with any medicine, using Entacapone Medochemie may cause side effects in some users. Do not be alarmed while reading the list of side effects; you may not experience any of them.

These side effects are usually mild to moderate in severity.

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 Medochemie, you should contact your doctor who may decide to adjust your dosage of levodopa.

Very common side effects (may affect more than one in ten people):

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

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

- Excessive movements (hyperkinesia), worsening of symptoms of Parkinson's disease, prolonged muscle cramps (dystonia);
- vomiting, diarrhea, 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;
- cardiac or arterial disease events (e.g. chest pain).

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

- Heart attack.

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

- rashes;
- abnormal results in liver function tests.

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

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

Side effects of unknown frequency (the frequency of these effects has not been established yet):

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

When Entacapone Medochemie 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:

- In rare cases, Entacapone Medochemie taken with levodopa may 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 characterized 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 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 behavior of significant concern to you or to others, for example, 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 behaviors; he/she will discuss ways of managing or reducing the symptoms.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor or pharmacist.

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which links you to an online form for reporting side effects. You can also use the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce

vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package/tray. The expiry date refers to the last day of that same month.

Storage conditions:

Store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Tablet core:

Cellulose microcrystalline 102, mannitol E421, sodium starch glycolate type A, magnesium stearate E572

Tablet coating:

Hypromellose 5MPA.S E464, titanium dioxide E171, talc E553b, macrogol 400, macrogol 6000, iron oxide yellow (E172) iron oxide red (E172), iron oxide black (E172)

What the medicine looks like and contents of the package:

Brown colored capsule-shaped, convex, film-coated tablet.

Marketed in a carton containing 30,60, 100, 500 tablets in blister packs. Not all package sizes may be marketed.

Registration holder's name and address: Devries & Co. Ltd. 32 HaBarzel St., Tel-Aviv

Manufacturer's name and address: Medochemie Ltd. 1-10 Constantinoupoleos Street, 3011, Limassol, Cyprus

Edited in October 2020

Drug registration number in the Ministry of Health's National Drug Registry:

160-98-35150