

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ENTAPONE

Entacapone Tablets 200 mg



What is in this leaflet

This leaflet answers some common questions about ENTAPONE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ENTAPONE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ENTAPONE is used for

ENTAPONE is used to treat the symptoms of Parkinson's disease in people who are already taking levodopa. Levodopa is usually supplied as a combination medicine with carbidopa or benserazide. When levodopa/carbidopa or levodopa/benserazide do not control the symptoms, ENTAPONE can be added.

Parkinson's disease is a disorder of the nervous system. It is caused by a lack of dopamine, a natural substance that is produced in the brain. Dopamine relays messages in the part of the brain that controls muscle movement. When too little dopamine is produced, problems with movement result.

ENTAPONE contains the active ingredient entacapone. This medicine belongs to a group of medicines called catechol-O-methyl transferase (COMT) inhibitors.

ENTAPONE is always used together with levodopa. Levodopa works by increasing the level of dopamine in the brain and ENTAPONE works by making the effect of levodopa last longer. Together, ENTAPONE and levodopa help to relieve symptoms such as shaking of the limbs, stiffness and slowness of movement, which make it difficult to perform normal daily activities. Other medicines can also be added to help treat this condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take ENTAPONE

When you must not take it:

Do not take ENTAPONE if you have an allergy to:

- any medicine containing entacapone
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may 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.

Do not take this medicine if you have:

- liver problems
- phaeochromocytoma, a rare tumour of the adrenal

gland which can cause your blood pressure to rise to a dangerous level

- a history of neuroleptic malignant syndrome (NMS), a serious condition with symptoms such as sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure
- rhabdomyolysis, a condition with severe muscle weakness that was not due to injury.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Do not take ENTAPONE if you are pregnant.

There is not enough information to recommend its use during pregnancy.

Do not breastfeed while you are taking this medicine.

It is not known if the active ingredient in ENTAPONE passes into breast milk and could affect your baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- severe kidney disease requiring dialysis
- heart attack or any other heart disease.

ENTAPONE tablets contain sucrose.

Tell your doctor if you have problems with sucrose intolerance, fructose intolerance or glucose-galactose malabsorption.

If you have not told your doctor about any of the above, tell him/her before you start taking ENTAPONE.

Taking other medicines

Do not take ENTAPONE if you are taking a medicine called a monoamine-oxidase inhibitor (MAOI) without first checking with your doctor.

MAOI medicines are usually used to treat depression. Taking ENTAPONE together with some, but not all, MAOI medicines may cause serious side effects. Your doctor will know whether or not the MAOI medicine you are taking can be safely taken with ENTAPONE.

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ENTAPONE may interfere with each other. These include:

- other medicines used for Parkinson's disease
- some medicines used to treat depression
- methyldopa, a medicine for high blood pressure
- warfarin, a medicine used to prevent blood clots
- iron supplements.

These medicines may be affected by ENTAPONE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ENTAPONE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose is one ENTAPONE tablet (200mg) each time you take a dose of levodopa.

People with moderate to severe Parkinson's disease usually take from 4 to 7 tablets of ENTAPONE each day. The maximum dose is 10 tablets each day.

Because ENTAPONE increases the action of levodopa, it can also increase some of its side effects, especially at the start of treatment. To prevent this from happening, your doctor may lower your usual dose of levodopa for a few days or weeks. However, it is still important that you take an ENTAPONE tablet each time you take a dose of levodopa.

How to take it

Swallow the tablets whole with a full glass of water at the same time as you take a dose of levodopa.

If your stomach is upset after taking the tablet, take it with a meal or after a snack.

It does not matter if you take this medicine before or after food.

Take your medicine at about the same times each day.

Taking it at the same times each day will have the best effect. It will also help you remember when to take it.

If you take iron supplements, take the iron supplement at least 2 to 3 hours before or after your dose of ENTAPONE.

How long to take it

Do not stop taking your medicine or change the dosage without checking with your doctor.

This medicine helps to control your condition, but does not cure it. You may need to take ENTAPONE for a long time to control your symptoms.

If your doctor wants you to stop taking ENTAPONE, he or she may want you to gradually reduce the amount of ENTAPONE you take before stopping the medicine completely.

If you stop taking ENTAPONE, your doctor may increase the dose of your other medicines for Parkinson's disease to prevent your symptoms from getting worse.

If you forget to take it

If you forget to take a tablet of ENTAPONE with your dose of levodopa, wait until the next dose of levodopa is due and start taking ENTAPONE again at this time.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ENTAPONE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include sleepiness, confusion, decreased activity, low muscle strength and itchy rash.

While you are using ENTAPONE

Things you must do

If you are to be started on any new medicine, remind your doctor and pharmacist that you are taking ENTAPONE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take ENTAPONE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking ENTAPONE suddenly, or change the dosage without first checking with your doctor. Stopping ENTAPONE suddenly can cause some people to have side effects.

Things to be careful of

Be careful driving or operating machinery until you know how ENTAPONE affects you. This medicine may cause dizziness, light-headedness, sleepiness or drowsiness in some people. If you

have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. These symptoms may be a sign of low blood pressure. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ENTAPONE. Like all medicines, ENTAPONE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting
- diarrhoea or constipation
- aches and pains including abdominal pain
- dry mouth
- dizziness or light-headedness
- spinning sensation (vertigo)
- tiredness
- shakiness
- leg cramps
- headache
- trouble sleeping
- increased sweating
- a reddish-brown colour to the urine (this is known to happen with ENTAPONE and is usually harmless)

- discolouration of hair, beard, skin or nails.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements
- extreme sleepiness or sudden onset of sleep in the middle of daytime activities
- worsening of your Parkinson's disease
- feeling depressed, confused or agitated
- hallucinations (seeing, hearing or feeling things that are not there)
- behavioural changes like the urge to gamble, compulsive spending/buying or increased sexual desire urges
- binge/compulsive eating
- signs of possible liver problems such as loss of appetite, feeling generally unwell, fever, itching
- signs of possible anaemia (low amount of iron in your blood) such as tiredness, headaches, shortness of breath when exercising, dizziness and looking pale
- progressive loss of appetite and asthenia (weakness, exhaustion) and weight decrease in a short period of time. Your doctor may decide to conduct a general medical evaluation including liver function.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- jaundice (yellowing of the skin or eyes)
- skin rash, itching or hives

- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or troubled breathing
- chest pain
- symptoms such as sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, extremely high blood pressure or severe convulsions. These may be symptoms of neuroleptic malignant syndrome (NMS)
- temporary paralysis or severe weakness of the muscles
- prolonged diarrhoea or diarrhoea with blood, mucus, stomach pain and fever.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, anaemia, changes in liver function and blood pressure) can only be found when your doctor does tests from time to time to check your progress.

After using ENTAPONE

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Heat and dampness can destroy some medicines.

Do not store ENTAPONE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ENTAPONE tablets are light orange coloured, oval shaped, biconvex tablets.

They are debossed with “EE200” on one side of the tablet and “M” on the other side.

ENTAPONE tablets are supplied in bottles of 100 tablets.

Ingredients

Each ENTAPONE tablet contains 200 mg of entacapone as the active ingredient.

Each tablet also contains:

- microcrystalline cellulose
- mannitol
- low-substituted hydroxypropylcellulose
- magnesium stearate
- hydrogenated vegetable oil

The film-coating also contains:

- HPMC 2910 / hypromellose 6cP
- titanium dioxide
- glycerin
- magnesium stearate
- iron oxide yellow
- sucrose
- polysorbate 80
- iron oxide red.

This medicine does not contain lactose, gluten, tartrazine or any azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Eilerslie,
Auckland.

Telephone: (09) 579 2792

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