

PACKAGE LEAFLET

Package leaflet: Information for the user

Encapia 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 Encapia is and what it is used for
2. What you need to know before you take Encapia
3. How to take Encapia
4. Possible side effects
5. How to store Encapia
6. Contents of the pack and other information

1. What Encapia is and what it is used for

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

2. What you need to know before you take Encapia

Do not take Encapia

- 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 Encapia);
- 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 if any of the following applies to you:

- 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 Encapia 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 Encapia. 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 Encapia 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 Encapia and other medicines to treat Parkinson's disease.

Encapia 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 Encapia

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:

- rimiterole, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpramethyldopa, apomorphine;
- antidepressants including desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin used to thin the blood;
- iron supplements. Encapia may make it harder for you to digest iron. Therefore, do not take Encapia 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 Encapia 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 for advice before taking this medicine.

Driving and using machines

Encapia 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, Encapia 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Encapia

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

Encapia 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 Encapia 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.

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 Encapia in patients under 18 years is limited. Therefore, the use of Encapia in children or adolescents cannot be recommended.

If you take more Encapia than you should

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

If you forget to take Encapia

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

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

If you stop taking Encapia

Do not stop taking Encapia 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 Encapia and other medicines to treat Parkinson's disease may result in unwanted side effects. See Section 2.

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

4. Possible side effects

Like all medicines, Encapia can cause side effects, although not everybody gets them. Usually side effects caused by Encapia 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 Encapia 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 Encapia 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:

- Encapia 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 behaviors; 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 national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Encapia

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

Brown amber glass bottles (hydrolytic class III) with white LDPE closures: This medicinal product does not require any special storage conditions.

White HDPE bottles with white LDPE closure and PVC/PVDC-Alu blisters opaque: Store below 30°C.

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

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 Encapia contains

The active substance is entacapone.

The other ingredients are:

Core: Cellulose microcrystalline 102, Mannitol E421, Sodium Starch Glycolate – Type A, Magnesium Stearate E572

Coating: Hypromellose 2910 5mPa•s E464, titanium dioxide E171, Macrogol 400, Iron oxide yellow E172, Iron oxide red E172, Iron oxide black E172, Talc E553b, Macrogol 6000

What Encapia looks like and contents of the pack

Encapia is a brown, capsule-shaped, convex, film-coated tablets with dimension 19x10 mm.

The tablets are packed in:

- Brown amber glass bottles (hydrolytic class III) containing 30 or 60 tablets, with white LDPE closures and with one white cylindrical silica gel desiccant pill with a warning in red “DESICCANT SILICA GEL, DO NOT EAT”. Each bottle also includes one piece of white polyurethane foam to offer the tablets protection while transportation.

- White HDPE bottles containing 30, 60 or 100 tablets, with white LDPE closure and with one white cylindrical silica gel desiccant pill with a warning in red “DESICCANT SILICA GEL, DO NOT EAT”. Each bottle also includes one piece of white polyurethane foam to offer the tablets protection while transportation.

- PVC/PVDC-Alu opaque blisters containing 30, 60, 100 or 500 tablets.

Not all pack sizes may be marketed.

In het register ingeschreven onder nummer:

RVG 111101

Marketing Authorisation Holder and Manufacturer:

Vergunninghouder

MEDOCHEMIE LTD

1-10 Constantinoupoleos street

3011 Limassol

Cyprus

Fabrikant

Medochemie Ltd – Central Factory

1-10 Constantinoupoleos street 3011 Limassol

Cyprus

For any information about this medicine, please contact the Marketing Authorisation Holder.

This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands	Encapia
Bulgaria	ENCAPIA
Cyprus	ENCAPIA
Estonia	ENCAPIA
Romania	ENCAPIA

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2021