

Entacapone Niche 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.

In this leaflet:

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

1. What Entacapone Niche is and what it is used for

Entacapone Niche film-coated tablets contain entacapone and are used together with levodopa to treat Parkinson's disease in adults. Entacapone Niche improves the therapeutic effect of levodopa in relieving the symptoms of Parkinson's disease. Entacapone Niche 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 Niche

Do not take Entacapone Niche:

- 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 Entacapone Niche);
- 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 or pharmacist before taking Entacapone Niche:

- 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 excessive gambling or excessive sexual activity;
- 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 an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

As Entacapone Niche 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 Niche. 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 Niche 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 Entacapone Niche and other medicines to treat Parkinson's disease

Entacapone Niche 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 Entacapone Niche

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, alpha-methyldopa, apomorphine;
- antidepressants including desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin used to thin the blood;
- iron supplements. Entacapone Niche may make it harder for you to digest iron. Therefore, do not take Entacapone Niche and iron supplements at the same time. After taking either one of them, wait at least 2 to 3 hours before taking the other.

Pregnancy, breast-feeding and fertility

Do not use Entacapone Niche 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 Niche 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 Niche taken with levodopa may make you feel very drowsy, or cause you to sometimes find yourself suddenly falling asleep. Do not drive or operate machinery if you experience these side effects.

Entacapone Niche contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Entacapone Niche

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

Entacapone Niche 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 Niche 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 Niche.

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 Entacapone Niche in patients under 18 years is limited. Therefore, the use of Entacapone Niche in children cannot be recommended.

If you take more Entacapone Niche than you should

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

If you forget to take Entacapone Niche

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

If you stop taking Entacapone Niche

Do not stop taking Entacapone Niche 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 Niche and other medicines to treat Parkinson's disease may result in unwanted side effects. See section 2 Warnings and precautions.

If you have any further questions on the use of this product, 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 Niche 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 side effects at the start of treatment with Entacapone Niche you should contact your doctor who may decide to adjust your dosage of levodopa. The following side effects have been observed during treatment with entacapone:

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 Entacapone Niche 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:

- Entacapone Niche taken with levodopa may rarely make you feel 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 central 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 behaviours; 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

United Kingdom

You can report side effects directly using the Yellow Card scheme at: www.mhra.gov.uk/yellowcard.

5. How to store Entacapone Niche

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

This medicine does not require any special storage conditions.

Entacapone tablets can be used up to 45 days after first opening of the container.

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 Niche contains

- The active substance is entacapone. Each tablet contains 200 mg of entacapone.
- The other ingredients in the tablet core are: maize starch, sodium starch glycollate (type A), silica (colloidal anhydrous), povidone, polysorbate, mannitol and magnesium stearate.
- The film-coating contains: hypromellose, lactose monohydrate, titanium dioxide (E 171), macrogol, iron oxide yellow (E 172), talc and iron oxide red (E 172).

What Entacapone Niche looks like and contents of the pack

- Entacapone Niche 200mg film-coated tablets are brown, capsule-shaped, biconvex film-coated tablets, with debossing "70" on obverse side and plain on reverse.
- There are four different pack sizes (bottles containing 30, 60, 100 or 175 tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Niche Generics Limited, 1 The Cam Centre, Wilbury Way, Hitchin, Herts SG4 0TW, United Kingdom.

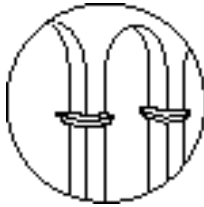
Manufacturer:

Niche Generics Limited, Unit 5, 151 Baldoyle Industrial Estate, Dublin 13, Ireland.

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

United Kingdom, Ireland: Entacapone Niche 200mg film-coated tablets
Germany: Entacapone Unichem 200mg Filmtabletten
The Netherlands: Entacapone Unichem 200mg filmomhulde tabletten

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Title:	Entacapone Niche 200mg Film Coated Tablets for Niche UK/IE
MA Number/s:	IE: PA 1063/55/1 UK: PL 19611/0183
Date of Origination:	11/04/2011
Dimensions:	310mm x 160mm
Colours:	Black ■
Item Code:	TBC
Pharmacode:	N/A
Version Number:	9
Revision Date:	29/03/2016
Reason for Revision:	Update in line with current QRD templates including ADR reporting statements

Software: QuarkXpress 4.1