

Package Leaflet: information for the user

Navalem 10 mg/10 mg modified-release capsules, hard

Doxylamine Succinate / Pyridoxine Hydrochloride

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

1. What Navalem is and what it is used for

This medicine belongs to a group of medicines called antiemetics and antinauseants and is indicated for symptomatic treatment of nausea and vomiting during pregnancy in adults.

Navalem contains two medicines ('active substances') called: 'doxylamine succinate' and 'pyridoxine hydrochloride'. Doxylamine succinate belongs to a group of medicines called 'antihistamines'. Pyridoxine hydrochloride is another name for Vitamin B6"

2. What you need to know before you take Navalem

Do not take Navalem:

- If you are allergic to doxylamine, pyridoxine, or any of the other ingredients of this medicine listed in section 6.
- If you are hypersensitive to antihistamines (allergy medications) derived from ethanolamine (such as diphenhydramine or carbinoxamine).
- If you are taking antidepressants such as monoamine oxidase inhibitors (MAOIS) since XXXX can intensify and extend the adverse effects on the nervous system.
- If you are taking potent inhibitors of the CYP450 isoenzymes.
- If you suffer from porphyria (a very rare metabolic disorder)
- If you have problems of hereditary fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency.
- If you suffer from vomiting for another reason.

Warnings and precautions

Talk to your doctor or pharmacist before taking Navalem.

You should talk to a doctor before taking this medicine if you suffer from:

- Glaucoma (increased pressure in the eyes),
- If you suffer from a peptic ulcer (break in the lining of the stomach or first part of the intestine with narrowing of the digestive tract), pyloroduodenal obstruction (difficulty in passing food from the stomach into the intestine) or bladder neck obstruction (urinary tract disorder), urinary obstruction (difficulty urinating),
- Thyroid disorder,
- Heart disease and high blood pressure as Navalem can aggravate the disease,
- Prolonged QT interval syndrome (heart disease),
- Asthma and other respiratory disorders, such as chronic bronchitis (persistent inflammation of the bronchi) and pulmonary emphysema (disease that affects the lungs making breathing difficult) or chronic obstructive pulmonary disease (COPD), since Navalem can aggravate the disease,
- Kidney and/or liver diseases,
- Epilepsy, since it can aggravate the disease,
- Low levels of potassium in the blood or other electrolytic alterations.

Navalem can increase sensitivity to light, so sunbathing is not recommended during the treatment.

Navalem can mask symptoms that may affect your ears (such as dizziness), so you should talk to your doctor if you are taking other medications that may have the same effects.

Be aware of any signs of abuse or dependence on this treatment. If you have any substance use disorders (alcohol, medication or other), talk to your doctor

Navalem contains pyridoxine hydrochloride (vitamin B6), therefore additional levels from diet and vitamin B₆ supplements should be assessed

Navalem can increase dehydration and cause heat stroke due to decreased sweating.

You may feel sleepy after taking Navalem. If this happens do not do other activities that need your full attention - unless your doctor tells you it is ok to do so.

Children and adolescents

There are no data available on the safety and efficacy of Navalem in children under 18 years.

Other medicines and Navalem

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medication.

Navalem should not be taken concomitantly with the following medications:

- Anticholinergics such as antidepressants or medicines for the treatment of Parkinson's, monoamine oxidase inhibitors or MAOIS (treatment for depression), antipsychotics (medicines for the treatment of mental disorders), atropine for the treatment of spasms or disopyramide (for the treatment of certain heart problems) because it can increase the toxicity.
- Central nervous system depressants (e.g. barbiturates, hypnotics, sedatives, anxiolytics, opioid analgesics, antipsychotics, procarbazine or sodium oxibate).
- Antihypertensive medicines (medicine for controlling blood pressure) which have an effect on the central nervous system such as guanabenz, clonidine or alpha-methyldopa.
- If you are taking other medicines which have a toxic effect on the ear, such as carboplatin or cisplatin (for cancer treatment), chloroquine (to prevent and treat malaria) and some antibiotics (medicines to treat infections) such as erythromycin or intravenous aminoglycosides among others since Navalem could mask the toxic effects of these medicines, so you should have periodic check ups on your ears.
- Medicines which decrease the elimination of others such as azole or macrolide derivatives, since they could increase the effect of Navalem.
- Some diuretics (medicines which promote the production of urine).
- Medicine which can have an effect on the heart such as those used for treating arrhythmias (irregular heartbeat), some antibiotics, certain medicines for malaria, certain antihistamines, certain medicines

used to reduce lipids (fats) in the blood or certain neuroleptics (medicines for the treatment of mental disorders).

- Medicines which have a photosensitizing effect (increased reaction of the skin when exposed to sunlight) such as some antiarrhythmics (amiodarone, quinidine), some antibiotics (tetracyclines, fluoroquinolones azithromycin, and erythromycin, among others), some antidepressants (imipramine, doxepin, amitriptyline), some antifungals (griseofulvin), antihistamines (promethazine, chlorphenamine, and diphenhydramine, among others), some anti-inflammatory agents (piroxicam, and naproxen, among others), some antivirals (amantadine, ganciclovir), some diuretics (furosemide, chlorothiazide) because it can cause an additive photosensitizing effect.
- Levodopa since the pyridoxine contained in Navalem could reduce its effect.
- Medicine for the treatment of epilepsy (phenobarbital, phenytoin) as pyridoxine could decrease their levels in the blood.
- Medicines such as hydroxyzine, isoniazid or penicillamine, since their combination with pyridoxine could cause vitamin B6 deficiency.

Interference with diagnostic tests

This medicine can alter the following analytical results: a false negative may result in skin tests in which allergenic extracts are used (allergy tests). You should stop taking this medicine several days before taking the test.

Navalem with food, drink and alcohol

It may take longer for Navalem to take effect when the capsules are taken with food.

You should avoid drinking alcohol while taking Navalem as it can increase the toxicity of the medicine.

See section 3 *How to take Navalem*.

Pregnancy and breast-feeding:

Navalem is intended for use in pregnant women.

Taking Navalem is not recommended during breastfeeding.

Driving and using machines:

Navalem can cause drowsiness in some patients, therefore you should avoid any situations which require you to be alert, such as driving or operating machinery, at least for the first few days of treatment until you know how it affects you.

Navalem contains sucrose:

This medicine contains sucrose. 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 Navalem

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

The recommended dose is 2 capsules before going to bed if nausea and vomiting occurs in the morning (Day 1). If this dose allows you to control the symptoms, continue to take two capsules. However, if symptoms persist into the afternoon of Day 2, the patient should continue the usual dose of two capsules at bedtime (Day 2) and on Day 3 take three capsules (one capsule in the morning and two capsules at bedtime). If these three capsules do not adequately control symptoms on Day 3, the patient can take four capsules starting on Day 4 (one capsule in the morning, one capsule mid-afternoon and two capsules at bedtime).

The maximum daily dose is 4 capsules (one in the morning, another in the middle of the afternoon and two at bedtime).

The capsules should be swallowed whole, without chewing and on an empty stomach, with a sufficient quantity of liquid, preferably water.

Use in children and adolescents

Safety and efficacy have not been established in children under 18 years of age.

If you take more Navalem than you should

If you have taken more Navalem than you should, inform your doctor or pharmacist immediately.

Symptoms of possible intoxication could be neurological alterations such as agitation, hallucinations or intermittent seizures, which in extreme cases could lead to a decrease in vital signs and result in coma. If you suffer from any of these symptoms, you will be given the appropriate treatment.

If you forget to take Navalem:

If you miss a dose, you should take it as soon as possible. However, if it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for forgotten doses.

4. Possible side effects

Like all medicines, Navalem can cause side effects, although not everybody gets them.

The side effects of Navalem in general, are mild and transient, being more frequent in the first days of treatment.

Common side effects (may affect up to 1 in 10 people): drowsiness and other side effects such as a dry mouth, constipation, blurred vision, urinary retention or increased bronchial secretion.

Uncommon side effects (may affect up to 1 in 100 people): asthenia (weakness), peripheral oedema (swelling of the arms and legs), nausea, vomiting, diarrhoea, skin rash, tinnitus (ringing in the ears), orthostatic hypotension (head rush due to change of posture), diplopia (double vision), glaucoma, confusional state or photosensitivity reactions..

Rare side effects (may affect up to 1 in 1,000 people): restlessness, tremors, convulsions or blood problems such as haemolytic anaemia.

Other side effects (frequency cannot be estimated from available data): tachycardia (faster heart rate (heart beats), vertigo or dyspnea.

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 System of Pharmacovigilance of Medicines for Human Use. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Navalem 10 mg/10 mg hard capsules of modified release

Store below 25°C

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 container. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away containers and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Navalem contains

- The active substances are doxylamine succinate 10 mg and pyridoxine hydrochloride 10 mg
- The other ingredients are:
 - The capsules contain: sucrose, corn starch, shellac, povidone, talc, methacrylic acid - methyl methacrylate copolymer and colloidal anhydrous silica.
 - The capsule is composed of gelatin, indigo carmine (E132), yellow quinoline (E104) and titanium dioxide (E171).

What Navalem looks like and contents of the pack

Navalem is supplied in packs containing 12, 24 or 48 green capsules and in multipacks with 48 green capsules (2 packs of 24 capsules) in PVC/PVdC-aluminium blister packs, of 12 capsules each.

Not all pack sizes may be marketed

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