
Package leaflet: Information for the user

Nitoman® 25 mg Tablets Tetrabenazine

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

1. What Nitoman is and what it is used for

Nitoman contains a substance called tetrabenazine. This affects some of the chemicals that are released by the nerves in the brain which helps to control jerky and irregular movements of the body (called chorea).

Nitoman is used for the treatment of jerky, irregular uncontrollable movements that can be caused by conditions such as Huntington's chorea, senile chorea, and hemiballismus.

2. What you need to know before you take Nitoman

Before you start taking Nitoman, please read the information given below. If you think that any of this information applies to you, or you are not sure, please tell your doctor, nurse or pharmacist:

Do not take Nitoman :

- If you are allergic to tetrabenazine or any of the other ingredients of this medicine (listed in section 6).
- If you are actively suicidal (feel like killing yourself).
- If you have been diagnosed as having depression that has been untreated or difficult to treat.
- If you are breast-feeding.
- If you are taking antidepressants which belong to the group of medicines called monoamine oxidase inhibitors or MAOIs, or have taken them at any time in the last two weeks.
- If you have liver trouble.
- If you are taking a medicine called reserpine.
- If you have been diagnosed as having parkinsonism and hypokinetic-rigid syndrome. The signs of parkinsonism are trembling in the hands and jerky movements in the arms and legs.

Warnings and precautions

Talk to your doctor before taking Nitoman:

- If you have been diagnosed with depression or have thought about or tried to commit suicide.
- If you have ever had depression.
- If you start to experience angry or aggressive behaviour.
- If you have a heart condition known as long QT syndrome. Tetrabenazine should be used with caution with other medicines known to prolong QT syndrome (listed in Other medicines and Nitoman) and in patients with congenital long QT syndromes and a history of cardiac arrhythmias.
- If you have a recent history of chest pain or heart disease.
- If you have ever had trembling in the hands and jerky movements in the arms and legs, known as parkinsonism. If you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and a temperature, you may be developing a condition called Neuroleptic Malignant Syndrome. If you have these symptoms, please contact your doctor straight away.
- If you start to have difficulty in swallowing.
- If you have a reaction with worm-like movements of the tongue or other uncontrolled movements of the mouth, tongue, cheeks or jaws, which may progress to the arms and legs (tardive dyskinesia).
- If you feel restless, agitated, or have difficulty sitting still.
- If you experience sleepiness or drowsiness.
- If you experience dizziness or light-headedness when standing.
- If you have hyperprolactinemia (higher-than-normal blood levels of the hormone prolactin – the hormone responsible for lactation).
- If you have problems digesting certain sugars, such as galactose.
- If you know that you are a slow or intermediate metaboliser of an enzyme called CYP2D6, because a different dose may be applicable for you.

Children and adolescents

Nitoman should not be used in children and adolescents.

Other medicines and Nitoman

Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines can cause problems if you take them with Nitoman.

These are:

- Levodopa used to treat Parkinson's disease.
- Antidepressants which belong to the group of medicines called monoamine oxidase inhibitors (or MAOIs). At least 14 days should lapse between the discontinuation of MAOIs and initiation of treatment with Nitoman.
- Medicines which affect the brain and nervous system such as haloperidol, chlorpromazine and thioridazine (called neuroleptic medicines).
- Metoclopramide used to treat nausea and vomiting.
- Strong painkillers such as morphine and codeine (opioids).
- Medicines to help sleep (hypnotics).
- Medicines used to treat high blood pressure (antihypertensives and beta blockers).
- Anti-depressant medicines such as fluoxetine, paroxetine.
- Certain antibiotics e.g. gatifloxacin, moxifloxacin.
- Some medicines used to treat problems with heart rhythm conditions e.g. quinidine, procainamide, amiodarone, sotalol.
- Reserpine used for the control of high blood pressure and for the relief of psychotic symptoms.

Nitoman with food, drink and alcohol

Drinking alcohol while you are taking Nitoman may cause you to feel abnormally sleepy.

Pregnancy, breast-feeding and fertility

Nitoman should not be taken during pregnancy, or when 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.

When animals were tested, there was a delay in fertility seen. The effect on fertility in humans has not been tested. If you are concerned, ask your doctor for advice.

Driving and using machines

Nitoman may cause drowsiness and other side effects.

Depending on how you respond to this medicine, you may find that your ability to drive a car or operate machinery is affected.

Nitoman contains lactose

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Nitoman

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The dose required varies from person to person.

Adults

- The recommended starting dose is half a tablet (12.5 mg) to one tablet (25 mg) every day.
- The dose is usually increased gradually by your doctor to a maximum of eight tablets a day (a total of 200 mg), depending on any side effects you may experience.
- Tablets should then be taken two or three times daily, as instructed by your doctor.

Elderly patients

Your doctor will decide the best dose for elderly patients.

Use in children

If your doctor decides your child should take this medicine, your doctor will tell you how much to take.

Taking Nitoman

- The tablet can be divided into equal doses. Swallow the tablet or tablets with water or another non-alcoholic drink.
- If there is no improvement at the maximum dose in seven days, it is unlikely that the medicine will be of benefit to you. If you have any concerns, please talk to your doctor.
- If you get certain side effects, your dosage will be reduced.
- Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor. Always tell your doctor if you want to stop taking your medicine.

If you take more Nitoman than you should

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist, or nearest hospital straight away. Symptoms of overdose include uncontrollable muscle spasms affecting the eyes, head, neck and body, uncontrolled rolling of the eyes, excessive eye

blinking, nausea, vomiting, diarrhoea, sweating, dizziness, feeling cold, confusion, hallucinations, drowsiness, redness/inflammation, and tremor.

If you forget to take Nitoman

Do not take a double dose to make up for a forgotten dose. Instead you should simply continue with the next dose when it is due.

If you stop taking Nitoman

Your doctor will decide when your treatment can be stopped. He may decide to gradually reduce the dose, although it may not be necessary. This is usually done so you avoid side effects that may arise as a result of suddenly stopping your medication.

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

4. Possible side effects

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

Please seek advice immediately or go to your emergency department if you experience the following side effects:

Very Common (may affect more than 1 in 10 people)

- Nitoman can cause depression, which can, in some people, lead to thoughts of committing suicide. If you feel down or very sad you may be starting to become depressed and you should tell your doctor about this change.
- If you feel restless and feel that you can't sit or stand still you may have something called akathisia. If you feel like this, please contact your doctor.

Common (may affect up to 1 in 10 people)

- If you develop trembling or uncontrollable movements in your hands, arms, legs and head, drooling, problems swallowing or problems with your balance you may have something called parkinsonism. If you have any of these problems please contact your doctor.

Very Rare (may affect up to 1 in 10,000 people)

- If you have tried to commit suicide.
- If you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and a temperature, you may be developing a condition called Neuroleptic Malignant Syndrome. If you have these symptoms, please contact your doctor straight away.
- If you have intentionally hurt yourself or if you have started to think about intentionally hurting yourself.

Not known (frequency cannot be estimated from the available data)

- If you have a severe increase in blood pressure (hypertensive crisis).

Please seek advice as soon as possible if you experience the following side effects:

Very Common (may affect more than 1 in 10 people)

- Anxiety, confusion or restlessness.
- Movement disorders.
- Sleepiness.
- Problems with sleeping (insomnia).
- Involuntary blinking or eye spasms.
- Cough, sore throat, runny nose, nasal congestion, headache, low grade fever, facial pressure and sneezing (upper respiratory tract infection).

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- Feeling sick.
 - Tiredness.
 - Fall.

Common (may affect up to 1 in 10 people)

- Decreased appetite.
- Feeling agitated or irritable.
- Anxiety characterized by intrusive thoughts that produce uneasiness, apprehension, fear, or worry and by repetitive behaviours aimed at reducing the associated anxiety (Obsessive Compulsive Disorder).
- Difficulty balancing.
- Slowness in moving.
- Uncontrollable muscle spasms affecting the eyes, head, neck and body.
- Lack of energy.
- Dizziness.
- Difficulty in speaking.
- Headache.
- Fever, chills, shortness of breath, cough, chest pain and dizziness, phlegm and occasionally blood (pneumonia).
- Shortness of breath.
- A cough that often brings up mucus, as well as shortness of breath, wheezing, and chest tightness (bronchitis).
- Diarrhoea.
- Vomiting.
- Constipation.
- Pain when passing urine.
- Bruising, Cuts.
- Self-inflicted injuries.

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

- Difficulty in swallowing.

Very Rare (may affect up to 1 in 10,000 people)

- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Feeling aggressive or angry.
- Nervousness.
- Sleep disorder.
- Clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech.
- Tremor.
- Fast or irregular heart beats (palpitations).
- Uncontrolled rolling of the eyes, Sensitivity to sunlight, Blurred vision (due to hypertension) Allergic reaction, interactions with other medicines, abnormal sensitivity or allergy to the medicine.
- Dehydration.
- Excess salivation.
- Cough.
- Pneumonia with choking (pneumonia aspiration).
- Dry mouth.
- Excessive sweating.
- Rash, Itching, Hives.
- Urge to urinate with a possible burning sensation (urinary tract infection).
- Problems with or having no menstrual periods.

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- Generally feeling unwell.
 - Fever, high temperature or feeling hot.
 - Weight loss.
 - Taking more medicine than prescribed by your doctor (see **If you take more Nitoman than you should**).

Not known (frequency cannot be estimated from the available data)

- Memory loss.
- Feeling dizzy when standing up after sitting or lying down.
- Abnormal liver test results, which may indicate liver damage.
- Weakness.
- Dizziness and postural hypotension (sudden dizziness and fainting when standing up).
- Increased appetite, increased body weight.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nitoman

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others even if their symptoms are the same as yours.

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 Nitoman contains

- The active substance is tetrabenazine. Each tablet contains 25 milligram of tetrabenazine.
- The other ingredients are maize starch, lactose monohydrate, talc, magnesium stearate, and the colorant iron oxide yellow (E172).

What Nitoman looks like and contents of the pack

Nitoman tablets are round and yellowish-buff in colour. They have 'CL25' stamped on one side and a single scoreline on the other. The tablet can be divided into equal halves.

Nitoman is supplied in bottles which each contain 112 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Bausch Health Ireland Limited, 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

Manufacturer: Astrea Fontaine, Rue des Près Potets, 21121 Fontaine-Lès-Dijon, France.

This product is distributed in Ireland by Alliance Pharmaceuticals Ltd, Avonbridge House, Bath Road, Chippenham, Wiltshire SN15 2BB, UK.

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Detailed information on this medicine is available on the website of HPRA: <http://www.hpra.ie>