

**Nortem 10 mg Tablets**  
**Nortem 20 mg Tablets**  
temazepam

**Package leaflet: Information for the user**

**Read all of this leaflet carefully before you start using 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. 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 Nortem Tablets are and what they are used for**
- 2. What you need to know before you take Nortem Tablets**
- 3. How to take Nortem Tablets**
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**1. What Nortem Tablets are and what they are used for**

Nortem Tablets contain temazepam as the active ingredient. Temazepam is an anti-anxiety drug which is used in the short-term to help people sleep. It belongs to a group of drugs called benzodiazepines.

Nortem Tablets are used for:

- short-term treatment of insomnia (difficulty in sleeping) which is severe, disabling or causing extreme distress
- pre-medication before minor surgery or other procedures.

**2. What you need to know before you take Nortem Tablets**

**Do not take Nortem Tablets if you:**

- are allergic to temazepam or other benzodiazepines (e.g. diazepam) or any of the other ingredients of this medicine
- have difficulty in breathing or lung problems
- have a condition called sleep apnoea syndrome (where breathing stops during sleep)
- have myasthenia gravis (a condition where the muscles become weak and tire easily)
- have severe liver problems

**Warnings and precautions** **Talk to your doctor before you start to take this medicine if you:**

- have long-term lung problems (taking Nortem Tablets may cause fatal breathing problems)
- have kidney problems
- have liver problems (taking Nortem Tablets may cause a disease of the brain)
- have a history of problems with alcohol or drug abuse (your risk of dependence is higher)
- suffer from mental illness, depression or depression with anxiety
- are elderly or debilitated (taking Nortem Tablets may lead to sleepiness and/or muscle weakness that can increase the risk of falls, resulting in serious injury).

**Other medicines and Nortem Tablets**

**Talk to your doctor if you are taking any of the following**

- medicines to help you sleep and treat allergies such as promethazine
- medicines used to treat depression such as amitriptyline or monoamine oxidase inhibitors such as phenelzine
- medicines used to treat mental illness such as chlorpromazine
- medicines to help you sleep or to treat anxiety such as zopiclone or diazepam
- medicines used to treat fits or seizures such as phenytoin
- medicines used for surgery such as anaesthetics
- medicines used to treat pain such as tramadol, codeine or methadone
- medicine used to treat alcoholics known as disulfiram
- medicines for birth control such as oral contraceptive steroids (OCS).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription.

Concomitant use of Nortem and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) or with sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Nortem together with opioids or sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines or sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

#### **Important safety messages about Nortem Tablets:**

- When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse, or suffer from a personality disorder.
- You may become tolerant to the effects of Nortem Tablets after you have been taking it repeatedly for a few weeks (see section 3, **How to take Nortem Tablets**).
- When stopping this medicine you may experience withdrawal effects (see section 3, **If you stop taking Nortem Tablets**).
- Behavioural effects may occur while taking Nortem Tablets (see section 4, **Possible Side Effects**).
- To reduce the risk of amnesia (loss of memory), you should make sure that you are able to have an uninterrupted sleep of at least 7 hours.
- If you have been given Nortem Tablets for pre-medication, you should be accompanied home.

#### **Taking Nortem Tablets with food and drink**

Do NOT drink alcohol while taking these tablets, as taken together they could make you feel very drowsy which could be dangerous.

#### **Pregnancy and breast-feeding**

If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms.

#### **Driving and using machines**

Your tablets may make you feel drowsy during the day, make you forgetful and impair your concentration, vision and muscle function. Also you will be less alert if you have not been able to sleep for long enough. If affected, do NOT drive or operate machinery.

#### **Nortem Tablets contain lactose**

Patients who are intolerant to lactose should note that Nortem Tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Nortem Tablets contain sodium**

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

### **3. How to take Nortem Tablets**

Always take Nortem Tablets exactly as your doctor has told you. You should continue to take these tablets for as long as your doctor tells you to. You should check with your doctor or pharmacist if you are not sure.

Your doctor will usually treat you with Nortem Tablets for up to a maximum of 4 weeks (this will include a period of time when your dose is reduced).

The tablets should be swallowed preferably with a glass of water.

Your doctor will decide the correct dosage; the usual dose is:

#### **Insomnia**

- **Adults:** 10-20 mg should be taken when going to bed or up to 30 minutes before going to bed. Very occasionally, the dose may be increased to 30-40 mg daily.
- **Elderly patients:** the dose is 10 mg daily. Very occasionally, this may be increased to 20 mg daily.
- **Children:** Nortem Tablets are NOT recommended for use in children.

For patients who have certain problems with their kidneys or liver the dosage may be lower.

You may become tolerant to the effects of Nortem Tablets after you have been taking it for a few weeks. If you notice that the tablets are not working as well as they did when you first started taking them, you should go and see your doctor as an adjustment to your dose may be necessary. **Do NOT change the dose yourself.**

#### **Pre-medication**

- **Adults:** 20-40 mg should be taken 30-60 minutes before surgery.
- **Elderly:** Lower doses may be required for elderly patients; up to half the normal adult dose may be adequate.
- **Children:** Nortem Tablets are NOT recommended for use in children.

#### **If you take more Nortem Tablets than you should**

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause drowsiness, difficulty in controlling movements, slurred speech and involuntary eye movements; coma, low blood pressure and breathing problems can also occur.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

#### **If you forget to take Nortem Tablets**

If you fall asleep without having taken a dose and wake up some hours later, do not take the missed dose. If necessary, return to your normal dose schedule the following night. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Nortem Tablets**

After you have taken these tablets for the recommended time, your doctor may decide to stop your tablets as dependence may occur. Do not stop taking your tablets suddenly, or without your doctor telling you, as you may suffer from withdrawal effects. If your doctor decides to stop your tablets, they will reduce the dose gradually to minimise any withdrawal effects.

- These effects may include headache, muscle pain, tension, severe anxiety, confusion, restlessness and irritability. In severe cases of withdrawal you may experience a feeling of things being unreal (depersonalisation), a feeling of detachment from your surroundings, numbness and tingling in the hands and feet, sounds seeming to be louder than usual and which can sometimes be painful if the sound is loud, sensitivity to light or touch, hallucinations and fits. In addition, problems with sleeping, feeling restless and anxious, and mood changes may return.

If you experience any of these effects when you stop taking Nortem Tablets, and you are concerned about them, ask your doctor for advice.

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. Please ask your doctor, if you think that the effect of this medicine is too strong or too weak.

**Stop taking the tablets and tell your doctor immediately** or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing, or severe skin rash or hives.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you suffer from:

- behavioural changes such as restlessness, agitation, irritability, aggressiveness, delusions, excitement, rages, nightmares, hallucinations, confusion, psychiatric disorders and inappropriate behaviour, as your treatment may be stopped; you are more likely to suffer these effects if you are elderly.

The following side effects may also occur:

- confusion
- changes in sex drive
- physical and psychological dependence
- depression (pre-existing depression symptoms may return)
- daytime drowsiness
- numbed emotions
- reduced alertness
- impaired concentration
- headache
- dizziness
- restless sleep
- memory loss
- difficulty in controlling movements/loss of co-ordination
- double vision
- dry mouth
- stomach upset

- skin reactions or rash
- muscle, joint or bone pain caused by musculoskeletal (organ system responsible for form, support, stability, and movement to the body), connective tissue and bone disorders
- muscle weakness which may lead to falls and the risk of hip fractures in the elderly
- tiredness.

Withdrawal effects are known to occur. Please see section 3, **If you stop taking Nortem Tablets**.

### **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. See section 4. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Nortem Tablets**

### **Keep out of the sight and reach of children.**

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer packaging after 'EXP'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Nortem Tablets contain**

- The active ingredient is 10 mg or 20 mg of temazepam.
- The other ingredients are lactose, cellulose microcrystalline, titanium dioxide E171, croscarmellose sodium and magnesium stearate.

### **What Nortem Tablets looks like and contents of the pack**

- Nortem 10 mg tablets are white to pale yellow, flat bevel edged tablets with a breakline on one side, 5K1 on reverse.
- Nortem 20 mg tablets are white to pale yellow, flat bevel edged tablets with a breakline on one side, 5K2 on reverse.
- They come in blister packs of 28 tablets.

### **Marketing Authorisation Holder**

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