

Package leaflet: Information for the patient

ANXICALM 2mg Tablets

ANXICALM 5mg Tablets

ANXICALM 10mg Tablets

Diazepam

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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4..

What is in this leaflet

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

1. What Anxicalm is and what it is use for

Anxicalm Tablets contain diazepam. Diazepam belongs to a group of medicines called benzodiazepines. It works by depressing activity in the part of the brain that controls emotion, by promoting the action of a chemical called gamma-aminobutyric acid (GABA).

Anxicalm is used to treat a number of conditions, including:

- Severe anxiety, which is an emotional state where you may sweat, tremble, feel anxious and have a fast heartbeat
- Insomnia (trouble sleeping)
- Control of muscle spasm including that associated with tetanus
- Epilepsy (when taken with other medicines)
- Sedation before minor dental or surgical procedures

Both adults and children can take a small dose of Diazepam before an operation to help with relaxation and to cause sleepiness.

2. What you need to know before you take Anxicalm Tablets

Do not take Anxicalm

- if you are allergic to diazepam or any of the other ingredients of this medicine (listed in section 6)
- if you are breathless or have difficulty breathing
- if you suffer from sleep apnoea syndrome (a condition whereby your breathing stops at intervals while you are sleeping)
- if you suffer from phobias (a fear of a particular object or situation) or obsessions
- if you are being treated for mental illness
- if you have myasthenia gravis (a condition which causes muscles to weaken and tire easily)
- if you have severe liver problems
- if you have a mental problem (chronic psychosis) which may make you confused, lose contact with reality or become unable to think and judge clearly.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Anxicalm

- if you have problems with your liver, kidneys or lungs
- if someone close to you has recently died.

Take Special care with Anxicalm

You should not take Anxicalm for longer than 4 weeks for insomnia and 8-12 weeks in cases of anxiety (See Section 3, 'How to take Anxicalm Tablets').

Taking Anxicalm can lead to you becoming dependent on the medicine (**physical or psychological dependence**). This is more likely with higher doses of the medicine, if you have a history of alcohol or drug abuse or if you take the medicine for a long time.

If after a few weeks you **notice the tablets are not working as well as they did when first starting treatment**. You may be developing **tolerance** to Anxicalm.

If you suddenly stop taking Anxicalm you may suffer **withdrawal symptoms** which may include:

- Extreme anxiety
- Tension
- Restlessness
- Confusion
- Irritability
- Headaches
- Muscle pain

In severe cases you may:

- Feel out of touch with reality
- Feel strange in familiar surroundings
- Have hallucinations
- Have numbness and tingling sensation in your arms and legs
- Become over-sensitive to light, noise and physical contact
- Have epileptic seizures

When you stop taking Anxicalm you may experience **sleeplessness (rebound insomnia) or anxiety**. The risk of this is greater if you stop suddenly.

Anxicalm may cause a short term memory loss (**anterograde amnesia**). This occurs most often after taking your medicine. Make sure you will be able to sleep without interruption for at least 7-8 hours in order to reduce this risk.

You are more likely to fall while taking Anxicalm especially if you are an older patient. This is because of some of the side effects of Anxicalm including loss of coordination, muscle weakness, dizziness, sleepiness and tiredness.

Talk to your doctor if you have experienced side effects such as restlessness, irritability, aggression, delusion, rage, nightmares, hallucinations, psychoses or inappropriate behaviour while taking benzodiazepines (See Section 4, 'Possible Side Effects').

Anxicalm is not recommended as the main treatment for psychotic illness, depression or anxiety.

Other medicines and Anxicalm

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

Concomitant use of Anxicalm and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) 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 Anxicalm together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid 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.

Tell your doctor if you are taking any of the following medicines:

- Antidepressants (e.g. amitriptyline), sedatives (to calm you down, e.g. chlordiazepoxide), hypnotics (to help you sleep, e.g. temazepam), or strong pain relieving medicines (e.g. morphine). These medicines act in the same way as Anxicalm and could make you very sleepy.
- Medicines for epilepsy (e.g. barbiturates or phenytoin). These can make the side effects of Anxicalm worse
- Cimetidine or omeprazole (for ulcers) or ketoconazole (to treat fungal infections of the skin) as these can cause diazepam to be removed from the body more slowly than usual. This may lead to increased and prolonged sedation
- Drugs such as rifampicin (an antibiotic) which can cause Anxicalm to be removed from the body more quickly than usual
- Drugs which affect liver enzymes (cytochrome P450), e.g. fluoxetine and paroxetine (drugs that are used to treat depression)
- Antihistamines, used to relieve allergic conditions (e.g. chlorpheniramine)
- Cisapride, which is used for gastrointestinal disorders.

Anxicalm with food, drink and alcohol

Do not take alcohol while you are taking Anxicalm. Alcohol may increase the sedative effects of Anxicalm and make you very sleepy.

Pregnancy and breast-feeding

You should not take Anxicalm if you are pregnant, 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. If you take Anxicalm late in your pregnancy or during labour your baby might have a low body temperature, floppiness, and breathing and feeding difficulties. If you take this medicine regularly during late pregnancy, your baby may develop withdrawal symptoms. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Anxicalm may make you feel sleepy or affect your concentration. **Do not** drive or use any tools or machines if you are affected in this way and do not drink alcohol, as this will make these effects worse.

Anxicalm contains lactose and sodium

Anxicalm contains **lactose monohydrate (milk sugar)**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

Anxicalm 5 mg tablets contain tartrazine (E102)

Anxicalm 5 mg tablets contain tartrazine (E102) which may cause allergic reactions.

3. How to take Anxicalm tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The number of tablets you take will depend on what you are taking the tablets for. **You should not take Anxicalm for longer than 4 weeks for insomnia and 8-12 weeks in cases of anxiety.** Swallow the tablets whole with a drink of water.

Adults

Anxiety: If you are taking the tablets for anxiety the usual dose is 2 mg three times a day. This amount can be increased up to 10 mg three times a day.

Insomnia: If you are taking Anxicalm to help you sleep, the usual dose is 5 mg to 15 mg at bedtime. Your doctor will treat you with the lowest effective dose.

Muscle spasm: If you are taking Anxicalm to help control muscle spasm your doctor may tell you to take 2 mg to 15 mg of Anxicalm each day. This dose should be divided up into 2 or 3 doses throughout the day.

Cerebral spasticity: If you are taking Anxicalm to help cerebral spasticity or epilepsy your doctor may tell you to take 2 mg to 60 mg of Anxicalm each day, divided up into 2 or 3 doses throughout the day.

For treatment of muscle spasm in tetanus: 3 to 10 mg/kg in bodyweight daily.

Sedation before dental procedures or an operation: If you are given Anxicalm before a dental procedure or an operation a single dose of between 5 mg and 20 mg of Anxicalm is usual.

Use in children

For treatment of muscle spasm in tetanus: 3 to 10 mg/kg in bodyweight daily.

For tension and irritability in cerebral spasticity the dose is usually between 2 mg and 40 mg each day divided up into 2 or 3 doses throughout the day.

If your doctor has given your child Anxicalm to take before an operation or dental procedure a single dose of between 2 mg and 10 mg of Anxicalm is usual.

Elderly

If you are elderly or frail you are likely to be more sensitive to the effects of Anxicalm and your doctor will give you much lower doses than those mentioned above.

If you have liver or kidney problems or breathing difficulties you may also be given a lower dose.

If you take more Anxicalm than you should

If you take more Anxicalm than you should contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

If you forget to take Anxicalm tablets

If you forget to take a dose of Anxicalm tablets, take it as soon as you remember, unless it is almost time for your next dose, in which case miss out the forgotten dose completely and carry on as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Anxicalm tablets

If you stop taking Anxicalm suddenly, you may experience unpleasant side effects including depression, nervousness, sleeplessness, irritability, sweating or diarrhoea and occasionally confusion, convulsions, or unusual behaviour.

Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

The following side effects have been reported. If you experience any of these see your doctor at once, as you should not take this medicine:

Significant side effects:

- Feeling over excited or nervous
- Feeling or seeing things that are not there (hallucinations)
- Experiencing rage
- Changes in sleep pattern and having tight stiff muscles

You may become dependent on Anxicalm or similar medicines (physical or psychological dependence).

If you suddenly stop taking Anxicalm you may suffer withdrawal symptoms. These include extreme anxiety, tension, restlessness, confusion, irritability, headaches and muscle pain. In severe cases you may feel out of touch with reality, feel strange in familiar surroundings, have hallucinations, have numbness and tingling sensation in your arms and legs, become over-sensitive to light, noise and physical contact or have epileptic seizures.

When you stop taking Anxicalm you may experience difficulty sleeping (rebound insomnia). Tell your doctor if this happens.

Paradoxical (not typical or unexpected) reactions such as restlessness, agitation, irritability, aggression, delusion, anger, nightmares, abnormal behaviour and other adverse behavioural effects are known to occur when using Anxicalm. Should this occur, **contact your doctor immediately**. They are more likely to occur in children and in the elderly.

This medicine may induce a temporary loss of memory (anterograde amnesia)

Other side effects include:

The most common side effects are:

- Feeling sleepy (drowsiness)
- Fatigue (mental or physical tiredness)
- Unsteadiness
- Clumsiness and loss of co-ordination
- Muscle weakness

You could notice the above common side-effects even after a single dose and they may continue for more than 24 hours. If you are elderly you are more likely to suffer from side effects, especially confusion, as well as increased risk of falls and fractures.

Other side effects that occur less often are:

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| – Ataxia (difficulty in controlling movements) | – Yellowing of the skin or whites of the eyes (jaundice) |
| – Trembling hands | – Constipation |
| – Reduced alertness | – Nausea |
| – Double vision or blurred vision | – Blood cell changes |
| – Numbed emotions | – Dry mouth or increased saliva production |
| – Confusion | – Slurred speech |

- Heart problems (cardiac failure including cardiac arrest)
- Loss of memory
- Headache
- Dizziness or spinning (vertigo)
- Low blood pressure
- Stomach upsets
- Skin rashes
- Changes to eye sight
- Depression
- Difficulty breathing (respiratory depression including respiratory failure)
- Irregular heart rate
- Increased risk of falls and fractures in the elderly
- Increase or lack of sexual drive
- Difficulty passing urine
- Incontinence

Your doctor may want to carry out occasional tests to monitor enzyme levels in your blood as Anxicalm can affect them.

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 Anxicalm tablets

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

Do not store above 25°C. Keep the container tightly closed. Store in the original container in order to protect from moisture.

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 Anxicalm tablets contain

The active substance is Diazepam.

Each tablet contains 2, 5 or 10 mg Diazepam.

The other ingredients are

Pregelatinised maize starch, lactose monohydrate, sodium laurilsulfate, sodium starch glycollate (Type A), stearic acid, magnesium stearate and the colours tartrazine (E102, 5 mg tablets) and brilliant blue FCF (E133, 10 mg tablets).

What Anxicalm tablets look like and contents of the pack

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| Anxicalm 2 mg Tablets: | White, circular, flat tablets engraved with 'D2' on one side and a single scoreline on the reverse. Each tablet contains diazepam 2 mg. |
| Anxicalm 5 mg Tablets: | Yellow, circular, flat tablets engraved with 'D5' on one side and a single scoreline on the reverse. Each tablet contains diazepam 5 mg. |
| Anxicalm 10 mg Tablets: | Mottled light blue, circular, flat tablets engraved with 'D10' on one side and a single scoreline on the reverse. Each tablet contains diazepam 10 mg. |

Anxicalm 2, 5 and 10 mg tablets are available in packs containing 30, 50, 90, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

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