Package leaflet: Information for the patient

Alprazolam Hexal 0,5 mg, tabletten
Alprazolam Hexal 1,0 mg, tabletten

alprazolam

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 illnes 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 [Nationally completed name] is and what it is used for

[Nationally completed name] is a tranquilliser containing the active substance alprazolam. Alprazolam belongs to one of a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain to promote sleep and to reduce anxiety and worry.

[Nationally completed name] is used to **treat anxiety** that is severe, disabling or causing the sufferer great distress.
[Nationally completed name] tablets should only be used for short-term treatment of anxiety. The overall duration of treatment should not be more than 12 weeks including a period where the dose is gradually reduced (this is called dose 'tapering').

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name] if you
- are allergic to alprazolam or any of the other ingredients of this medicine (listed in section 6),), or previously had an allergic reaction to another benzodiazepine.
- suffer from myasthenia gravis (severe muscle weakness)
- have a severe lung disease e.g. bronchitis, emphysema
- have "sleep apnoea", where breathing temporarily stops during sleep
- have a severe liver disease.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name]

- if you have ever suffered any mental illness that requires hospital treatment.
- if you are under 18 years old.
- if you have problems with your lungs, kidneys or liver.
- if you have abused drugs or alcohol in the past or find it difficult to stop taking medicines, drinking or taking drugs. Your doctor may want to give you special help when you need to stop taking these tablets.
- if you notice that the effect of the tablets becomes less after a few weeks of use.

if you are troubled by symptoms that indicate physical and psychological dependence on alprazolam. You notice psychological dependence by not wanting to stop taking the medicine. Physical dependence means that withdrawal symptoms occur when the treatment with this medicine is stopped suddenly (see the section "If you stop taking [Nationally completed name]").
The risk of dependence increases with higher doses and a longer period of treatment. Therefore, the duration of treatment must be as short as possible.

- if you experience memory loss.

This mostly occurs a few hours after taking the tablet. See section 4 "Possible side effects".
To reduce the risk patients should ensure that they will be able to have uninterrupted sleep of 7-8 hours.

- if you experience psychiatric and "paradoxical" reactions such as
  - anxiety
  - irritability
  - attacks of rage
  - nightmares
  - increased insomnia
  - perceptions of things that do not exist (hallucinations)
  - severe mental disorders in which control over one's own behaviour and actions is disturbed (psychosis)
  - inappropriate behaviour and other behavioural disturbances

  These conflicting reactions occur more frequently in children and elderly patients. Tell your doctor if such symptoms occur as the treatment may possibly need to be stopped.
- if you suffer from chronic tightness of the chest you should be aware that [Nationally completed name] can aggravate this.
- if you suffer from severe depression.
  [Nationally completed name] can sometimes cause an excessively lively mood (mania) or an increase in suicidal tendencies.
- if you suffer from psychosis - a severe mental illness which disturbs your behaviour, actions and self control, then [Nationally completed name] is not appropriate.
- if you have a certain form of suddenly raised eyeball pressure (narrow-angle glaucoma) or if you are at risk of experience this.

Please tell your doctor if any of the above apply or have previously applied to you.

Children and adolescents
Alprazolam is not recommended for children and adolescents under the age of 18 years.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription especially medicines listed below, as the effect of [Nationally completed name] may be stronger when taken at the same time:

Medicines that increase [Nationally completed name]**´s sedative effect:**

- sleep-inducing and tranquillising medicines
- medicines used to treat severe mental disorder like schizophrenia (antipsychotics)
- medicines used to treat severe depression
- any other medicines to treat anxiety or depression

- medicines used to treat epilepsy
- medicines that are used for anaesthesia
- certain medicines used to treat allergies, so called sedative antihistamines

Concomitant use of [Nationally completed name] 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 [Nationally completed name] 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.

These painkillers can also increase the euphoria and dependence risk.

Medicines that increase [Nationally completed name]**´s effect** as a result of suppression of the breakdown of alprazolam in the liver:
- nefazodone, fluvoxamine, fluoxetine, sertraline, medicines used to treat severe depression
- cimetidine, a medicine used to treat gastric disorders
- certain medicines used to treat AIDS (known as HIV protease inhibitors, e.g.ritonavir, saquinavir, indinavir)
- dextropropoxyphene, a medicine used to treat pain
- the oral contraceptive pill
- diltiazem, a medicine used to treat high blood pressure and heart disorders
- macrolide antibiotics such as erythromycin, medicines used to treat infections
- certain medicines used to treat fungal infections, such as ketoconazole and itraconazole.

Medicines that decrease [Nationally completed name]**´s effect** due to the increased alprazolam breakdown in the liver:
- carbamazepine or phenytoin, medicines used to treat epilepsy and other conditions.
- St John's wort, a herbal medicine used to treat depression.
- rifampicin, a medicine to treat tuberculosis.

Medicines whose effects may be increased by [Nationally completed name]**:**
- digoxin, a medicine used to treat heart failure and heart rhythm disturbances;
  The risk of digoxin poisoning is particularly increased in elderly patients and, where doses exceeding 1 mg [Nationally completed name] are taken daily.
- muscle relaxants, such as pancuronium, atracurium
  The muscle-relaxant effect may be greater, especially on beginning Alprazolam HEXAL treatment.
- Imipramine and desipramine, certain medicines used to treat severe depression
- Clozapin, a medicine used to treat severe mental disorder (psychosis).
  The risk of respiratory and/or cardiac arrest may be higher.

[Nationally completed name] **with alcohol**
It is important not to drink any alcohol while you are taking [Nationally completed name], as alcohol increases the effects of the medicine

Pregnancy and 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.

Pregnancy

There are no adequate experiences from the use of Alprazolam in pregnant women. Do not take [Nationally completed name] if you are pregnant or planning to become pregnant, unless your doctor considers it strictly indicated. Observations in humans have indicated that the substance alprazolam can be harmful to the unborn child. If you are pregnant or planning a pregnancy, consult your doctor about the possibility to stop the treatment. If you are taking [Nationally completed name]until birth, let your doctor know as your newborn might have some withdrawal symptoms when it is born.

Breast-feeding
There is a risk of an effect on the baby. Therefore you should not breast-feed during [Nationally completed name] treatment.

Driving and using machines
[Nationally completed name] can cause side effects such as
- drowsiness
- memory loss
- muscle relaxation and
- decreased concentration.

Therefore your ability to react may be affected, particularly if you have had insufficient sleep. These effects may be increased if you drink alcohol. Do not drive or operate machines during treatment with [Nationally completed name].

[Nationally completed name] contains lactose, sodium and sodium benzoate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially `sodium-free´.
This medicine contains 0.12 mg sodium benzoate in each tablet. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take [Nationally completed name]

Always take [Nationally completed name] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults
- Starting dose: 0.25 - 0.5 mg three times daily.
- If the effect is insufficient the dose may be increased by your doctor to a maximum of 3 mg per day (= 24 hours), divided into several doses.

Elderly, debilitated patients and patients with disturbed kidney function or mild liver dysfunction
- Starting dose: 0.25 mg two to three times per day (= 24 hours).
- If the effect is insufficient the dose may be increased by your doctor to a maximum of 0.75 mg per day (= 24 hours), divided into several doses.

There is a reduced clearance of the medicine and an increased sensitivity to the medicine in elderly patients.

[Nationally completed name] must not be taken by patients with severely reduced liver function. See chapter 2 What you need to know before you take [Nationally completed name].

Use in children and adolescents
[Nationally completed name] is not recommended for children and adolescents under the age of 18 years
If you feel that [Nationally completed name] is too strong or not strong enough, ask your doctor or pharmacist for advice.

Method of administration

[Nationally completed name] is intended for oral use. The tablets should be taken at the same time everyday with a glass of water. The tablet can be taken independently of mealtimes and can be divided into equal doses.

Duration of treatment
Treatment with [Nationally completed name] should be as short as possible. This means that you will not normally be given [Nationally completed name] for more than 8 to 12 weeks., including the tapering-off period. In some cases your doctor may decide to extend the duration of treatment. Treatment with [Nationally completed name] should not be for more than 12 weeks without review of your condition by your doctor. This is because use of benzodiazepines may lead to the development of physical and psychic dependence upon these products. The risk of dependence increases with the dose and duration of treatment; but it is also greater in patients with a history of alcohol or drug abuse. Talk to your doctor if you are worried about this.

If you take more [Nationally completed name] **than you should**
Please contact your doctor or pharmacist immediately if this occurs. Overdose symptoms can include:
- drowsiness
- confusion and
- lethargy

In a severe overdose the symptoms can be coordination problems, for example:
- drunken gait
- reduced muscle tone
- lowered blood pressure
- suppressed breathing
- in rare cases coma
- fatal in very rare cases.

If you forget to take [Nationally completed name]
If you have forgotten to take a dose, you can still take it unless it is almost time for your next dose. In this case follow the normal dosing schedule.
Do not take a double dose of [Nationally completed name] to make up for the forgotten dose.

If you stop taking [Nationally completed name]
If you suddenly stop taking [Nationally completed name], directly after stopping treatment or several days later withdrawal symptoms may occur, such as mood changes, insomnia and restlessness. This risk will increase if your dose is reduced too quickly or, if you suddenly stop the treatment.

Suddenly stopping this medicine is therefore not recommended. Your doctor will gradually reduce the dose. This should be done by reducing the dose every three days, by a maximum of 0.5 mg. It may be necessary in some cases to reduce the dose more slowly.

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.

Reasons for stopping [Nationally completed name] treatment immediately
If you get any of these symptoms, see your doctor straight away as treatment will need to be discontinued. Your doctor will then advise how treatment will be stopped.

- Treatment with [Nationally completed name] can cause serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.
- Sudden wheeziness, difficulty in swallowing or breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

Reasons for seeing your doctor straight away
Tell your doctor straight away if you get the following symptoms as your dose or treatment might need to be changed:
- Memory loss (amnesia) (uncommon)
- Yellowing of the skin and whites of the eyes (jaundice) (frequency not known)

Dependence and withdrawal symptoms
- It is possible to become dependent on medicines like [Nationally completed name] while you are taking them which increases the likelihood of getting withdrawal symptoms when you stop treatment.
- Withdrawal symptoms are more common if you:
  - stop treatment suddenly
  - have been taking high doses
  - have been taking this medicine for long time
  - have a history of alcohol or drug abuse.

This can cause effects such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, difficulty sleeping and irritability.
In severe cases of withdrawal you can also get the following symptoms: nausea (feeling sick), vomiting, sweating, stomach cramps, muscle cramps, a feeling of unreality or detachment, being unusually sensitive to sound, light or physical contact, numbness and tingling of the feet and hands, hallucinations (seeing or hearing things which are not there while you are awake), tremor or epileptic fits.

Other side effects that may occur are:
Very common: may affect more than 1 in 10 people
- Depression
- Sleepiness and drowsiness
- Jerky, uncoordinated movements
- Inability to remember bits of information
- Slurred speech
- Dizziness, light-headedness
- Headaches
- Constipation
- Dry mouth
- Tiredness
- Irritability

Common: may affect up to 1 in 10 people
- Decreased appetite
- Confusion and disorientation
- Increased or decreased sex drive (men and women) and sexual dysfunction
- Nervousness or feeling anxious or agitated
- Insomnia (inability to sleep or disturbed sleep)
- Problems with balance, and unsteadiness (similar to feeling drunk) especially during the day
- Loss of alertness or concentration
- Inability to stay awake, feeling sluggish
- Shakiness or trembling
- Double or blurred vision
- Feeling sick
- Skin reactions

- Change in your weight

Uncommon: may affect up to 1 in 100 people
- Feeling elated or over-excited, which causes unusual behaviour
- Hallucination (seeing or hearing things that do not exist)
- Feeling agitated or angry
- Incontinence
- Cramping pain in the lower back and thighs, which may indicate menstrual disorder
- Muscle spasms or weakness
- Vomiting
- Drug dependence
- Withdrawal syndrome

Not known: frequency cannot be estimated from the available data
- In women, irregular periods or production of too much prolactin (the hormone that stimulates milk production)
- Feeling hostile or aggressive
- Abnormal thoughts
- Twisting or jerking movements
- Being hyperactive
- Stomach upsets
- Problems with liver function (this shows up in blood tests), inflammation of the liver (hepatitis)
- Imbalance to part of nervous system. Symptoms may include: fast heart beat and unstable blood pressure (feeling dizzy, light-headed or faint)
- Serious allergic reaction which causes swelling of the face or throat
- Swelling of the ankles, feet or fingers
- Skin reaction caused by sensitivity to sunlight
- Difficulty urinating or bladder control problems
- Increased pressure in the eyes, which can also affect your vision
- Drug abuse

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 national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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

Do not store above 25°C.

Keep the blister in the outer carton in order to protect from light.

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 [Nationally completed name] contains

- The active substance is alprazolam.
  Each tablet contains 0.25 mg of alprazolam.
  Each tablet contains 0.5 mg of alprazolam.
  Each tablets contains 1 mg of alprazolam.

- The other ingredients are sodium docusate, sodium benzoate, pregelatinised maize starch, microcrystalline cellulose, lactose, magnesium stearate, colloidal anhydrous silica, Erythrosine aluminium lake (E 127) (only for 0.5 mg), Aluminium salt of indigo carmine (E 132) (only for 1 mg).

What [Nationally completed name] looks like and contents of the pack

0.25 mg tablets:
White, oblong tablet with a score line and debossed "APZM 0.25".
The tablet can be divided into equal halves.

0.5 mg tablets:
Pink, oblong tablet with a score line and debossed "APZM 0.5".
The tablet can be divided into equal halves.

1 mg tablets:
Light blue, oblong tablet with a score line and debossed "APZM 1".
The tablet can be divided into equal halves.

The tablets are packed in in aluminium/PVC blisters which are inserted in a carton.

Pack sizes:
10, 20, 30, 40, 50, 60 or 100 tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Hexal AG
Industriestrasse 25
83607 Holzkirchen
Duitsland

Fabrikant
Lek Pharmaceuticals d.d.
Trimlini 2D
9220 Lendava
Slovenië

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1

39179 Barleben
Duitsland

Dragenopharm Apotheker Püschl GmbH
Göllstrasse 1
84529 Tittmoning
Duitsland

In het register ingeschreven onder:
Alprazolam Hexal 0,5 mg, tabletten is in het register ingeschreven onder RVG 100526
Alprazolam Hexal 1,0 mg, tabletten is in het register ingeschreven onder RVG 100531

Dit geneesmiddel is geregistreerd in de lidstaten van de EEA onder de volgende namen:

Nederland:	Alprazolam Hexal 0,5 mg, tabletten
	Alprazolam Hexal 1,0 mg, tabletten
Duitsland:	Alprazolam -1 A Pharma 0,5 mg Tabletten
	Alprazolam -1 A Pharma 1 mg Tabletten

Deze bijsluiter is goedgekeurd in januari 2024