Package leaflet: Information for the user

Alprazolam Stada 0.5 mg and 1 mg tablets
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 illness 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 Alprazolam Stada is and what it is used for

Alprazolam Stada contains the active substance alprazolam and belongs to a group of medicines called “benzodiazepines” (anxiety-relieving medicines).

Alprazolam Stada is used in adults for treatment of anxiety symptoms which are severe, disabling or causing the patient great distress.

This medicine is for short-term use only.

2. What you need to know before you take Alprazolam Stada

DO NOT take Alprazolam Stada and tell your doctor if:
- you are **allergic** to alprazolam, other benzodiazepines or any of the other ingredients of this medicine (listed in section 6)
- you suffer from a condition known as **‘sleep apnoea’** where you occasionally stop breathing for a short time while you are sleeping.
- you have the muscle disease **Myasthenia Gravis**
- you have severe **breathing problems**
- you have severe **liver problems**
- you have an **acute intoxication** caused by alcohol or other drugs which affect the central nervous system

Tell your doctor if you are not sure about any of the above.

Warnings and precautions
Talk to your doctor or pharmacist before taking Alprazolam Stada
- if you **abuse** or have been abusing alcohol, drugs or medicines
- if you have been taking Alprazolam Stada for a long time as the effect may decrease
- if you have an impaired general condition
- if you have problems with your lungs, kidneys or liver

- if you are taking painkillers containing dextropropoxyphene. This combination should be avoided as it may cause breathing problems
- if you are taking other medicines for mental illness

Use of Alprazolam Stada may lead to **physical and mental dependence** on the medicine. The risk for dependence is increased by dose and time of treatment. Therefore the duration of treatment must be as short as possible. Follow your doctor's dose recommendations (see section 3). 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 also section 3 "If you stop taking Alprazolam Stada"). The risk is also greater in patients who abuse or have been abusing alcohol and medicines.

Medicinal product abuse is a known risk with this medicine. If this medicine is abused, it may lead to overdose and death. Always follow your doctor's dosage recommendations. This medicine may be sought after by people who abuse prescription medicines, and should be stored out of the reach of other people.

During treatment with Alprazolam Stada your **memory may be disturbed**.
This usually occurs several hours after you have taken this medicine. Contact your doctor if you notice such a symptom.

If you suffer from psychosis, a severe mental illness which disturbs your behaviour, actions and self-control, then Alprazolam Stada is not appropriate.

Impact on mood
Use of Alprazolam Stada may increase the risk of episodes of hypomania (a milder form of mania) and mania (hyperactive mental state, excessive elation and energy) in patients with depression. Contact your doctor immediately if you develop signs of hypomania or mania.

The treatment with Alprazolam Stada may increase the risk to develop thoughts of harming or killing yourself if you have depression. Please ask your doctor before starting treatment with Alprazolam Stada.

If treatment with Alprazolam Stada is necessary and if you are depressed or have previously had thoughts about harming or killing yourself your doctor will monitor you closely. If you develop thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital **straight away.**

Elderly patients
Be especially careful when using Alprazolam Stada if you are elderly, because it may cause increased tiredness and/or muscle weakness that can increase the risk of falling.

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

Other medicines and Alprazolam Stada
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment may be affected if Alprazolam Stada is used together with other medicines to treat the listed conditions. Your doctor may need to adjust your dosage.
- **mental problems** (antipsychotic medicines including clozapine)
- **sleep disorders** (sleeping tablets)
- **allergies** or hay fever (some antihistamines)
- if you undergo **major surgery** (anaesthetics)

- **severe pain** (narcotic analgesics, e.g. dextropropoxyphene)
- **therapy against drug addiction** (substitutive treatment)
- problems such as **anxiety or depression**, including certain antidepressants containing fluoxetine, fluvoxamine, nefazodone or imipramine
- **heart failure** (digoxin)
- **infections** (antibiotics) containing erythromycin, clarithromycin or telithromycin
- **fungal infections** (itraconazole, fluconazole, ketoconazole, posaconazole, voriconazole)
- medicines to treat **angina pectoris** and **high blood pressure**, such as diltiazem
- **HIV and AIDS** called HIV-protease inhibitors, such as ritonavir
- **heartburn and stomach ulcer**, such as cimetidine or omeprazole
- **asthma and bronchitis** such as theophylline
- **epilepsy**, such as carbamazepine
- **muscle relaxant medicines**. When used together with alprazolam there may be an increase of the muscle relaxing effect and a risk of falling.

Concomitant use of Alprazolam Stada 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 Alprazolam Stada 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.

It is also possible that the treatment effect of Alprazolam Stada could be affected by concomitant treatment with any of the following drugs: **the pill**, **rifampicin** (for infections) or **St. John's wort** (herbal medicine).

Alprazolam Stada with food, drink and alcohol
You should **not** drink alcohol when taking Alprazolam Stada as the combination may make you sleepy.

The tablets should be taken together with some fluid and with or without food**.**

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
You must tell your doctor immediately if you are pregnant or plan to become pregnant. Observations in humans have shown that alprazolam may be harmful to the foetus (increased risk of malformation (cleft palate)). During pregnancy, Alprazolam should only be used after a careful benefit / risk consideration by your doctor. Your doctor will decide if the possible benefit of a treatment overweighs the risk to the unborn child and if the tablets are suitable for you.

If you use Alprazolam Stada until birth, tell your doctor because your newborn baby may have withdrawal symptoms after birth.

Breast-feeding
Alprazolam Stada should not be taken if you are breast-feeding. Alprazolam passes into breast milk.

Driving and using machines
Treatment with Alprazolam Stada may impair your ability to react and concentrate by making you feel drowsy and/or forgetful. **Do not** drive or operate machinery if you feel affected in this way. **Ask your doctor for advice if you´re not sure**

Alprazolam Stada contains lactose, sodium benzoate and sodium.

Lactose:	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Sodium benzoate:	This medicine contains 0.12 mg sodium benzoate in each tablet.
Sodium:	This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Alprazolam Stada

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Treatment should preferably be started, monitored and completed by the same doctor. The dose is determined by your doctor, who will tailor it to your individual needs.

The recommended dose is
- Initial dosage: 0.25 – 0.5 mg three times daily
- Maintenance dosage: 0.5 mg – 3 mg daily divided in separate doses as your doctor has prescribed.

This medicine is for short-term use only. The risk of dependency and abuse may increase with the dose and duration of treatment. The doctor will therefore prescribe the lowest effective dose and treatment duration possible, and frequently reassess the need for continued treatment (see section 2 "Warnings and precautions"). The maximum duration of treatment should not exceed **2-4 weeks**. Long-term treatment is not recommended.

The tablets should be taken together with some fluid. The tablets may be divided into two equal parts.

Patients with breathing difficulties
If you suffer from difficulty in breathing (chronic respiratory insufficiency) your doctor may prescribe you a lower dose. Alprazolam STADA must not be used in patients with severe breathing difficulties.

Elderly patients or patients with kidney and/or liver problems
These patients might need a lower dose. Your doctor will determine your individual dose.

If you take more Alprazolam Stada than you should
If you accidentally take too many tablets, call your doctor straight away, or go to the nearest hospital casualty department. Always take any leftover tablets with you, as well as the container and label, so that the medical staff knows what you have taken.

Symptoms of overdose can be
- dizziness
- sleepiness
- breathing problems
- confusion
- unconsciousness
- muscle weakness
- lack of coordination while performing movements (ataxia)
- or reactions such as aggressiveness, hallucinations and agitation.

If you forget to take Alprazolam Stada
If you have forgotten to take your medicine at your usual time, take it as soon as you remember. If it is nearly time for your next dose, leave out the forgotten dose and take the next dose as usual. Do not take a double dose to make up for a forgotten tablet. If you are not sure ask your doctor or pharmacist for advice.

If you stop taking Alprazolam Stada
Always check with your doctor before stopping the treatment. It is important that you gradually reduce your dose in consultation with your doctor.

Stopping treatment suddenly may lead to withdrawal symptoms such as headache, muscle pain, severe anxiety, restlessness, confusion, irritation and sleep disorders.

In severe cases the following symptoms may occur: loss of sense of reality, depersonalisation (a feeling that you are outside of your own body), loss of sensation and tingling sensations in arms and legs, oversensitivity to light, sound, and touch, hallucinations and epileptic seizures (fits). Withdrawal symptoms can occur several days after you have stopped taking the tablets.

Also when treatment with alprazolam stops, symptoms that prompted treatment with Alprazolam Stada in the first place can reoccur and with greater intensity than before. Besides the symptoms listed above, this can also lead to mood swings.

Therefore, your doctor will reduce your dose gradually when stopping treatment. He/she will decide about the dose reduction on an individual base, as the dose tapering depends on several factors (e.g. the duration of treatment and your daily dose). Please ask your doctor how you should reduce your dose gradually.

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.

Stop taking this medicine and contact a doctor immediately if you experience any of the following symptoms (angioedema):
- swelling of the face, tongue, or throat
- difficulty swallowing
- hives and breathing difficulties.

Angioedema has been observed but the frequency is not known.

Stop taking the medicine and contact your doctor as soon as possible if you notice:
- a yellow discolouration of the eye whites or skin (jaundice)
- conflicting reactions such as anxiety, restlessness, agitation, irritability, aggression, delusions, 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 disorders. These conflicting reactions occur more frequently in elderly patients.
- a depression/depressive thoughts.

The following side effects may occur during treatment with Alprazolam Stada
You may consult your doctor at regular intervals. Please inform him during these routine examinations, if you experience or experienced one of the following possible side effects.

Very common (may affect more than 1 in 10 people):
- depression
- feeling numb (sedation)
- drowsiness
- muscle coordination disorder (ataxia)
- impaired memory
- difficulty in speaking
- dizziness
- headache
- constipation
- dry mouth
- tiredness (fatigue)
- irritability

Common (may affect up to 1 in 10 people):
- decreased appetite
- loss of appetite
- increased appetite
- confusion
- disorientation
- decreased sexual drive (libido decreased)
- feeling anxious
- difficulty in sleeping (insomnia)
- nervousness
- increased sexual drive (libido increased)
- feeling unsteady when standing or walking (balance disorder)
- coordination difficulties
- extreme fatigue
- feeling listless (lethargy)
- shaking or trembling (tremor)
- concentration disturbances
- blurred vision
- nausea
- vomiting
- skin inflammation (dermatitis)
- sexual dysfunction
- weight change

Uncommon (may affect up to 1 in 10 people):
- overactive mental state, excessively excited and energetic (mania)
- seeing or hearing things that are not real (hallucinations)
- feeling angry
- restlessness (agitation)
- drug dependence (see section 2 “Warnings and precautions”)
- memory loss (amnesia)
- feeling of intoxication
- muscular weakness
- incontinence
- irregular menstruation
- withdrawal syndrome (see section 2 “Warnings and precautions”)

Not known (frequency cannot be estimated from the available data):
- overproduction of the hormone prolactin
- feeling over-excited (hypomania, a milder form of mania)

- feeling aggressive or hostile
- abnormal thoughts (delusions)
- restlessness (psychomotor hyperactivity)
- drug abuse (see section 2 "Warnings and precautions")
- autonomic nervous system imbalance (such as heart palpitations, increased salivation and nasal congestion)
- involuntary muscle contractions
- impaired reactivity
- speech difficulties
- low blood pressure
- gastrointestinal disorders
- difficulty swallowing
- liver inflammation (hepatitis)
- problems with liver function
- jaundice (causes yellowing of the skin and whites of the eyes)
- swelling of the ankles, feet or fingers (peripheral oedema)
- skin reactions caused by sunlight
- difficulty urinating or bladder control problems
- increased fluid pressure in the eye

Previously unnoticed depression may become apparent when using benzodiazepines such as Alprazolam Stada.
Physical and mental dependence may develop during the treatment. Stopping treatment suddenly can therefore lead to certain symptoms (see also section 3 “If you stop taking Alprazolam Stada”).

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 Alprazolam Stada

Keep this medicine out of the sight and reach of children.

Do not store above +30 °C.

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

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 Alprazolam Stada contains
- The active substance is alprazolam. Each tablet contains 0.5 mg or 1 mg alprazolam.
- The other ingredients are docusate sodium, sodium benzoate, pregelatinised starch, microcrystalline cellulose, lactose monohydrate, magnesium stearate, colloidal anhydrous silica.

Alprazolam Stada 0.5 mg tablets additionally contain erythrosine aluminium lake (colouring

agent E127)

Alprazolam Stada 1.0 mg tablets additionally contain indigo carmine aluminium lake (colouring agent E132)

What Alprazolam Stada looks like and contents of the pack
Alprazolam Stada 0.5 mg: pink, oval, scored tablets
Alprazolam Stada 1 mg: light blue, oval, scored tablets

Content of the packs: 0.5 mg: 7, 10, 14, 20, 21, 28, 30, 40, 50, 60, 70, 80, 84, 90, 100, 200, 250, 500 and 1000 tablets in blister.
1 mg: 10, 14, 20, 21, 28, 30, 40, 50, 60, 70, 80, 84, 90, 100, 200, 250, 500 and 1000 tablets in blister.

Marketing Authorisation Holder
[To be completed nationally]

In Sweden:
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Germany

Manufacturer
[To be completed nationally]

This leaflet was last revised in 2023-06-02.

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: Alprastad 0,5 mg – Tabletten, Alprastad 1 mg – Tabletten
Germany: Alprazolam AL 0,5 mg Tabletten, Alprazolam AL 1 mg Tabletten
Sweden: Alprazolam STADA