Package leaflet: Information for the user

Alprazolam-ratiopharm 1 mg, tabletten

Active substance: 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 1.0 mg* is and what it is used for

Alprazolam 1.0 mg is one of a group of medicines called benzodiazepines. They work by acting on brain transmitters and help in the treatment of anxiety.

Alprazolam 1.0 mg is used
- for the symptomatic treatment of anxiety.

2. What you need to know before you take *Alprazolam 1.0 mg*

Do not take *Alprazolam 1.0 mg*
- if you are allergic to alprazolam , other benzodiazepines or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from a condition that causes severe muscle weakness (myasthenia gravis)
- if you suffer from a severe breathing disorder
- if you sometimes suddenly stop breathing during the night (sleep apnoea syndrome)
- if you suffer from severe liver dysfunction
- in cases of acute alcohol poisoning or intoxication with other substances that act on the nervous system

Warnings and precautions

Talk to your doctor or pharmacist before taking *Alprazolam 1.0 mg*

- if you have a history of any addictive disorder (abuse of alcohol, other medicines or drugs)
- if you suffer from difficulty in breathing or have breathing problems
- if you suffer from impaired renal function or mild to moderate liver dysfunction

Talk to your doctor if this applies to you, as your dose may have to be reduced.

You should only use *Alprazolam 1.0 mg* if your anxiety is severely affecting your everyday life.

Benzodiazepines such as *Alprazolam 1.0 mg* should not be used on their own to treat depression or other mental/ psychiatric disorders. Depressive symptoms may get worse if you do not receive suitable treatment for their underlying disease. If you have ever felt that you are so useless or worthless that you have thought about taking your life, it is very important that you tell your doctor or your family about this as they may be able to help you.

Length of treatment should be as short as possible and should not exceed 8-12 weeks (see section 3: "How to take *Alprazolam 1.0 mg*").

Alprazolam 1.0 mg may become less effective if you take it constantly over a period of several weeks.

Long-term use of *Alprazolam 1.0 mg* can lead to physical and mental addiction. The higher the dose and the longer the course of treatment, the greater you are at risk of addiction, particularly if you have a history of alcohol and drug abuse. In patients with physical addiction, withdrawal symptoms will develop when the treatment is stopped. These symptoms include headache, muscle pain, severe anxiety and tension, sleep disorders, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: depersonalisation and derealisation (feeling 'divorced' from ones own identity and sense of reality), heightened sense of hearing, pins and needles in the limbs, sensitivity to light, sound and touch, hallucinations and epileptic seizures.
Withdrawal symptoms may occur several days after treatment has ended.

When treatment with *Alprazolam 1.0 mg* is stopped, the symptoms for which you were originally treated may return, but in a more intense form. At the same time, you may also experience mood swings, anxiety, insomnia or restlessness.

As the risk of such side effects is greater when the dose is reduced too quickly or when treatment is stopped too suddenly, your dose should be gradually reduced (tapered off).

Patients with reduced liver function

Talk to your doctor if your liver does not work properly. Your dose may have to be reduced (See section 2. "Do not take *Alprazolam 1.0 mg*").

Patients with reduced kidney function

Talk to your doctor if your kidney function is poor. Your dose may have to be reduced.

Elderly and infirm patients

Benzodiazepines and related products should be used with caution in elderly, due to the risk of sedation and/or musculoskeletal weakness that can promote falls, often with serious consequences in this population.
The doctor may prescribe a lower dose for elderly and infirm patients.

Children and adolescents

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

Other medicines and *Alprazolam 1.0 mg*

Tell your doctor or pharmacist if you are taking/ using, have recently taken/ used or might take / use any other medicines.
In particular, ask your doctor for advice if you are already taking any of the following medicines:
- medicines to treat fungal infections (e.g. ketoconazole, itraconazole, posaconazole, voriconazole)
- sleeping tablets, antipsychotic medicines or anaesthetics
- painkillers (e.g. dextropropoxyphene or opioids)

- medicines used to treat depression (e.g. St. John's wort, fluoxetine, fluvoxamine, sertraline, nefazodone, imipramine and desipramine)
- anxiolytics (used to treat anxiety)
- medicines to treat schizophrenia (e.g. clozapine)
- anti-epilepsy medication (e.g. carbamazepine, phenytoin)
- sedative antihistamines (used to treat allergies and with sedation as a side effect)
- oral hormone-based contraceptives (the 'Pill')
- antibiotics (e.g. erythromycin, troleandomycin, rifampicin, clarithromycin, telithromycin)
- medicines used to treat heart conditions (e.g. digoxin)
- medicines that lower the blood pressure (e.g. diltiazem)
- muscle relaxants
- medicines used to treat HIV
- cimetidine (medicine to combat stomach acid)

Concomitant use of *Alprazolam 1,0 mg* 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 1,0 mg* 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.

***Alprazolam 1.0 mg* with alcohol**

Do not drink alcohol whilst on treatment with *Alprazolam 1.0 mg*! Alcohol can change the way in which *Alprazolam 1.0 mg* works and can make its sedative effect even stronger.

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

During pregnancy, *Alprazolam 1.0 mg* should only be used in exceptional cases and when there is a compelling need for its use. You must tell your doctor immediately if you want to become pregnant - or suspect that you may be pregnant – at any time during treatment with *Alprazolam 1.0 mg*. He/she can then decide whether to continue or stop your treatment.

Breast-feeding

Alprazolam passes into breast milk. You should therefore not breastfeed whilst on treatment with *Alprazolam 1.0 mg*.

Driving and using machines

Alprazolam 1.0 mg may affect your ability to drive or operate machinery by causing sedation, loss of memory and alteration of concentration and muscular function during treatment. These effects are potentiated by alcohol. If you don't get enough sleep the risk of reduced alertness increases. You are advised not to drive or operate machinery during treatment with Alprazolam.

***Alprazolam 1.0 mg* contains lactose, sodium benzoate and sodium**

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 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).

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

3. How to take *Alprazolam 1.0 mg*

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the recommended dose is:

Adults

Starting dose:	0.25-0.5 mg alprazolam three times a day. If required, the dose can be increased every 3-4 days up to:
Maintenance dose:	½ - 3 (maximum) tablets *Alprazolam 1.0 mg* a day, divided into several single doses (equivalent to 0.5-3 mg alprazolam a day).

Elderly and infirm patients; patients with liver or kidney dysfunction

Starting dose:	0.25 mg alprazolam twice or three times a day. If required, and if the patient's condition allows it, the dose can be increased every 3-4 days up to:
Maintenance dose:	a maximum of 1½ *Alprazolam 1.0 mg* a day, divided into several single doses (equivalent to 1.5 mg alprazolam a day). For frail patients or infirm patients with poor kidney or liver function, a lower dose is recommended (0.75 mg alprazolam a day).

For dosages that cannot be maintained with *Alprazolam 1.0 mg*, tablets containing 0.25 mg and 0.5 mg alprazolam are available.

If you experience any side effects, please contact your doctor. Your dose may have to be reduced.

If an increase in dose is required, the evening dosage should firstly be increased before increasing the dosage during the day.

Directions for use

Swallow *Alprazolam 1.0 mg* tablets whole with plenty of liquid (e.g. a glass of water). Do not chew the tablets.

Duration of treatment

The duration of treatment with *Alprazolam 1.0 mg* should be as short as possible.
If used over longer periods, the treatment should be withdrawn gradually. The daily dose should be reduced by no more than 0.5 mg every three days.
Overall, the course of treatment should not exceed 8-12 weeks, including the gradual withdrawal phase. However, your treating doctor will ultimately decide how long treatment will last.

If you have the impression that the effect of *Alprazolam 1.0 mg* is too weak or too strong, talk to your doctor or pharmacist.

If you take more *Alprazolam 1.0 mg* than you should

Always seek immediate medical advice (e.g. call your local hospital's accident and emergency department).
An overdose generally manifests in the form of drowsiness, sometimes progressing to coma. In cases of mild overdose, symptoms of sleepiness, mental confusion and lethargy occur. In more severe cases, movement disorders, muscle relaxation, low blood pressure and breathing disorders are observed. Coma may rarely occur and can be fatal in very rare cases.
The severity of any overdose should be assessed by a doctor, who will determine which further measures are necessary.

If you forget to take *Alprazolam 1.0 mg*
Do not take a double dose to make up for a forgotten dose.

If you stop taking *Alprazolam 1.0 mg*
For a short time after long-term use or after treatment is suddenly stopped, your original symptoms may return, but in a more intense form. At the same time, you may also experience mood swings, anxiety, insomnia and restlessness.
When stopping your treatment, your treating doctor should therefore 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.

The following effects occur mainly at the start of treatment or at higher doses. They generally disappear during the course of treatment: drowsiness, numbness of feeling, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, movement disorders, visual disorders (e.g. double or blurred vision).

The following side effects are very common (affecting more than 1 in 10 patients):
sedation, drowsiness

The following side effects are common (affecting more than 1 in 100 patients but fewer than 1 in 10):
irritability, confusion, depression, decreased appetite, coordination disorders, uncoordinated movements, memory impairment, slurred speech, impaired concentration, light-headedness, constipation, nausea, headache, dizziness, blurred vision, weakness

The following side effects are uncommon (affecting more than 1 in 1000 patients but fewer than 1 in 100):
muscle weakness, high levels of prolactin in the blood, hallucinations, rage, aggressive behaviour, hostile behaviour, anxiety, agitation, changes in sex drive, insomnia, abnormal thinking, nervousness, stimulation, involuntary movements, trembling, loss of memory, vomiting, abnormal liver function, jaundice (yellowing of the skin), dermatitis, incontinence, difficulty urinating, sexual dysfunction, in women irregular periods, change in weight, increased pressure in the eye

Other side effects that may occur (frequency not known):
hepatitis, swelling (particularly of the lower legs and feet), numbness of feeling, reduced alertness, fatigue, double vision, diarrhoea, increased appetite, difficulties in swallowing, low blood pressure, skin reactions, dry mouth, increased saliva flow, blocked nose, rapid heartbeat, swelling (particularly of the eyelids, face, lips, tongue and throat) which can cause difficulty in breathing

Amnesia
Alprazolam can cause temporary memory loss (anterograde amnesia). This means that patients may not be able to remember what they have been doing for a few hours (in most cases) after taking alprazolam. This risk is greater at higher doses.

Depression
Manic episodes have been described in a few cases in patients with latent depression (i.e. existing depression without any symptoms).

Psychiatric and “paradoxical” reactions
Particularly in elderly patients, the use of *Alprazolam 1.0 mg* can lead to hallucinations and so-called “paradoxical reactions” such as restlessness, irritability, aggressive behaviour, nightmares,

hallucinations, delusions, inappropriate behaviour and other behavioural disorders. In such cases, the doctor should stop treatment with this product.

Dependence
Using alprazolam can lead to physical and mental addiction. It may also become less effective after several weeks of treatment. When stopping treatment, withdrawal symptoms may occur, such as headache, muscle pain, severe anxiety and tension, sleep disorders, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: depersonalisation and derealisation (feeling 'divorced' from ones own identity and sense of reality), heightened sense of hearing, pins and needles in the limbs, sensitivity to light, sound and touch, hallucinations and epileptic seizures. Original symptoms may also return, but in a more intense form.
Cases of misuse have been reported.

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 1.0 mg*

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 outer carton. The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in the original package 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 *Alprazolam 1.0 mg* contains
The active substance is alprazolam.
One tablet contains 1 mg of alprazolam.

The other ingredients are:
Docusate sodium, sodium benzoate (E210), pregelatinised starch, microcrystalline cellulose, lactose monohydrate, magnesium stearate, silica colloidal anhydrous, indigotin blue (E132)

What *Alprazolam 1.0 mg* looks like and contents of the pack
Oblong, light-blue tablets with a score line

Alprazolam 1.0 mg is available in packs of 10, 20, 30, 40, 50, 60 and 100 tablets.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Registratiehouder
ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm
Duitsland

Fabrikant
Merckle GmbH

Ludwig-Merckle-Str. 3
D-89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 26306 - Alprazolam-ratiopharm 1 mg, tabletten

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Oostenrijk:	Alprazolam "ratiopharm" 1 mg - Tabletten
Duitsland:	Alprazolam-ratiopharm 1,0 mg Tabletten
Nederland:	Alprazolam-ratiopharm 1 mg, tabletten
Portugal:	Alprazolam ratiopharm 1 mg Comprimidos

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2018.