PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Alpralid Tablets 0.25, 0.5, 1 mg

Alpralid 0.25: Each tablet contains:
Alprazolam 0.25 mg
Alpralid 0.5: Each tablet contains:
Alprazolam 0.50 mg
Alpralid 1: Each tablet contains:
Alprazolam 1.00 mg

Inactive ingredients and allergens in the preparation - see section 6.

Read this leaflet carefully in its entirety before taking the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others; it may harm them, even if it seems to you that their medical condition is similar.

Do not use this medicine in children under 6 years of age.

This medicine is not usually intended for children and adolescents under 18 years of age. The safety and effectiveness of the medicine for this age group have not been proven.

This medicine belongs to the benzodiazepines group, which has special characteristics that require extra caution with its use.

- It is especially important to be under close medical surveillance when taking this medicine.
- When taking this medicine, be sure to refer to the doctor after 2-4 weeks, as the treatment is only intended for short durations (up to 12 weeks, including the time during which the dosage is reduced until discontinuing use of the medicine).
- Prolonged use of the medicine may reduce the effect of the medicine.
- Such use may cause severe dependence, which will make it difficult for the patient to discontinue taking the medicine.
- Uncontrolled discontinuation of treatment is accompanied by withdrawal symptoms, such as: tension, nervousness, confusion, tremor, insomnia, abdominal pain, vomiting, nausea, sweating, spasms.
- Occasionally, prolonged use of the medicine can cause changes in behavior patterns and troublesome thoughts.
- Especially in the elderly, care should be taken while walking, since the medicine impairs alertness and, occasionally, coordination of body movements, and there is therefore concern of slipping or falling.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to relieve anxiety and tension.

Therapeutic group: The active ingredient belongs to the benzodiazepines group.

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:

- you are pregnant, planning to become pregnant, or are breastfeeding.
- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine or to other medicines from the benzodiazepines group.
- you suffer from severe muscle weakness (myasthenia gravis), breathing difficulties, sleep apnea, severe liver disease.
- you suffer from closed-angle glaucoma.
- Do not use the medicine in children under 6 years of age.
- you are taking medicines to treat fungal infections, such as: ketoconazole and itraconazole.

Special warnings regarding use of the medicine:

- Do not use the medicine without consulting the doctor before commencing treatment, if you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the eyes (e.g. severe closed-angle glaucoma, open-angle glaucoma being treated with medications), the liver, the kidney/urinary tract, if you suffer from epilepsy or spasms.
- Do not use the medicine without consulting the doctor before commencing treatment, if you are suffering, or have suffered in the past, from addiction to drugs, medicines or alcohol, from a feeling of depression accompanied by suicidal thoughts, if you have suffered from a mental disease that required hospital treatment.
- Prolonged use may cause dependence!
- Use of this medicine may cause blurring of vision.
- If you are sensitive to any food or medicine, especially benzodiazepines, inform the doctor before taking the medicine.
- If you are scheduled to undergo surgery under general anesthesia, you must notify the doctor that you are taking alprazolam.

❗ If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- medicines which affect the central nervous system (for example: sedatives, hypnotics, medicines for Parkinson's, epilepsy).
- surgical anesthetics.
- strong analgesics (propoxyphene, morphine, codeine).
- anti-allergics (antihistamines).
- medicines for treatment of anxiety and depression (for example, nefazodone, sertraline, fluvoxamine),
- medicines for treatment of cough and cold.
- oral contraceptives.
- antacids.
- antibiotics (for example, erythromycin, clarithromycin).
- cimetidine (for ulcer).
- rifampicin, isoniazid (for tuberculosis).
- zidovudine, ritonavir (for AIDS).
- antipsychotics, such as medicines for treatment of schizophrenia (from the phenothiazines group).
- antifungals (ketoconazole, itraconazole).
- alcohol.
- grapefruit juice – may raise concentrations of Apralid in the blood.
- medicines to lower blood pressure and for treatment of angina pectoris (diltiazem).
- Digoxin (to treat heart conditions), since digoxin level in the blood may rise when taken in combination with Apralid.

❗ Use of the medicine and alcohol consumption

During the course of treatment with the medicine, do not consume wines or alcoholic beverages. Alcohol increases the effect of the medicine.

❗ Pregnancy and breastfeeding

Consult the doctor if you are pregnant or planning to become pregnant, since this preparation may harm the unborn baby.
Do not use the medicine if you are breastfeeding.

❗ Driving and use of machines

Use of this medicine may impair alertness, and therefore caution should be exercised when driving, operating dangerous machinery or in any activity that requires alertness.

❗ Smoking

If you smoke, inform your doctor before taking this medicine.

❗ Important information about some of the ingredients in this medicine

This preparation contains lactose which may cause allergic reaction in people sensitive to lactose.
Alpralid 0.25: Each tablet contains: 97.4 mg lactose.
Alpralid 0.5: Each tablet contains: 97 mg lactose.
Alpralid 1: Each tablet contains: 96.6 mg lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is usually: initial dosage is one 0.25 mg tablet or one 0.5 mg tablet, three times a day. The daily dosage can be increased up to 1 mg, three times a day.

If a larger dosage is required, the dose given before bedtime can be increased so as to remain alert during the day.

If you are elderly or suffer from liver or kidney problems, it is possible to commence with a dosage of 0.25 mg two to three times daily. The dosage may be increased as required if no side effects appear.

Do not exceed the recommended dose.

Do not chew! Swallow the tablet with a little water.

If necessary, the tablet can be halved or crushed.

Tests and follow up: During prolonged treatment with this medicine (if approved by the doctor), blood, urine and liver function tests should be performed.

Alprazolam may cause dependence when taken regularly at high dosages for a prolonged period.

There may also be a reduction in its effect over time. For these reasons, the effectiveness of treatment with the medicine is evaluated at regular intervals. Stay in regular contact with your doctor, who will determine, in accordance with the periodic meetings between you, the individualized dosage appropriate for you.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Possible side effects from an overdose include: sleepiness, confusion, a feeling of coldness, slurred speech, a drop in blood pressure and breathing difficulties.

If you forgot to take the medicine at the required time, take a dose as soon as you remember, unless it is time for the next dose. Do not take a double dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not abruptly discontinue treatment, rather, do so gradually, as per the doctor's instructions.

There have been isolated cases of withdrawal effects, primarily after taking high dosages or after prolonged treatment (as authorized by the doctor). Therefore, if you experience withdrawal symptoms such as anxiety, restlessness, sleep difficulties or any other effect, consult the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Alpralid may cause side effects in some patients. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor immediately if the following effects occur:

- Treatment with Alpralid can infrequently cause serious behavioral or psychiatric effects – for example, agitation, restlessness, aggressiveness, nervousness, violent anger, false beliefs, nightmares and hallucinations, forgetfulness, confusion, depression or other inappropriate behavior.
- Sudden wheeziness, difficulty in swallowing or breathing, swollen eyelids, face or lips, rash or itching (especially affecting the whole body), hives, increased and irregular heart rate, urinary incontinence and retention.

Refer to a doctor as soon as possible if the following effects occur:

Hallucinations, skin rash or itching, behavioral changes, fever, sore throat, mouth or throat ulcers, unusual bleeding, yellowing of the skin and eyes, muscle weakness, restlessness, irritability, aggressive behavior, sleep disturbances, spasms, mood changes, impaired body movement coordination, tremor, tiredness, marked weakness, memory loss (amnesia), or yellowing of the skin or the whites of the eyes (jaundice).

Addiction and withdrawal symptoms:

Withdrawal symptoms appear if you discontinue treatment with Alpralid suddenly, are taking high dosages, are taking the medicine for prolonged periods, or if you suffer or have suffered from addiction to alcohol or medicines. This may lead to effects such as headache, muscle pain, extreme anxiety, tension, restlessness, confusion, mood changes, sleep difficulties and nervousness.

In severe cases of withdrawal, the following effects may occur: nausea, vomiting, sweating, abdominal pain, muscle cramps, a feeling of unreality or detachment, sensitivity to sound, touch or light, numbness and a tingling sensation in the soles of the feet and hands, hallucinations, tremor or epileptic fits.

Additional side effects that occur very frequently:

Drowsiness, sleepiness, instability and dizziness.

Additional side effects that occur frequently:

Loss of appetite, increased thirst, disorientation, depression, altered sex drive (in men and women), difficulty controlling movements (ataxia), coordination problems, balance problems, memory problems, speech disturbances, concentration disturbances, inability to stay awake, apathy, headache, double or blurred vision, constipation, diarrhea, dry mouth, nausea, vomiting, excessive production of saliva.

Palpitations, vertigo, gastrointestinal discomfort, abdominal pain, malaise, upper respiratory tract infection, chest pain, back pain, muscle contractions and cramps, anxiety, derealization, difficulty passing urine, nasal congestion, hyperventilation, shortness of breath, increased sweating, involuntary movements, increased appetite, anorexia, joint pains, limb pains, hot flashes, allergic rhinitis.

Additional side effects that occur infrequently:

Agitation, motor problems, epilepsy, random ovulation and menstrual irregularities in women, muscle cramps, weight changes, elated or excited mood, leading to unusual behaviour, hallucinations, feeling hostile and angry, abnormal thoughts, abdominal pains or cramps, upset stomach, hyperactivity, liver function problems, hepatitis, jaundice, allergic reactions and anaphylactic shock, increased intraocular pressure, impaired muscle tone (dystonia), swelling of breasts in men.

Tinnitus, ear pains, dilated pupils, falls, pyrexia, feeling hot and cold, edema, sluggishness, exhaustion, feeling drunk, chest tightness, sensation of increased energy, feeling of relaxation, hangover, lack of control in the legs, muscle stiffness, clumsiness, loss of consciousness, depressed level of consciousness, sleep apnea syndrome, sleep talking, stupor, abnormal dreams, apathy, euphoria, slowness of thought, excessive talkativeness, homicidal thoughts, suicidal thoughts, uncontrolled impulses, psycho motor retardation, urinary frequency, choking sensation, nosebleed, clammy skin, urticaria, high levels of prolactin (hormone) in the blood, decrease in blood pressure.

Additional side effects that occur at an unknown frequency:

- Imbalance in part of the nervous system. Symptoms can include: rapid heartbeat and uncontrolled blood pressure (dizziness, fainting).
- Serious allergic reaction causing swelling in the face or throat.
- Swelling of ankles, soles of the feet or fingers.

If one of these side effects worsens, or should you suffer from any other side effects not mentioned in this insert, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
Alpralid 0.25: Lactose, Microcrystalline Cellulose (PH-101), Pregelatinized Oxidized Potato Starch, Microcrystalline Cellulose (PH-102), Magnesium stearate, Docusate Sodium, Colloidal Silicone Dioxide, Sodium Benzoate.
Alpralid 0.5: Lactose, Microcrystalline Cellulose (PH-101), Pregelatinized Oxidized Potato Starch, Microcrystalline Cellulose (PH-102), Magnesium stearate, Docusate Sodium, Colloidal Silicone Dioxide, Sodium Benzoate, Iron Yellow Oxide.
Alpralid 1: Lactose, Microcrystalline Cellulose (PH-101), Pregelatinized Oxidized Potato Starch, Microcrystalline Cellulose (PH-102), Magnesium stearate, Docusate Sodium, Colloidal Silicone Dioxide, Sodium Benzoate, Indigo Carmine (E132).

What the medicine looks like and the contents of the package:
Alpralid 0.25: An elongated, white-yellowish tablet, with a score line and "CTS" imprinted on it.
Alpralid 0.5: An elongated, light yellow tablet, with a score line and "CTS" imprinted on it.
Alpralid 1: An elongated, light blue tablet, with a score line and "CTS" imprinted on it.
Packs of 10, 20, 30, 60, 100, 1000 tablets are available.
Not all pack sizes may be marketed.

License holder, manufacturer and address: CTS Chemical Industries Ltd., 3 Hakidma Street, Kiryat Malachi
This leaflet was checked and approved by the Ministry of Health in 08.2014.
Registration number of the medicines in the National Drug Registry of the Ministry of Health: Alpralid 0.25: 1030128371
Alpralid 0.5: 1030228372
Alpralid 1: 1030328373