

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

The medicine is dispensed with a doctor's prescription only

Tranxal 5 mg Capsules Tranxal 15 mg Capsules

The active ingredient and its quantity:

Tranxal 5 mg: Each capsule contains Potassium Clorazepate 5 mg

Tranxal 15 mg: Each capsule contains Potassium Clorazepate 15 mg

Inactive ingredients and allergens in the preparation – see section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

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

Introduction

The introduction is intended for users taking this medicine for the indication of anxiety and tension only.

This medicine belongs to the benzodiazepine group, which has special characteristics that require extra care during use.

- It is highly important to be under close medical supervision when taking this medicine.
- When taking this medicine, be sure to refer to your doctor after 2-4 weeks, as the treatment is intended for short time periods only.
- Prolonged use of this medicine may cause the effect of the medicine to decrease.
- Prolonged use may cause severe dependency, which will make it difficult for the patient to stop taking the medicine.
- Uncontrolled discontinuation of the treatment may be accompanied by withdrawal effects, such as: stress, nervousness, confusion, tremor, insomnia, abdominal pain, vomiting, nausea, sweating, spasms, cramps and muscle pain.
- Prolonged use of this medicine may sometimes cause changes in behavioral patterns and obsessive thoughts.

- Care should be taken when walking, especially in the elderly, since the medicine impairs alertness and sometimes the coordination of body movements, which may lead to tripping or falling down.

Taking this medicine together with opioid medicines, with other medicines that depress the central nervous system (including drugs) or with alcohol, may cause a sensation of deep drowsiness, breathing difficulties (respiratory depression), coma and death.

1. What is the medicine intended for?

Treatment and relief of tension and anxiety. Symptomatic relief of alcohol withdrawal symptoms.

Adjunctive prophylactic treatment for a particular type of epilepsy.

Therapeutic class: The active ingredient belongs to the benzodiazepine group.

2. Before using the medicine

❗ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6)
- You are breastfeeding
- You are suffering from narrow-angle glaucoma

❗ Special warnings regarding the use of the medicine

• Before treatment with Tranxal, tell the doctor if:

- You have impaired liver or kidney function
- You have or have had depression, mood problems or suicidal thoughts or behaviors
- You have a history of abnormal behavior or thinking (psychotic reactions)
- Prolonged use may lead to dependence!
- In patients who have been under prolonged treatment with this preparation, treatment should not be discontinued abruptly, but rather tapered gradually in order to prevent withdrawal symptoms.
- Some people who were treated with antiepileptic medicines, such as Tranxal, had thoughts of harming themselves or suicidal thoughts. If you had such thoughts at any

time during treatment with this medicine, contact your doctor immediately!

❗ Children and adolescents

This medicine is not intended as an adjunctive prophylactic treatment for a particular type of epilepsy in children under 9 years of age.

This medicine is not intended for treatment and relief of tension and anxiety, and for symptomatic relief of alcohol withdrawal symptoms, in children under 6 years of age.

❗ Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or the pharmacist.

❗ Use of the medicine and food

The medicine may be taken with or without food, since food has absolutely no effect on the medicine.

❗ Use of the medicine and alcohol consumption

Do not drink alcoholic beverages during treatment with Tranxal. Alcohol may worsen sleepiness and dizziness.

❗ Pregnancy, breastfeeding and fertility

Medicines such as Tranxal may cause congenital defects. Consult the doctor if you are pregnant or planning to become pregnant. Inform the doctor immediately if you become pregnant during treatment with Tranxal. The doctor will decide whether you should continue taking the medicine during pregnancy.

The active ingredient in the medicine is excreted into breastmilk. Do not breastfeed during treatment with the medicine.

❗ Driving and operating machinery

Use of this medicine may impair alertness and therefore caution should be exercised when driving a car, operating dangerous machinery and during any activity which requires alertness.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is:

Dosage for adults and children over 12 years of age:

5-90 mg per day (up to 15 mg may be taken in a single dose. A higher dosage should be divided into two or three doses). For divided doses (of less than 15 mg per dose) use 5 mg capsules only.

Dosage for children:

From 6-12 years of age:

5-15 mg per day in divided doses.

Do not exceed the recommended dose.

The duration of treatment should be as short as possible. Treatment should be discontinued gradually – see the introduction to this leaflet. Do not chew! The tablet should be swallowed with some water.

No information is available regarding opening the capsule and scattering its contents.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the dose as soon as you remember and consult a doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment without consulting your doctor, and even then, discontinuation should be done gradually to avoid withdrawal symptoms.

If you stop taking the medicine you may experience withdrawal symptoms – see the introduction to this leaflet.

Before discontinuing the treatment you should discuss the consequences with your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, the use of Tranxal may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Refer to a doctor immediately if one of the following symptoms occurs:

- Suicidal thoughts

- Suicide attempts
- New or more severe depression
- New or more severe anxiety
- Feeling nervous or restless
- Anxiety attacks
- Sleep disturbances
- New or more severe irritability
- Aggressiveness, anger or violence
- Yielding to dangerous impulses
- An extreme increase in activity or speech (mania)
- A change in normal behavior patterns

Common side effects - side effects that occur in 1-10 out of 100 users:

- Drowsiness
- Dizziness
- Digestive system problems
- Blurry vision
- Dry mouth

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

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

Storage conditions: Store in the original package in order to protect from light and moisture, in a dry place, at a temperature below 25°C. Can be used for up to two months from opening.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Tranxal 5 mg:
Purified Talc, Gelatin, Potassium Carbonate, Titanium Oxide, Titanium Dioxide, Erythrosin, Quinoline Yellow.

Tranxal 15 mg:
Purified Talc, Gelatin, Potassium Carbonate, Titanium Oxide, Titanium Dioxide, Erythrosin, Indigo Carmine.

What does the medicine look like and what are the contents of the package:

Tranxal 5 mg: An amber colored glass jar, containing 30 pink colored capsules with a purple cap and an odorless yellowish-white powder within the capsules.

Tranxal 15 mg: An amber colored glass jar, containing 30 pink colored capsules with a yellow cap and an odorless white powder within the capsules.

Manufacturer/marketing authorization holder and address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi 83057, Israel. This leaflet was revised in May 2021 in accordance with the Ministry of Health guidelines.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Tranxal 5 mg: 298325179
Tranxal 15 mg: 298425178