

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

The medicine is dispensed with a doctor's prescription only

Clonex® 0.5 mg

Tablets

Composition

Each tablet contains:

Clonazepam 0.5 mg

For information regarding inactive ingredients and allergens, see section 2 under "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional 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 to the consumer leaflet for benzodiazepines

This medicine belongs to the benzodiazepines 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.

The following paragraph refers only to a short-term treatment with the medicine:

- When taking this medicine, be sure to refer to the doctor after 2-4 weeks, since the treatment is only intended for short time periods.
- 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, agitation, 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.

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?

- For treatment of certain kinds of seizures (epilepsy).
- For treatment of anxiety attacks.

Therapeutic class: benzodiazepines.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to other preparations of the benzodiazepines group, or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You have a severe hepatic disease.
- You have an eye disease called acute narrow-angle glaucoma.

Ask the doctor if you are uncertain whether you have any of the abovementioned conditions.

Special warnings regarding the use of the medicine

Before treatment with Clonex, inform the doctor about your medical condition, including if:

- You have liver or kidney problems.
- You have lung problems (respiratory diseases).
- You have or have experienced in the past depression, mood problems, or suicidal thoughts or behavior.
- You have any other medical issue.
- You are or have been addicted to alcohol, medicines or drugs.
- You are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed. See more information under the section "Pregnancy and breastfeeding".

Taking this medicine together with opioid medicines, or 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.

Seek immediate medical attention in the following cases:

- Slow, shallow breathing
- Cessation of breathing (which may lead to cardiac arrest)
- Excessive sleepiness (sedation)

Clonex may lead to abuse, misuse and dependence. There is a risk of abuse, misuse and dependence when taking medicines of the benzodiazepines group, including Clonex, which may lead to overdosing and severe side effects that include coma and death.

Severe side effects, including coma and death, have occurred in people who abused or misused this medicine. These severe side effects may also include acute confusion, paranoia, suicidal thoughts or actions, convulsions and breathing difficulties. **If any of these side effects occurs, refer immediately to the doctor or to the emergency room in the nearest hospital.**

You may develop an addiction even if you take the medicine as prescribed by the doctor.

Take the medicine exactly as prescribed by the doctor.

Do not pass the medicine to others.

The medicine should be kept in a safe place and away from children.

Clonex may cause physical dependence and withdrawal symptoms.

Do not stop taking Clonex suddenly. Sudden discontinuation of the medicine may cause severe and life-threatening side effects, including involuntary reactions, movements or facial expressions, convulsions, severe and sudden neurological or mental changes, depression, hearing or seeing non-existing things, an extreme increase in speaking or activity, losing touch with reality, suicidal thoughts or actions. **If any of these symptoms occur, refer immediately to the doctor or to the emergency room in the nearest hospital.**

Some people who stopped taking this medicine suddenly had symptoms that lasted from several weeks to more than 12 months, including anxiety, memory, learning or concentration difficulties, depression, sleeping difficulties, false sensation of insects crawling under the skin, weakness, tremor, muscle spasms, sensation of burning or tingling in the hands, arms, legs or feet and ringing in the ears.

Physical dependence is not the same thing as addiction to the medicine. The doctor will be able to tell you about the differences between physical dependence on the medicine and addiction.

Do not take the medicine at a higher dose or for longer than what the doctor prescribed to you.

Clonex may cause drowsiness or dizziness and slow down thinking and motor skills. Improvement is possible over time.

Do not drive and operate machinery or perform dangerous activities until you know how the medicine affects you. See also the section "Driving and operating machinery".

Coordination problems are also possible, especially when walking or lifting objects.

Do not drink alcohol or take other medicines that may cause drowsiness or dizziness while taking Clonex until you consult with the doctor. When taken with alcohol or with medicines that cause drowsiness or dizziness, Clonex may increase the drowsiness or dizziness.

Similar to other anticonvulsants, Clonex may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. For a list of possible symptoms, see section 4 under the title "Severe side effects".

How can I be aware of early symptoms of suicidal thoughts or actions?

- You should notice any change, especially a sudden change in mood, behavior, thoughts or emotions.
- All appointments to see the treating doctor should be kept as planned. Consult the treating doctor between appointments as necessary, especially if you are worried about the symptoms.

Suicidal thoughts or actions can be caused by non-pharmacological reasons. If you have suicidal thoughts or actions, the treating doctor may look at other reasons for them.

Do not stop taking Clonex without consulting with the doctor. Suddenly stopping to take Clonex may cause severe side effects, including a prolonged epileptic seizure (status epilepticus).

Clonex may lead to dependence and abuse. The medicine should be kept in a safe place to prevent improper use and abuse.

Children and adolescents

No information is available regarding safety and efficacy of the medicine in treating panic states in children under 18 years of age.

Drug interactions

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

- Taking this medicine with certain other medicines may cause side effects or affect the way Clonex or the other medicines work. Do not start or stop taking other medicines without consulting with the treating doctor.
- Do not take this medicine together with opioid medicines, with other medicines that depress the central nervous system (including drugs) or with alcohol – see the boxed warning in the beginning of this leaflet.
- Do not take together with alcohol or with other medicines that can cause drowsiness or dizziness without consulting with the treating doctor. When taken with alcohol or with medicines that cause drowsiness or dizziness, Clonex may aggravate the drowsiness or dizziness.

Use of the medicine and alcohol consumption

Do not drink alcohol while taking Clonex without consulting with the treating doctor. Alcohol consumption while taking Clonex may aggravate the drowsiness or dizziness.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, planning to become pregnant or think you might be pregnant, consult with a doctor before taking this medicine. It is unknown whether the medicine might harm the fetus.

If you become pregnant while taking Clonex, inform the treating doctor immediately. You and the treating doctor need to decide whether you should continue to take Clonex during the pregnancy.

Animal studies have shown harmful effects of medicines from the benzodiazepines group (including medicines containing clonazepam, which is the active ingredient in Clonex) on the developing fetus.

Children born to mothers who received medicines from the benzodiazepines group (including medicines containing clonazepam) during the late stages of pregnancy may be at risk for breathing problems, feeding problems, hypothermia and withdrawal symptoms.

Breastfeeding

If you are breastfeeding or are planning to breastfeed, consult with the doctor before using the medicine. The medicine can pass into breastmilk. If you are taking Clonex, you and the treating doctor should decide what would be the right way for you to feed your baby.

Driving and operating machinery

The medicine may cause drowsiness or dizziness and slow down thinking and motor skills. Do not drive, operate heavy machinery or perform other dangerous activities until you know how the medicine affects you.

Important information about some of the ingredients of the medicine

Clonex contains lactose. If your doctor told you that you have intolerance to certain types of sugars, consult a doctor before taking this medicine. Clonex 0.5 mg contains Sunset Yellow FCF – E110, which may cause allergic reactions.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor.

If you are taking this medicine to prevent seizures, your doctor may adjust the dosage until you find the suitable dose for you for controlling the seizures.

Do not exceed the recommended dose.

- Swallow the medicine with water.
- No information is available regarding chewing or crushing.
- Clonex 0.5 mg – the tablet can be halved.
- Clonex 2 mg – the tablet may be divided into 4 parts.

If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take your dose as soon as you remember, but under no circumstances should you take two doses at the same time.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

- Do not stop taking the medicine without consulting a doctor.
- Suddenly stopping to take the medicine may cause severe and life-threatening side effects.
- Consult with the doctor regarding gradually stopping the medicine, to avoid withdrawal symptoms.

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, using Clonex 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.

Severe side effects

Refer to a doctor immediately if one or more of the following symptoms occur, especially if these are new symptoms, if the symptoms worsen or if they concern you:

- Suicidal thoughts or actions
- Thoughts of suicide or death
- Suicide attempt
- Appearance of depression or worsening of existing depression
- Appearance of anxiety or worsening of existing anxiety
- Emotional turmoil or restlessness
- Anxiety attacks
- Sleeping problems (insomnia)
- Appearance of irritability or worsening of irritability
- Aggressive, angry or violent behavior
- Dangerous impulsive behavior
- An extreme increase in activity and speech (mania)
- Other abnormal changes in behavior or mood
- Clonex may cause worsening of seizures or increased frequency of seizures. Contact the doctor immediately if your seizures worsen due to taking Clonex.

The most frequent side effects:

- Drowsiness
- Walking and coordination problems
- dizziness
- Depression
- tiredness
- Memory impairment

Additional side effects:

- Palpitations.
- Hair loss, excessive hairiness in women, rash, edema in the ankle and the face.
- Anorexia, white-coated tongue, constipation, diarrhea, dry mouth, involuntary excretion of stool, gastritis, increased appetite, nausea, sensitive gums.
- Pain while urinating, incontinence, bedwetting, urinary retention.
- Anemia, leukopenia, thrombocytopenia, eosinophilia.
- Enlarged liver, transient elevation in serum levels of transaminases and alkaline phosphatase.
- Muscle weakness, muscle pain.
- Dehydration, general deterioration, fever, enlargement of the lymph nodes, weight loss or weight gain.
- Abnormal eye movements, loss of voice, dance-like movements, coma, double vision, mispronunciation of speech, rigidity of movement, lack of expression, headache, mild paralysis affecting half of the body, muscle weakness, darting eyes, respiratory depression, slurred speech, tremor, vertigo.
- Confusion, amnesia, hysteria, increased libido, psychosis (behavioral effects occur more in patients with a history of psychiatric disorders).
- Agitation, aggression, hostility, nightmares, abnormal dreams and hallucinations.
- Chest congestion, rhinitis, shortness of breath, excessive secretions in the upper respiratory tract.

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.

Reporting side effects

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. date) appearing on the package. The expiry date refers to the last day of that month.
- **Keep in a dry place below 25°C.**

6. Additional information

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

Clonex 0.5 mg:

Starch, Lactose Monohydrate, Talc, Magnesium Stearate, Color FD&C Yellow No. 6 (E 110), Color D&C Yellow No. 10.

Clonex 2 mg:

Lactose Monohydrate, Starch, Talc, Magnesium Stearate.

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

Clonex 0.5 mg:

A light orange, round, flat beveled tablet. Bisected on one side, plain on the other.

Clonex 2 mg:

A white, round, flat beveled tablet. Quadrisectioned on one side, debossed with "TEVA" on the other.

Each package contains 30 or 100 tablets packed in a blister. Not all package sizes may be marketed.

Name and address of the manufacturer and marketing authorization holder:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in April 2022 in accordance with the Ministry of Health guidelines.

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

Clonex 0.5 mg: 027.85.22043

Clonex 2 mg: 035.99.22044