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

The medicine is dispensed with a doctor's prescription only

Triclonam Elixir

The active ingredient and its concentration:
Triclofos Sodium 500 mg/5 ml
Inactive ingredients and allergens in the preparation - see section 6 "Additional information" and the "Important information about some ingredients of the medicine" section.
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 you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

This preparation is intended for the treatment of insomnia, for sedation in states of tension and anxiety and prior to various medical examinations.
Therapeutic class: Hypnotic medicines to induce sleep.

2. Before using the medicine

☒ Do not use this medicine if:

- You are sensitive to the active ingredient or to any of the additional components the medicine contains.
- You have acute intermittent porphyria (Triclonam aggravates symptoms of porphyria).

Special warnings regarding the use of the medicine

❗ Before treatment with Triclonam, inform the doctor if:

- You have liver or kidney impairment (may cause the medicine to accumulate in the blood, which may result in side effects).
- You are suffering from weakness (the preparation may cause respiratory depression).
- You are suffering from impaired respiratory function (the preparation may cause respiratory depression).
- You are suffering from impaired function of the heart or from arrhythmias (the preparation may aggravate the symptoms due to its effect on heart function).
- The treatment is intended for the elderly (see "The elderly" section).
- The treatment is intended for children (see "Children" section).
- Prolonged use may lead to dependence. Carefully evaluate the necessity of the treatment and avoid prolonged and long-term use (see "Side effects" section).
- The preparation may cause respiratory depression. See "Tests and follow-up" section.

❗ Tests and follow-up
During the treatment period and particularly in children, you may be required by the doctor to monitor your respiration rate, heart rate, oxygen saturation level in the blood etc.

❗ The elderly
The preparation may cause respiratory depression. Use with care; for example, start treatment with the lowest dose.

❗ Children
Use with care; for example, start treatment with the lowest dose. Children treated with the medicine should be monitored for fear of side effects (see "Side effects in children" subsection).

❗ Drug-drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist, especially if you are taking:

- Chloral hydrate (for fear of an overdose, as both preparations break down to the same metabolite).
- Medicines affecting the central nervous system (phenothiazine derivatives, barbituric acid derivatives). Triclonam may enhance depression of the nervous system caused by these medicines.
- Monoamine oxidase inhibitors. Triclonam may enhance depression of the nervous system caused by these medicines.
- Alcohol. Triclonam may enhance the effects of alcohol.
- Anticoagulant agents of the coumarin group. Triclonam may enhance the effects of these medicines.

❗ Use of the medicine and alcohol consumption
Do not drink wine or alcoholic beverages during treatment with this medicine.

❗ Pregnancy, breastfeeding and fertility
Use of the preparation is not recommended for women who are pregnant or might be pregnant (safety of use during pregnancy is unknown).

❗ 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 in any activity which requires alertness. Children should be cautioned against riding a bicycle or playing near a road etc.

❗ Important information about some ingredients of the medicine
The preparation contains about 2.7 grams of sucrose in every 5 ml. If you have been told by the doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine. This should be taken into consideration in diabetic patients. May harm your teeth.
The preparation contains ethanol in concentration of 4.8%. Each 5 ml contain about 0.3 ml ethanol. The ethanol content in the package is 6 ml. The preparation contains 240 mg of ethanol 95% (alcohol) in every 5 ml, which is equivalent to 6 ml of beer and 2.5 ml of wine. This is harmful for people with alcoholism. This should be taken into consideration in pregnant and breastfeeding women, children and patients at risk, such as patients with liver disease or epilepsy.
The preparation contains about 50 mg of sodium in every 5 ml, which is equivalent to about 2.5% of the maximum recommended daily intake in adults.
The preparation contains Sunset Yellow. This may cause allergic reactions.

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:
Sleep induction:
Adults and children over the age of 12 years: 10 ml. In certain cases a higher dosage may be required - up to 20 ml per day.
Children 6-12 years old: 5-10 ml per day.
Children 1-5 years old: 2.5-5 ml per day.
Infants up to 1 year old: 1-2.5 ml per day.
For sedation:
Adults and children over the age of 12 years: 5 ml twice per day.
Children 6-12 years old: 5 ml per day.
Children 1-5 years old: 2.5 ml per day.
Infants up to 1 year old: 1 ml per day.
Do not exceed the recommended dose.
With liquid medicines, use the measuring spoon, syringe or dropper intended for measuring the proper amount of medicine. If a spoon or any other measuring device was not provided with the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size and it is likely you will not receive the correct amount of medicine.
Child-proof safety caps have significantly reduced the number of poisoning incidents caused by medicines each year. However, if you find it difficult to open the package, you can refer to a pharmacist to ask to have the safety mechanism removed and to turn the cap into a regular, easy-to-open cap.
If you accidentally take a higher dosage, you may suffer from respiratory arrest, slowing of heart rate and a drop in blood pressure. **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.
Follow the treatment as recommended by the doctor.
If you stop taking the medicine or reduce your dosage suddenly after prolonged use, you may experience withdrawal symptoms, such as seizures, hallucinations, tremor, anxiety etc. When discontinuing treatment, the dosage should be reduced gradually. 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, using Triclonam 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.
Stop using this medicine and refer to a doctor immediately if:

- You experience anaphylactic shock: itch, edema, respiratory distress, a drop in blood pressure, cyanosis or a hypersensitivity reaction: rash, erythema, blisters, itch, fever.
- You experience respiratory arrest or respiratory depression which may lead to cardiac arrest.
- Changes in white blood cells count (eosinophilia, leukopenia) have occurred.

Severe side effects (with unknown frequency):

- Dependence.

Additional side effects (with unknown frequency):

- Slowing of heart rate.
- Liver enzymes elevation.
- Nausea, vomiting, flatulence, abdominal pain.
- Headache, dizziness, fainting sensation, ataxia, neurological disturbance, depression, speech disturbances, late wake up.
- Edema, reduced urine output, appearance of ketones in the urine.

Side effects in children:

- Respiratory arrest, respiratory depression which may lead to cardiac arrest.
- Seizures (clonic or partial).

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
Store at a temperature lower than 25°C.
The preparation may be used for up to 110 days following first opening.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sucrose, Ethanol 95%, Sodium Hydroxide, Orange Oil 926, Lemon Oil NO, Vanillaroma 200, Saccharin Sodium, Nipastat, Disodium Edetate, Hydrochloride acid 37%, Sodium Carbonate anhydrous, Sunset Yellow, Purified Water
What does the medicine look like and what are the contents of the package: an amber-colored glass bottle, containing 100 ml of a slightly viscous orange liquid.
Manufacturer and license holder: CTS Chemical Industries Ltd., Kiryat Malachi, Israel, p.o. box 385
The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health on April 2010, and has been updated in accordance with the Ministry of Health instructions on June 2020.
Registration number of the medicine in the national drug registry of the Ministry of Health: 047-92-23600-00.

LFL 222 06/20