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

This medicine is dispensed with a doctor's prescription only

HYPNODORM®
Tablets

COMPOSITION

Each tablet contains:
Flunitrazepam 2 mg.

For a list of the inactive ingredients, see section 6 in this leaflet.

Read this leaflet carefully in its entirety before using this 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.

Introduction

This medicine belongs to the benzodiazepine group, which has special characteristics that demand great caution when used. Medicines from this group impair the quality of sleep, suppress deep refreshing sleep and therefore cause ineffective and superficial sleep.

- Close medical monitoring is very important when taking this medicine. Therefore, when you are taking this medicine, be sure to refer to a doctor after 7-10 days of treatment, as the treatment is intended for a short period of time only.
- Prolonged use of this medicine may lead to a diminution in the efficacy of the medication. Such use may also cause severe dependence, in which the patient will find it difficult to discontinue the intake of this medicine. Sometimes, prolonged use of this medicine may cause changes in behavior patterns as well as bring on troublesome thoughts.
- Uncontrolled discontinuation of treatment may be accompanied by withdrawal symptoms such as: tension, nervousness, confusion, trembling, recurrence of insomnia, abdominal pain, nausea, vomiting, sweating, seizures.
- Elderly: Be careful to lean on something when standing up from a lying or sitting position, as this medicine impairs alertness and sometimes body movement coordination; therefore falling is a concern.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is intended to treat insomnia.

Therapeutic group:
Benzodiazepine group.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- During the first trimester of pregnancy or while breastfeeding
- If you have a known sensitivity to flunitrazepam or to any of the other medicine's ingredients or to other medicines from the benzodiazepine group
- In patients suffering from psychiatric problems, from respiratory depression, from severe pulmonary insufficiency, from acute angle-closure glaucoma, from myasthenia gravis (severe muscle weakness), from severe liver failure or from sleep apnea syndrome (paused breathing during sleep)
- Do not use in children

Special warnings regarding use of the medicine:

- The medicine contains lactose and may cause an allergic reaction in people sensitive to lactose.
- If you are sensitive to any type of food or medicine, inform the doctor before taking the medicine.

- Use of this medicine may impair alertness, cause drowsiness and/or dizziness and therefore caution is required when driving a car, operating dangerous machinery and when engaging any activity which requires alertness.

- Prolonged use may cause dependence! (See introduction above).
- Inform the doctor if you are about to undergo laboratory or diagnostic tests (e.g., EEG), as this medicine may affect the test results.
- Inform every doctor, including the dentist, that you are using this medicine, especially before undergoing a surgical procedure.

Before treatment with Hypnodorm® tell the doctor:

- If you are suffering, or have suffered in the past from impaired function of:
  - the respiratory system (e.g., asthma)
  - the liver
  - the kidney
  - low blood pressure
  - blood disorders
  - glaucoma (increased intraocular pressure)
  - depression
  - schizophrenia
  - psychosis
  - epilepsy
  - from severe muscle weakness
- If you have suffered in the past from dependence on medicines, drugs or alcohol

If you are taking, or 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 (e.g., sedatives, antiallergics, surgical anesthetics, muscle relaxants, narcotic painkillers, hypnotics, for Parkinson's [e.g., levodopa], for epilepsy, for mental illnesses)
- Antidepressants
- Anticholinergics
- Cisapride (for reflux)
- Cimetidine (for gastric ulcer)
- Oral contraceptives
- Disulfiram (for alcohol dependence)
- Digoxin (for the heart)
- Rifampin or isoniazid (for tuberculosis)

Use of the medicine and alcohol consumption

Do not drink wines or other beverages containing alcohol during the course of treatment with this medicine.

Use of the medicine and smoking

Do not smoke during the course of treatment with the medicine.
If you smoke, inform the doctor before commencing treatment with this medicine.

Pregnancy and breastfeeding

Consult a doctor before using this medicine if you are pregnant or trying to become pregnant.
Do not use this medicine during the first trimester of pregnancy or while breastfeeding.

Driving and use of machines

Use of this medicine may impair alertness and cause drowsiness and/or dizziness and therefore caution is required when driving a car, operating dangerous machinery and when engaging any activity which requires alertness.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.
Check with the doctor or pharmacist if you are unsure.
The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose under any circumstances.
Do not take more than one tablet before going to sleep.

Directions for use of the medicine:

Swallow the tablet with a glass of water before going to sleep.
Do not hold the tablet in your mouth beyond the time necessary to swallow it.

Tests and follow up

Upon prolonged treatment with this medicine, blood, urine and liver function tests should be performed.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to 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 before going to sleep, do not take the dose late at night or early in the morning, as it may affect your alertness during the day. Never take two doses together.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not discontinue treatment with this medicine without first consulting the doctor or pharmacist.

Discontinuation of treatment with the medicine

When discontinuing treatment with this medicine, isolated incidents of withdrawal symptoms may occur, especially after prolonged use. Withdrawal symptoms can also occur after a controlled discontinuation, as instructed by the doctor. These reactions usually appear only after a few days after the end of treatment. Therefore, if you experience withdrawal symptoms, such as those listed above (see the "Introduction" section in this leaflet), or any new symptom, consult a doctor.

How can you contribute to the success of this treatment?

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

4. SIDE EFFECTS:

As with any medicine, use of Hypnodorm® 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.
The most common side effects are:
Drowsiness, fatigue and muscle weakness.
Other side effects:

- Being less alert, dizziness, unsteadiness when walking, drowsiness during the day, fatigue, headache, confusion, slurred speech, vision disturbances
- Gastrointestinal problems, dry mouth
- Decreased blood pressure, tremor
- Changes in sexual function
- Sweating

The effects listed above usually decrease after the period of adaptation to the medicine. If these effects are bothersome, consult a doctor.

Discontinue treatment with the medicine and refer to a doctor immediately if the following side effects occur:

- Increased heart rate, chest pain, that sometimes radiates to the neck, shoulders and down the left arm, which can be a sign of a heart attack.
- Sudden onset of allergic reactions, manifested by swelling of the face, lips, tongue or throat, with breathing or swallowing difficulties (rare), other reactions, including sudden swelling of the hands, feet, skin rash or itching.
- Breathing problems (respiratory depression), where the early signs can include uneven breathing and breathing difficulty.
- Urgent need to empty the bladder and difficulty in doing so.
- Change in mood and regular behavior patterns such as: nervousness, tension, excitability, restlessness, appearance of nightmares and hallucinations, severe sleep disturbances, violent behavior, irregular, troublesome, thoughts, confusion, forgetfulness, psychosis, muscle weakness.

If any of the side effects worsen or if you experience a side effect not mentioned in this leaflet, consult the doctor immediately.

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 and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the 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 below 25°C.
Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of unused medicines. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose, lactose (monohydrate and spray dried), talc, magnesium stearate.

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

Description of the tablet:
The tablet is round and white, with a score line on one side and "TEVA" imprinted on the other side.

Manufacturer and address:

Teva Pharmaceutical Industries, Ltd., P.O.B. 3190, Petah-Tiqva.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

032.33.22417.00

This leaflet was checked and approved by the Ministry of Health in 05.2013.

TEVA