

HYPNOX TABLET®

(Flunitrazepam 2mg)

COMPOSITION:

Each tablet contains:

Flunitrazepam..... 2 mg.

Excipients.....q.s

PHARMACOLOGICAL CLASSIFICATION

Benzodiazepine sedative and anxiolytics

CLINICAL PHARMACOLOGY

The main pharmacological effects of flunitrazepam are the enhancement of GABA at the [GABA_A receptor](#).^[9] Like other [benzodiazepines](#), flunitrazepam's pharmacological effects include sedation, muscle relaxation, reduction in anxiety, and prevention of convulsions.

Intermediate-[half-life](#) benzodiazepines (such as [loprazolam](#), [lormetazepam](#), and [temazepam](#)) are also useful for patients with difficulty in maintaining sleep; these may be preferable to long-half-life benzodiazepines, which typically cause next-day sedation and impairments. While 80% of flunitrazepam that is taken orally is absorbed, bioavailability in suppository form is closer to 50%.^[10]

Flunitrazepam has a long half-life of 18–26 hours and an active metabolite that has a half-life of 36–200 hours, which means that flunitrazepam's effects after nighttime administration persist throughout the next day.^[11] Residual "[hangover](#)" effects after nighttime administration of flunitrazepam, such as sleepiness and impaired psychomotor and cognitive functions, may persist into the next day. This may impair the ability of users to drive safely, and increase risks of falls and hip fractures.^[12]

Flunitrazepam is [lipophilic](#) and is metabolised hepatically via oxidative pathways. The enzyme [CYP3A4](#) is the main enzyme in its [phase 1 metabolism](#) in human liver.

INDICATIONS

HYPNOX is a short acting benzodiazepine with actions, uses and adverse effects similar to that of diazepam. HYPNOX is used in short term management of insomnia, for induction of anaesthesia and as a premedication in surgical procedures.

CONTRAINDICATION (WHEN NOT TO TAKE HYPNOX)

HYPNOX is contraindicated in conditions like Myasthenia gravis, Respiratory depression, acute pulmonary insufficiency, Sleep apnoea syndrome, chronic psychosis and severe liver problems, also if you have a history of drug or alcohol abuse, marked personality disorder; avoid regular use during pregnancy (risk of neonatal withdrawal symptoms); use only if clear indication such as seizure control (high doses during late pregnancy or labour may cause neonatal hypothermia, hypotonia and respiratory depression); breast-feeding (present in milk, avoid if possible); reduce dose in elderly and debilitated, and in hepatic (avoid if severe) and renal impairment (start with small doses if severe); avoid prolong use (abrupt withdrawal thereafter); porphyria. It should not be used alone to treat depression (or anxiety associated with depression) or psychosis.

WARNINGS AND PRECAUTIONS

DO NOT GIVE HYPNOX TO INFANTS OR CHILDREN

INTERACTIONS

The use of HYPNOX in combination with alcohol synergizes the adverse effects, and can lead to toxicity and death. HYPNOX is metabolized almost completely by cytochrome P450 3A4. Atorvastatin administration along with HYPNOX results in a reduced elimination rate of this molecule. Grapefruit juice reduces intestinal 3A4 and results in less metabolism and higher plasma concentrations of HYPNOX, which could result in overdose.

Disulfiram and Cimetidine both inhibit oxidative metabolism of HYPNOX, and plasma HYPNOX levels may be increased by co-administration.

The anti-cholinergic adverse effects of atropine-like drugs, anti-histamines and certain anti-depressants may be potentiated. HYPNOX may interact with anti-convulsant levels are monitored.

Cisparide leads to a temporary increase in HYPNOX levels via increased absorption rates.

DOSAGE AND ADMINISTRATION

HYPNOX tablet 2mg should be taken orally 3 times daily and increased if necessary to 15-30mg daily in divided doses.

Insomnia associated anxiety, 5-15mg at bedtime

Overdosage

HYPNOX is a drug that is frequently involved in drug intoxication, including overdose. Overdose of HYPNOX may result in excessive sedation, or impairment of balance or speech. This may progress in severe overdoses to respiratory depression or coma and possibly death. The risk of overdose is increased if HYPNOX is taken in combination with CNS depressants such as alcohol and opiates. HYPNOX overdose responds to the benzodiazepine receptor antagonist flumazenil, which thus can be used as a treatment.

Drug Dependence

HYPNOX as with other benzodiazepine drugs can lead to physical dependence, addiction, and what is known as the benzodiazepine withdrawal syndrome.

Discontinuation may result in the appearance of withdrawal symptoms when the drug is discontinued. Abrupt withdrawal may lead to a severe benzodiazepine withdrawal syndrome characterised by seizures, psychosis, severe insomnia, and severe anxiety. Rebound insomnia, worse than baseline insomnia, typically occur after discontinuation of HYPNOX even after short-term single nightly dose therapy.

SIDE EFFECTS

HYPNOX is considered to be one of the most addictive of the benzodiazepines, along with clonazepam, midazolam, alprazolam, and particularly, temazepam, nitrazepam, and mimetazepam. Its use causes several notable side effects, including: Drowsiness, loss of motor control; dizziness, lack of coordination, slurred speech, amnesia, confusion, gastrointestinal disturbances, lasting 12 or more hours. Respiratory depression in higher doses.

PRESENTATION

3 X 10 tablets

STORAGE

Should be stored in a cool dry place

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN

Manufacturer Address

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