

INFORMATION FOR THE PATIENT



APO-NITRAZEPAM Tablets BP

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Facts on APO-NITRAZEPAM (nitrazepam) Tablets

Introduction

APO-NITRAZEPAM is intended to help you sleep. It is one of several benzodiazepine sleeping pills that have generally similar properties. If you are prescribed one of these medications, you should consider both their benefits and risks. Important risks and limitations include the following:

- the longer you use the medication, the less effective it may become,
- you may become dependent on the medication,
- the medication may affect your mental alertness or memory, particularly when not taken as prescribed.

In order to guide you in the safe use of the product, this leaflet will inform you about this class of medication in general, and about APO-NITRAZEPAM in particular.

BUT THIS LEAFLET SHOULD NOT REPLACE A DISCUSSION BETWEEN YOU AND YOUR DOCTOR ABOUT THE RISKS AND BENEFITS OF APO-NITRAZEPAM.

Safe Use Of APO-NITRAZEPAM Sleeping Pills

- APO-NITRAZEPAM is a prescription medication, intended to help you sleep. Follow your doctor's advice about how to take APO-NITRAZEPAM, when to take it, and how long to take it. DO NOT TAKE APO-NITRAZEPAM if it is not prescribed for you.
- DO NOT TAKE APO-NITRAZEPAM for more than 7-10 days without first consulting your doctor.
- DO NOT TAKE APO-NITRAZEPAM when a full night's sleep is not possible before you would again need to be active and functional; e.g., an overnight flight of less than 8 hours. Memory lapses may occur in such situations. Your body needs time to eliminate the medication from your system.
- DO NOT TAKE APO-NITRAZEPAM at any time during pregnancy. Tell your doctor if you are planning to become pregnant, if you are pregnant, or if you become pregnant while taking this medication.
- Tell your doctor about any alcohol consumption (present or past) or any medicine you are taking now, including drugs you can buy without a prescription. DO NOT CONSUME ALCOHOL WHILE TAKING APO-NITRAZEPAM.
- DO NOT INCREASE THE PRESCRIBED DOSE.
- DO NOT DRIVE A CAR or operate potentially dangerous machinery until you experience how this drug will affect you.
- If you develop any unusual disturbing thoughts or behaviour while using APO-NITRAZEPAM, discuss the matter immediately with your doctor.
- You may experience an increase in sleep difficulties (rebound insomnia) and/or increased daytime anxiety (rebound anxiety) for one or two days after discontinuing APO-NITRAZEPAM.

Effectiveness of Benzodiazepine Sleeping Pills

Benzodiazepine sleeping pills are effective medications and are relatively free of serious problems when used for the short-term management of insomnia. Symptoms of insomnia may vary: you may have difficulty in falling asleep, or awaken often during the night, or awaken early in the morning, or you may have all three symptoms. Insomnia may last only for a short time and may respond to brief treatment. The risks and benefits of prolonged use should be discussed with your doctor.

Side Effects

Common Side Effects:

Benzodiazepine sleeping pills may cause drowsiness, dizziness, lightheadedness, and difficulty with coordination. Users must be cautious about engaging in hazardous activities requiring complete mental alertness, e.g., operating machinery or driving a motor vehicle.

Avoid alcohol while using APO-NITRAZEPAM. DO NOT USE benzodiazepine sleeping pills along with other medications without first discussing this with your doctor.

How sleepy you are the day after you use one of these sleeping pills depends on your individual response and on how quickly your body gets rid of the medication. The larger the dose, the more likely that you will experience drowsiness, etc., the next day. For this reason, it is important that you use the lowest effective dose. Benzodiazepines, which are eliminated rapidly, tend to cause less drowsiness the next day, but may cause withdrawal problems the day after use.

Special Concerns:

Memory Problems:

All benzodiazepine sleeping pills can cause a special type of memory loss (amnesia); you may not recall events that occurred during some period of time, usually several hours, after taking the drug. This lapse is usually not a problem, because the person taking the sleeping pill intends to be asleep during this critical period of time. But it can be a problem if you take the medication to induce sleep while travelling, such as during an airplane flight, because you may wake up before the effect of the drug is gone. This has been called "traveller's amnesia".

Tolerance/Withdrawal Symptoms:

After nightly use for more than a few weeks benzodiazepines may lose some of their effectiveness. You may also develop a degree of dependence.

"Withdrawal" effects can occur when patients stop taking benzodiazepine sleeping pills. The effects may occur following use for only a week or two but may be more common and severe after long periods of continuous use. One type of withdrawal symptom is known as "rebound insomnia", i.e., on the first few nights after stopping the medication, insomnia may be worse than before the sleeping pill was given.

Other withdrawal symptoms, similar in character to those noted with barbiturates and alcohol (convulsions, tremor, abdominal and muscle cramps, vomiting, sweating, dysphoria, perceptual disturbances, insomnia, headache, extreme anxiety, tension, restlessness, confusion and irritability) have occurred following abrupt discontinuation of benzodiazepines, and may follow the discontinuation of APO-NITRAZEPAM. In severe cases, the following symptoms may occur: sense of detachment from one's surroundings, unreal feeling with a sensation that the extremities have changed in size, abnormal sensitivity to sound, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, hallucinations and epileptic seizures. The more severe symptoms are usually associated with higher dosages and longer usage.

Dependence/Abuse:

All benzodiazepine sleeping pills can cause dependence (addiction) especially when used regularly for more than a few weeks, or at higher doses. Some people develop a need to continue taking these drugs, either at the prescribed dose or at higher doses -- not only for continued therapeutic effect, but also to avoid withdrawal symptoms or to achieve non-therapeutic effects.

Individuals who depend, or have depended at any time in the past, on alcohol or other drugs may be at particular risk of becoming dependent on drugs of this class. But ALL PEOPLE ARE AT SOME RISK. Consider this matter before you take these medications beyond a few weeks.

Mental and Behavioural Changes:

A variety of abnormal thinking and behaviour changes may occur when you use benzodiazepine sleeping pills. Some of these changes include aggressiveness and extroversion which seem out of character. Other changes, although rare, can be more unusual and extreme such as confusion, strange behaviour, restlessness, illusions, hallucinations, feeling like you are not yourself, and worsening depression, including suicidal thinking.

It is rarely clear whether such symptoms are caused by the medication, or by an underlying illness, or are simply spontaneous happenings. In fact, worsened insomnia may in some cases be associated with illnesses that were present before the medication was used.

Excessive Salivation:

On rare occasions in infants and young children, as well as elderly, bed-ridden patients, there may be excessive secretion of saliva and fluid in the lungs which may lead to chest infections.

Important Note

Regardless of the cause, if you take these medications, report any mental or behavioural changes promptly to your doctor.

Effects of Pregnancy

Certain benzodiazepine sleeping pills have been linked to birth defects when taken during the early months of pregnancy. In addition, benzodiazepine sleeping pills taken during the last weeks of pregnancy have been known to sedate the baby. Therefore, **AVOID USING THIS MEDICATION DURING PREGNANCY.**



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