Nitrazepam 5mg Tablets

Make sure that you can sleep without interruptions for 7 to 8 hours after taking the tablets. Because Nitrazepam tablets relax the muscles, elderly patients should take extra care when they get up at night as there is a risk of falls and consequently of injuries including hip fractures.

Other considerations
- Dependence - when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse.
- Tolerance - if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should speak to your doctor.
- Withdrawal - treatment should be gradually withdrawn. Withdrawal symptoms occur with nitrazepam even when normal doses are given for short periods of time. See section 3, if you stop taking Nitrazepam tablets'.

Children
Do not give this medicine to children.

Other medicines and Nitrazepam tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:
- Antidepressants, other tranquillisers or sleeping pills, or other such medicines that act on the brain and nerves.
- Medicines used to relieve pain or anaesthetics.
- Antihistamines (used for treating allergies) that cause drowsiness.
- Lofexidine (to help relieve symptoms when you stop taking opioids), nalbopine (to treat nausea and vomiting).
- Opioids (strong pain killers, medicines for substitution therapy and some cough medicines). Taking these medicines with Nitrazepam tablets increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Nitrazepam tablets together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- Medicines for treating epilepsy (e.g. phenytoin and phenobarbital).
- Medicines that affect the liver (e.g. the antibiotic rifampicin).
- Medicines used to relieve pain or anaesthetics.
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- Other medicines that act on the brain and nerves.

Nitrazepam tablets with alcohol
Do not drink alcohol while you are taking Nitrazepam tablets. Alcohol may increase the sedative effects of nitrazepam and make you very sleepy.

Pregnancy and breast-feeding
Pregnancy
Tell your doctor before taking Nitrazepam Tablets if you are pregnant, think you may be pregnant or intend to become pregnant during treatment. Your doctor will then decide whether you should take this medicine. If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, hiccups and breathing and feeding difficulties. Also, your unborn baby may be at risk of developing dependency to this medicine and after birth may be at some risk of developing withdrawal symptoms.

Breast-feeding
Tell your doctor before taking Nitrazepam Tablets if you are breast-feeding. Avoid taking Nitrazepam Tablets if you are breast-feeding as nitrazepam passes into breast-milk.

Driving and using machines
Nitrazepam tablets may affect how your muscles work or may make you feel sleepy or forgetful. It may also impair your alertness (especially if you don’t have 7-8 hours uninterrupted sleep). Do not drive or use any tools or machines if you are affected in this way.

Continued over page
The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in
    the information provided with the medicine and
  - It was not affecting your ability to drive safely.
  - Talk to your doctor or pharmacist if you are not sure whether it is safe for you
to drive while taking this medicine.

Nitrazepam tablets contain lactose (a type of sugar). If you have been told by
your doctor that you have intolerance to some sugars, contact your doctor before
taking this medicine.

How to take Nitrazepam tablets
Your doctor will find the lowest dose to control your symptoms. The dose that
your doctor prescribes will depend on the nature of your illness, your reaction to
the medicine, your age and body weight.
Always take this medicine exactly as your doctor has told you. Do not change
the prescribed dose yourself. You should check with your doctor or pharmacist
if you are not sure how to take this medicine. If you think that the effect of your
medicine is too weak or too strong, talk to your doctor.

Nitrazepam tablets are not for use in children.

The usual starting dose is 5 mg (one tablet). However, if you are elderly or suffer
from a lung, liver or kidney condition, or are generally unwell, your starting dose
will not usually be more than 2.5 mg (half a tablet).

You may not need to take this medicine every night. Swallow the tablet(s) whole
with water or another non-alcoholic drink.

Take the medicine just before going to bed. Make sure that you do not go
without interruptions for 7 to 8 hours after taking the tablets.

Treatment will not normally be continued for more than four weeks.

Nitrazepam tablets may become less effective if you take them for more than four
weeks. If you think that your medicine is no longer working or your insomnia does
not improve, you should consult your doctor. Also, you may become dependent
on the tablets if you use them at high doses and for long periods. Therefore,
Nitrazepam tablets are not suitable for long-term use and after a few weeks it is
worth trying to get by without these tablets. This will help to prevent you
becoming used to nitrazepam and reduce the risk of dependence.

Withdrawal symptoms may occur when you stop taking Nitrazepam tablets.
(see section below if you stop taking Nitrazepam tablets). Do not stop taking
Nitrazepam tablets without speaking to your doctor.

If you take more Nitrazepam tablets than you should
If you take too many tablets or someone else accidentally takes your medicine,
contact your doctor, pharmacist or nearest hospital straight away. Signs of an
overdose include slowing down of the nervous system (slumbering from tiredness
to death) such as confusion, drowsiness, lack of co-ordination, reduced muscle
tension, low blood pressure, slow heartbeat, breathing difficulties. In rare cases
overdose may lead to coma (unconsciousness) and in very rare cases may
lead to death.

If you forget to take Nitrazepam tablets
Do not take a double dose to make up for a forgotten dose. Instead you should
simply continue with the next dose when it is due.

If you stop taking Nitrazepam tablets
Do not stop taking Nitrazepam tablets abruptly. You may experience withdrawal effects if your
 treatment is stopped suddenly. This is less likely if your dose is gradually reduced
towards the end of your treatment.

Withdrawal symptoms may include: a recurrence of sleep problems, depression,
irritability, anxiety, tension, restlessness, confusion, mood changes, riveting
insomnia, sweating, diaphoresis, headache, muscle weakness.

In severe cases the following symptoms may occur: changes in behaviour,
numbness and tingling of the extremities, fits, over-sensitivity to light, noise and
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