Nitrazepam, the active ingredient in these tablets, belongs to a group of medicines known as benzodiazepines which are tranquillisers (medicines that are known to have a calming effect). Nitrazepam shortens the time taken to fall asleep and lengthens the duration of sleep. This medicine should only be used in adults and the elderly for the short-term treatment of sleeplessness (also known as insomnia) when it is severe, causing distress and where daytime sleepiness is unacceptable.

What is in this leaflet

1. What Nitrazepam Tablets are and what are they used for
2. What you need to know before you take Nitrazepam Tablets
3. How to take Nitrazepam Tablets
4. Possible side effects
5. How to store Nitrazepam Tablets
6. Contents of the pack and other information

1. What Nitrazepam Tablets are and what are they used for

Nitrazepam, the active ingredient in these tablets, belongs to a group of medicines known as benzodiazepines which are tranquillisers (medicines that are known to have a calming effect). Nitrazepam shortens the time taken to fall asleep and lengthens the duration of sleep. This medicine should only be used in adults and the elderly for the short-term treatment of sleeplessness (also known as insomnia) when it is severe, causing distress and where daytime sleepiness is unacceptable.

2. What you need to know before you take Nitrazepam Tablets

Do not take Nitrazepam Tablets and tell your doctor if you:
- are allergic (hypersensitive) to nitrazepam or any of the other ingredients in the tablets (listed in Section 6)
- are allergic (hypersensitive) to any of the group of medicines known as benzodiazepines (e.g. flunitrazepam, diazepam, chloridiazepoxide, or temazepam)
- have severe breathing problems or severe problems with your lungs
- have recently suffered the death of a close friend or relative
- are suffering from a mental illness or a personality disorder (phobia or obsession)
- have any other condition which may make Nitrazepam Tablets unsuitable for you

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to take Nitrazepam Tablets.

3. How to take Nitrazepam Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight.

Adults:
- The normal recommended starting dose is 5 mg.
- Doses greater than 10 mg a day should only be given under medical supervision.
- Do not exceed the maximum daily dose (10 mg). Your doctor may prescribe a lower dose for you (e.g., 2.5 mg).
- If you forget to take Nitrazepam Tablets:
  - If you forget to take one, do not make up for the missing dose by doubling the dose next time.
  - If you forget to take Nitrazepam Tablets:
    - You may become dependent on the tablets and find it difficult to stop taking them.
    - Children:
      - Do not give children to the age of 12 years.
      - 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. Take the medicine, its container, and this leaflet with you.

4. Possible side effects

Examples of medicines that can affect Nitrazepam Tablets are:
- medicines that act on the brain or nerves such as antidepressants, anxiolytics, other tranquilisers, sleeping pills and hypnotics
- drugs used to relax muscles, such as baclofen or tizanidine
- probenecid, used to treat gout
- drugs used to treat high blood pressure, such as ximelagran or medicines called alpha blockers
- antihistamines (that make you feel sleepy), used for hayfever and other allergies
- drugs used for alcohol or drug dependence such as dexamphetamine, or tolledine.

Taking nitrazepam can cause confusion, hallucinations, or disturbance of features, so it is not advisable to drive or use machines if you feel any of these effects.

5. How to store Nitrazepam Tablets

Keep this medicine out of the sight and reach of children.

The tablets should be stored below 25°C and protected from light.

6. Contents of the pack and other information

What Nitrazepam Tablets contain

This medicine contains lactose (a type of sugar). If you have been told by your doctor or pharmacist that you are allergic to one or more components of tablets, please inform your doctor or pharmacist before you take any medicine containing nitrazepam.

Common (occurs in less than 1 in 10 users)
- Dizziness, feeling lightheaded, loss of co-ordination
- Feeling of emptiness that you are not really there
- Feeling tired, drowsiness, less alert

Uncommon (occurs in less than 1 in 100 users)
- Confusion
- Hallucinations
- Sleepwalking
- Snoring
- Feeling ill
- Rash or any other skin rash
- Feeling fatigued, feeling unwell, fever, unusual tiredness, unusual weakness
- Muscle stiffness
- Infection
- Respiratory tract infection
- Allergic reaction (hypersensitivity) - swelling of the face, lips, tongue or throat
- High blood pressure
- Renal impairment
- Liver impairment
- Kidney impairment

These measures help protect the environment.

Marketing Authorisation Holder and Manufacturer
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