PATIENT INFORMATION LEAFLET FOR IVEDAL

SCHEDULING STATUS

S5

IVEDAL, 10 mg, film-coated tablets

Zolpidem tartrate

Contains sugar (90,4 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking IVEDAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- IVEDAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What IVEDAL is and what it is used for

IVEDAL contains a medicine called zolpidem tartrate and belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

IVEDAL is used to initiate sleep in adults with severe sleeping difficulties, also called insomnia, for a short term only.

2. What you need to know before you take IVEDAL

Do not take IVEDAL:

- If you are hypersensitive (allergic) to zolpidem tartrate or any of the other ingredients of IVEDAL (listed in section 6). Signs of an allergic reaction include rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- If you have myasthenia gravis (a condition in which the muscles become weak and tire easily).
- If you have sleep apnoea (a condition where you temporarily stop breathing while you sleep).
- If you have severe lung problems.
- If you have serious liver problems.
- If you are a child under 18 years of age due to an increased risk of adverse effects.
- If you are pregnant, intend to become pregnant or are breastfeeding.

Warnings and precautions

Take special care with IVEDAL:

- The use of IVEDAL may lead to the development of abuse and/or physical and psychological dependence. The risk of abuse and dependence is greater in patients with a history of mental disorders and/or alcohol, illicit substance, or medicine abuse. Tell your health care provider if you have ever had a mental disorder or have abused or have been addicted to alcohol or other medicines.
- Please consult with your doctor if you notice that you cannot or do not want to stop taking IVEDAL or if you feel that you need to take IVEDAL more often than prescribed to you by your doctor.
- Use with caution if you have mild to moderate breathing or chest problems.
- If your sleep problems persist or worsen after a short period of treatment, consult your doctor.
- If your sleep problems return while you are taking IVEDAL, consult your doctor. When medicines for sleep such as IVEDAL are used for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as “tolerance”.

- You may have temporary memory loss (amnesia) when taking IVEDAL. This can usually be avoided if you get a full night's sleep (7 to 8 hours) before being active again.
- Some people taking IVEDAL, may have changes in behaviour and thinking (see section 4). If you or your family notice any changes in your behaviour, or if you have any unusual or disturbing thoughts, consult your doctor immediately.
- If you ever had a history of sleep walking or other unusual behaviour (such as driving, eating, making a phone call or having sex) while not being fully awake after taking IVEDAL.
- Use with caution if you have mild to moderate liver problems.
- If you suffer from mental disorders (depression or schizophrenia) or epilepsy (fits).
- If you may be at risk of getting into a regular pattern or habit of taking IVEDAL.

Children and adolescents

Do not give IVEDAL to children or adolescents under 18 years of age.

Other medicines and IVEDAL

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

You should specifically tell you doctor if you take:

- Other medicines that act on the brain such as:
  - medicines used in the treatment of mental conditions (antipsychotics, hypnotics, anxiolytics/sedatives, antidepressants)
  - medicines used for strong pain relief (narcotic analgesics)
  - medicines used for the treatment of seizures/convulsions (antiepileptic medicines)
  - anaesthetics
  - medicines used in the treatment of allergies (antihistamines that cause sleepiness).

  The combination of these medicines with IVEDAL may make you drowsier than it should and may increase the next-day psychomotor impairment effects, including impaired driving ability.

In addition, you may be euphoric (increase of well-being) if narcotic analgesics (morphine and opiates) are combined with IVEDAL.

- Rifampicin (antibiotic used to treat infections) as it may decrease the effect of IVEDAL on sleep.
- Ketoconazole (used to treat infections) increases the effect of IVEDAL.
- Fluvoxamine (an antidepressant medicine) as it may increase the effect of IVEDAL. It is not recommended to take IVEDAL with fluvoxamine.
- Ciprofloxacin (antibiotic used to treat infections) as it may increase the effect of IVEDAL. It is not recommended to take IVEDAL with ciprofloxacin.
- St John's Wort (a herbal medicine used for mood swings and depression). It is not recommended to take IVEDAL with St. John's Wort.
- Opioids (medicines used for pain relief, and also contained in some cough medicines). Concomitant use of IVEDAL and opioids increases the risk of drowsiness, difficulties in breathing, coma and may be life-threatening. Because of this, the concomitant use with IVEDAL should only be considered when other treatment options are not possible. Please tell your doctor about all opioid medicines you are taking.

IVEDAL with food, drink and alcohol

You should not drink alcohol while taking IVEDAL.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, you should not take IVEDAL (see Do not take IVEDAL).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking IVEDAL.

Driving and using machines

IVEDAL makes you sleepy, therefore caution should be exercised when operating machinery or driving motor vehicles.

IVEDAL has a major influence on the ability to drive and use machines. On the day after taking IVEDAL, you should be aware that:

- you may feel drowsy, sleepy, dizzy or confused
- your decision-making abilities may be slowed down
- your vision may be blurred or double
- you may be less alert.

A period of at least 8 hours is recommended between taking IVEDAL and driving, using machinery and working at heights to minimise the above-mentioned effects.

Do not drink alcohol or take other psychoactive substances while you are taking IVEDAL as it can increase the above-mentioned effects.

IVEDAL contains lactose monohydrate

IVEDAL contains lactose monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking IVEDAL.

3. How to take IVEDAL

Do not share medicines prescribed for you with any other person.

Always take IVEDAL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose of IVEDAL is one tablet (10 mg) at night, immediately before bedtime or in bed. The dose of one tablet (10 mg) at night should not be exceeded.

Swallow the tablet whole with a full glass of water.

IVEDAL should be taken in a single intake and not taken again during the same night.

If you are over 65 years of age or have liver problems, the usual dose is half of a tablet (5 mg). A total dose of 10 mg should not be exceeded in these populations.

IVEDAL should only be used for a few days to 2 weeks with a maximum, including the tapering off (gradual reduction of your dose before stopping treatment over a period) process, of 4 weeks.

DO NOT TAKE MORE THAN THE DOSAGE RECOMMENDED BY YOUR DOCTOR.

If you have the impression that the effect of IVEDAL is too strong or too weak, tell your doctor or pharmacist.

If you take more IVEDAL than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre and tell them how many tablets have been taken.
If you take too much IVEDAL, your consciousness may be impaired, ranging from drowsiness to light coma.

If you forget to take IVEDAL

IVEDAL must only be taken at bedtime. If you forget to take the tablet before you go to bed, and you wake up late in the night or very early in the morning, do not take it. If you are not sure what to do, ask your doctor.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking IVEDAL

Keep taking IVEDAL until your doctor tells you to stop. Do not stop taking IVEDAL suddenly but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking IVEDAL suddenly, your sleep problems may come back and you may get a withdrawal effect. If this happens you may get some of the effects listed below.

See a doctor straight away if you experience any of the following effects:

- feeling anxious, restless, irritable or confused
- headache
- faster heartbeat or uneven heartbeat (palpitations)
- nightmares, seeing or hearing things that are not real (hallucinations)
- being more sensitive to light, noise and touch than normal
- relaxed grip on reality
- feeling distant from your body or feeling “puppet-like”
- numbness and tingling in your hands and feet
- aching muscles
- stomach problems
- sleep problems come back worse than before
- in rare cases fits (seizures) may also occur.

4. Possible side effects

IVEDAL can have side effects.

Not all side effects reported for IVEDAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IVEDAL, please consult your health care provider for advice.

If any of the following happens, stop taking IVEDAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to IVEDAL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. These may be signs of a problem with your liver.
- slower breathing or difficulty breathing (respiratory depression)
- IVEDAL may cause sleep walking or other unusual behaviour (such as driving, eating, making a phone call or having sex) while not being fully awake, some of which have been associated with serious injuries.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- drowsiness
- dizziness
- diarrhoea
- nausea
- vomiting
- abdominal pain
- headache
- increased sleep problems
- hallucinations
- agitation
- nightmares

- memory difficulties
- tiredness
- nose, throat or lung infections (respiratory infection)
- back pain.

Less frequent side effects:

- confusion
- irritability
- double vision, blurred vision
- decreased concentration
- restlessness
- aggressiveness
- delusion
- rage
- abnormal behaviour
- libido disorders (changes in sex drive)
- unsteadiness, fall (mainly in older patients and when IVEDAL is not taken in accordance with the prescribing recommendations)
- muscle weakness, muscle spasms, limp or weak muscles, muscle pain, joint pain
- tolerance (loss of effectiveness of the sleep medicine)
- dependence (need to continue the sleep medicine associated with unpleasant symptoms when the sleep medicine is suddenly stopped)
- depression
- tremor
- feeling overly happy or confident (euphoric)
- unusual skin sensations such as numbness, tingling, prickling, burning or creeping on the skin (paraesthesia)
- increased sweating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of IVEDAL.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

5. How to store IVEDAL

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Do not take IVEDAL after the expiry date shown on the carton and blister.

Keep the blisters in the outer carton until required for use.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. Contents of the pack and other information

What IVEDAL contains

The active substance is zolpidem tartrate.

Each IVEDAL film-coated tablet contains 10 mg zolpidem tartrate.

The other ingredients are hypromellose (6 mPa.s), lactose monohydrate, macrogol 400, magnesium stearate, microcrystalline cellulose (Avicel PH101), sodium starch glycolate (type A) and titanium dioxide (E171, CI 778891).

What IVEDAL looks like and contents of the pack

White to off-white film-coated oblong tablet, scored, engraved “SN 10” on one side.

IVEDAL is available in clear PVC and aluminium foil blister packs of 14 or 28 tablets.

Holder of certificate of registration

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This leaflet was last revised in

Date of registration: 07 May 2004

Date of revision: 01 July 2022

Registration number

37/2.2/0540