SCHEDULING STATUS

S5

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

ZOPICLONE-INNOVATA 7,5: Each Film-coated Tablet contains 7,5 mg zopiclone.

Contains: Sugar (lactose 31.50 mg)

Read all this leaflet carefully before you start taking ZOPICLONE-INNOVATA

What is in this leaflet

1. What **ZOPICLONE-INNOVATA** is and what it is used for

2. What you need to know before you take **ZOPICLONE-INNOVATA**

3. How to take **ZOPICLONE-INNOVATA**

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1. What ZOPICLONE-INNOVATA is and what is it used for:

ZOPICLONE-INNOVATA belongs to the class of medicines called hypnotics.

ZOPICLONE-INNOVATA is used for the short-term treatment of sleeping difficulties (insomnia) in adults. (The duration of treatment must be as short as possible: from a few days to two weeks, with a maximum of not more than 4 weeks.).

2. What you need to know before you take ZOPICLONE-INNOVATA:

Do not take ZOPICLONE-INNOVATA:

- if you are allergic (hypersensitive) to zopiclone, or any of the other ingredients of **ZOPICLONE-INNOVATA** listed in section 6
- you have severe muscle weakness (myasthenia gravis)
- your lungs do not work properly (respiratory failure)
- you have a problem where you stop breathing for short periods at night whilst sleeping (severe sleep apnoea)
- you have severe liver problems
- you are under the age of 18. **ZOPICLONE-INNOVATA** should not be used in children and young adults aged less than 18 years
- you are pregnant or breastfeeding or planning to become pregnant
- you have been drinking alcohol or you believe that you may have alcohol in your bloodstream. This may enhance some effects of **ZOPICLONE-INNOVATA** such as drowsiness or dizziness and your ability to drive may be at risk.

Warnings and precautions

Tell your doctor or health care provider before taking **ZOPICLONE-INNOVATA** if you:

- suffer or ever suffered from mild breathing problems; your doctor will decide if you should receive **ZOPICLONE-INNOVATA** (also see Do not take **ZOPICLONE-INNOVATA**)

- are using opioids (e.g. pain killers such as codeine), please tell your doctor that you are using opioid medicines and follow your doctor's dosage recommendations closely. Taking **ZOPICLONE-INNOVATA** together with opioids may cause dangerous side effects such as drowsiness, difficulties breathing, coma and death
- have depression (including suicidal thoughts) or have had another mental illness in the past, **ZOPICLONE-INNOVATA** may not be a suitable treatment and may make these conditions worse or mask it so that your doctor is not able to diagnose you properly
- have a history of alcohol or drug abuse
- have recently taken **ZOPICLONE-INNOVATA** or other similar medicines for more than four weeks
- do not feel you will ever be able to stop taking **ZOPICLONE-INNOVATA** or other medicines used to treat sleep problems
- have any liver problems (also see Do not use **ZOPICLONE-INNOVATA**). Your doctor may need to give you a lower dose of **ZOPICLONE-INNOVATA**
- have any kidney problems. Your doctor may need to start your treatment with **ZOPICLONE-INNOVATA** at a lower dose.

Other medicines and ZOPICLONE-INNOVATA:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Medicines that may influence **ZOPICLONE-INNOVATA**:

- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- Medicines used in surgery (anaesthetics)
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorpheniramine or promethazine
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol.

The following medicines can increase the chance of you getting side effects when taken with **ZOPICLONE-INNOVATA**. To make this less likely, your doctor may decide to lower your dose of **ZOPICLONE-INNOVATA**:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketaconazole and itraconazole
- Ritonavir (a protease inhibitor) - for HIV infections
- Concomitant use of **ZOPICLONE-INNOVATA** and opioids increases the risk of drowsiness, difficulties breathing, coma and death (also see Tell your doctor or pharmacist before taking **ZOPICLONE-INNOVATA**).

The following medicines can make **ZOPICLONE-INNOVATA** work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbitone phenytoin or rifampicin (an antibiotic) - for infections
- St. John’s Wort (a herbal medicine) - for mood swings and depression.

ZOPICLONE-INNOVATA with food, drink, and alcohol:

Do not drink alcohol while you are taking **ZOPICLONE-INNOVATA**. Alcohol can increase the effects of **ZOPICLONE-INNOVATA** and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy and breastfeeding and fertility:

If you are pregnant, think you may be pregnant, planning to have a baby or you are breastfeeding your baby, please consult your doctor pharmacist or healthcare provider before taking **ZOPICLONE-INNOVATA**.

The safety of **ZOPICLONE-INNOVATA** during pregnancy and breastfeeding has not been established. If **ZOPICLONE-INNOVATA** is taken during pregnancy your baby may have a low body temperature or breathing difficulties and show withdrawal symptoms after birth because of physical dependence. Therefore, **ZOPICLONE-INNOVATA** should not be taken during pregnancy or breastfeeding (see Do not take **ZOPICLONE-INNOVATA**).

Driving and using machines:

ZOPICLONE-INNOVATA causes drowsiness, dizziness, impaired concentration and can also cause slowing of your normal brain function (central nervous system). The risk of psychomotor impairment (reducing your physical movement and reactions) including driving ability, is increased if:

- you take **ZOPICLONE-INNOVATA** within 12 hours of performing activities that require mental alertness
- you take higher than the recommended dose of **ZOPICLONE-INNOVATA**

- you take **ZOPICLONE-INNOVATA** while already taking another central nervous system depressant or another medicine that increases levels of **ZOPICLONE-INNOVATA** in your blood, or while drinking alcohol.

Do not engage in hazardous activities requiring complete mental alertness such as driving or operating machinery after taking **ZOPICLONE-INNOVATA** and, in particular, during the 12 hours after taking your medicine.

For more information about possible side effects, e.g., drowsiness, which could affect your driving (**see Possible side effects**).

ZOPICLONE-INNOVATA contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ZOPICLONE-INNOVATA:

Your treatment will be at the lowest recommended dose and as short as possible, usually for less than 4 weeks, and the doctor may reduce your dose near the end of your course.

If you take **ZOPICLONE-INNOVATA** longer than this, **ZOPICLONE-INNOVATA** may not work as well, you may become dependent and you may have withdrawal symptoms when you stop.

- Do not share **ZOPICLONE-INNOVATA** prescribed for you with any other person.

- Always take **ZOPICLONE-INNOVATA** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow your tablet with a small glass of water, do not crush or chew it.
- Take **ZOPICLONE-INNOVATA** just before bedtime in a single intake and do not take it again during the same night.
- **ZOPICLONE-INNOVATA** should only be taken when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again.

The usual dose is:

Adults:

A dose is one **ZOPICLONE-INNOVATA** tablet (7,5 mg) just before bedtime. This dose should not be exceeded.

ZOPICLONE-INNOVATA should not be given to children and young adults under the age of 18.

Your doctor may have prescribed a lower dose, depending on your age and health status. Ask your doctor if you are unsure of the correct dose or if you have the impression that the effect of **ZOPICLONE-INNOVATA** is too strong or too weak. Your doctor will

If you take more ZOPICLONE-INNOVATA than you should:

Taking too much **ZOPICLONE-INNOVATA** can be very dangerous and my lead to shallow breathing or difficulty breathing and falling into a coma.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of ZOPICLONE-INNOVATA:

ZOPICLONE-INNOVATA must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking ZOPICLONE-INNOVATA:

When you stop using **ZOPICLONE-INNOVATA** your doctor will advise you to slowly taper down your dosage.

If you stop taking **ZOPICLONE-INNOVATA** 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 get any of the following effects:

- feeling anxious, tension, restless, shaky, irritable, agitated, confused or having panic attacks
- sweating
- headache
- faster heartbeat or uneven heartbeat (palpitations)

- a lower level of awareness and problems with focusing or concentrating nightmares, seeing or hearing things that are not real (hallucinations)
- being more sensitive to light, noise and touch than normal
- relaxed grip on reality
- numbness and tingling in your hands and feet
- aching muscles
- in some cases fits (seizures) may also occur.

In some cases, your insomnia or inability to sleep may appear worse for a short time (Rebound insomnia). Tell your doctor if this occurs of if you have any other problems when you stop taking **ZOPICLONE-INNOVATA**.

4. Possible side effects

ZOPICLONE-INNOVATA can have side effects.

Not all side-effects reported for **ZOPICLONE-INNOVATA** are included in this leaflet. Should your general health worsen while taking **ZOPICLONE-INNOVATA**, please consult your doctor, pharmacist, or other healthcare professional for advice.

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

Less frequent:

- you have an allergic reaction. The signs may include: a rash, swelling of your lips, face, throat or tongue, swallowing or breathing problems, fainting and collapse.

These are all serious side effects. If you have them, you may have had a serious reaction to **ZOPICLONE-INNOVATA**. You may need urgent medical attention.

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

Less frequent:

- poor memory since taking **ZOPICLONE-INNOVATA** (amnesia). By having 7-8 hours of uninterrupted sleep after taking **ZOPICLONE-INNOVATA**, this is less likely to cause you a problem
- seeing or hearing things that are not real (hallucinations)
- falling, especially in the elderly.

Frequency unknown:

- thinking things that are not true (delusions).

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:

- a mild bitter or metallic taste in your mouth or a dry mouth

- feeling drowsy or sleepy
- dry mouth.

Less frequent side effects:

- feeling confused
- nightmares
- agitation
- feeling irritable or aggressive
- feeling sick (nausea) or vomiting
- feeling dizzy
- headache
- feeling physically or mentally tired
- hives, rash and itching
- reduced sex drive
- difficulty breathing or being short of breath
- change in blood tests (increase of liver enzymes in the blood).

Frequency unknown:

- feeling restless or angry
- problems with your coordination
- double vision
- moving unsteadily or staggering
- muscular weakness
- indigestion
- becoming dependent on **ZOPICLONE-INNOVATA**

- slower breathing (respiratory depression)
- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- mental problems such as poor memory
- difficulty paying attention
- disrupted normal speech.

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 or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse drug Reaction reporting Form",** found online under SAHPRA's publications : https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf**.** By reporting side effects, you can help provide more information on the safety of **ZOPICLONE-INNOVATA.**

5. How to store ZOPICLONE-INNOVATA

ZOPICLONE-INNOVATA should be stored in the original packaging (keep blisters in the carton until required for use).

Store at or below 30 °C.

Protect from moisture and sunlight.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems

(e.g., toilets).

6. Contents of the pack and other information

What ZOPICLONE-INNOVATA contains:

The active substance in **ZOPICLONE-INNOVATA** is Zopiclone.

Each **ZOPICLONE-INNOVATA** 7,5 mg contains 7,5 mg of zopiclone.

The other ingredients are calcium hydrogen phosphate dihydrate, hydroxy propyl cellulose, lactose monohydrate, magnesium stearate, maize starch, opadry white (hypromellose, macrogol and titanium dioxide), starch pregelatinised.

ZOPICLONE-INNOVATA 7,5 contains: Sugar (lactose monohydrate 31.50 mg).

What ZOPICLONE-INNOVATA looks like and contents of the pack

ZOPICLONE-INNOVATA 7,5: White to off white, oval, biconvex film-coated tablets with breakline on one side.

ZOPICLONE-INNOVATA 7,5 mg Tablet: Tablets are packed in foil blister aluminium 0.02 mm plain & PVC film 250 mic transparent.
Available in blister packs of 10’s (1x10) tablets, 30’s (3x10) tablets, 60’s (6x10) tablets and 100’s (10x10) tablets

Holder of Certificate of Registration

Innovata Pharmaceuticals

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

New

Registration number

TBI

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **ZOPICLONE-INNOVATA.**