Approved Patient Information Leaflet

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ZOPICLONE 7,5 mg AUSTELL TABLETS

Read all of this leaflet carefully before you start taking ZOPICLONE 7,5 mg AUSTELL:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZOPICLONE 7,5 mg AUSTELL 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.

1.WHAT ZOPICLONE 7,5 mg AUSTELL CONTAINS

Each ZOPICLONE 7,5 mg AUSTELL tablet contains Zopiclone

Each ZOPICLONE 7,5 mg AUSTELL tablet also contains the following inactive ingredients: Calcium hydrogen phosphate dihydrate, hydroxypropylmethylcellulose, lactose monohydrate, maize starch, magnesium stearate, propylene glycol, sodium starch glycollate, talc and titanium dioxide.

ZOPICLONE 7,5 mg AUSTELL contains sugar (lactose).

2.-ZOPICLONE 7,5 mg AUSTELL **IS USED FOR**

These tablets are normally used for the short term treatment of severe sleeping difficulties.

3**.**BEFORE YOU TAKE ZOPICLONE 7,5 mg AUSTELL

Do not take ZOPICLONE 7,5 mg AUSTELL

• If you are sensitive to or allergic to zopiclone or any of the other ingredients of **ZOPICLONE 7,5 mg AUSTELL.**

• If you suffer from myasthenia gravis (a condition where the muscles easily tire and become weak)

• If you have any breathing problems, especially during sleep

• If you have any liver or kidney problems

• If you are pregnant, or think you might be pregnant

• If the patient is under 12 years of age

• If you are breastfeeding

• If you have a personality disorder

• If you have ever been treated for drug or alcohol abuse

• If you are taking any other medicines. Some medicines may change the way these tablets work e.g. any other treatment to help you sleep, any treatment for schizophrenia and psychotic disorders, any other treatment for anxiety or depression, any treatment for epilepsy, any strong pain killers such as codeine, morphine or diamorphine, sedative antihistamines (to treat allergies, skin irritation or vomiting) or erythromycin (an antibiotic used to treat infections).

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Take special care with ZOPICLONE 7,5 mg AUSTELL:

Zopiclone may lead to dependance and should be used with caution in patients with a history of drug or alcohol abuse. Do not take Zopiclone with alcohol as the sedative effect is increased.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

• Alcohol can affect the way Zopiclone works, you should not drink alcohol whilst taking these tablets.

• You should not drive if you drink alcohol whilst taking **ZOPICLONE 7,5 mg AUSTELL**.

• Rarely the tablets may cause daytime drowsiness. You should not drive or operate machinery unless you are sure that you are not affected.

• Do not drive or operate machinery whilst on Zopiclone

Important information about some of the ingredients of ZOPICLONE 7,5 mg AUSTELL:

ZOPICLONE 7,5 mg AUSTELL contains lactose monohydrate. Patients with rare hereditary conditions of lactose or galactose intolerance should not take **ZOPICLONE 7,5 mg AUSTELL**.

Using other medicines ZOPICLONE 7,5 mg AUSTELL:

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

(This includes complementary or traditional medicines).

Do not take **ZOPICLONE 7,5 mg AUSTELL** tablets if you are on the following medication:

• Drugs that work on the Central Nervous System (antipsychotics), hypnotics, anti-anxiety drugs, antidepressants, narcotic analgesics, epilepsy drugs, anaesthetics, sedative antihistamines

• Cisapride

• Carbamazepine, phenytoin

• Erythromycin may enhance the hypnotic effect of **ZOPICLONE 7,5 mg AUSTELL**

4.HOW TO TAKE ZOPICLONE 7,5 mg AUSTELL

Your doctor will have told you how much to take. The number of tablets you need to take will depend on your condition. The usual adult dosage is one **ZOPICLONE 7,5 mg AUSTELL** tablet. For elderly patients and people with liver or kidney problems, half a tablet can be used to start off with and then increased to one tablet per day. The tablets should be swallowed whole with a small glass of water shortly before going to bed. These tablets are not recommended for children.
Do not take medicines prescribed for you with others.

If you have the impression **ZOPICLONE 7,5 mg AUSTELL** is too strong or too weak, tell your doctor or pharmacist.

Do not stop taking this medication without discussing it with your doctor

If you take more ZOPICLONE 7,5 mg AUSTELL than you should:

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

5.POSSIBLE SIDE EFFECTS

ZOPICLONE 7,5 mg AUSTELL can have side effects

As well as benefits, all medicines may occasionally have unwanted effects in some patients.

These are called side effects.

If any of the following happens, stop taking ZOPICLONE 7,5 mg AUSTELL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty in breathing
- Mood changes such as irritability or aggressiveness
- Confusion
- Depression
- Loss of memory
- Hallucinations or nightmares
- Skin rashes, with or without itching.
- Swelling of lips, face and neck

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **ZOPICLONE 7,5 mg AUSTELL**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent:

- are mild bitter or metallic taste in the mouth
- stomach discomfort
- nausea or vomiting
- dizziness

- headache
- drowsiness
- dry mouth
- light headedness
- loss of coordination

frequency unknown:

- an increase in liver enzymes in your blood

All medicines may have unwanted effects which are not mentioned in the product leaflet. If you notice any other changes in your health whilst taking this medicine, tell your doctor immediately.

"Not all side effects reported for ZOPICLONE 7,5 mg AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6.STORING AND DISPOSING ZOPICLONE 7,5 mg AUSTELL

- Store at or below 25 °C.
- Protect from light.
- Do not remove the blister from the carton until required for use.
- Do not use after the expiry date stated on the blister and carton. (In both places it is given as 'EXP' followed by the month and year.)
- **"STORE ALL MEDICINES OUT OF REACH OF CHILDREN."**
- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7.**PRESENTATION ZOPICLONE 7,5 mg AUSTELL**

Blister packs of 30 tablets. Three blister strips, each containing 10 tablets.

8.IDENTIFICATION OF ZOPICLONE 7,5 mg AUSTELL

White coloured, circular biconvex film coated tablets with a score line on one side.

9. **REGISTRATION NUMBER**

A39/2.2/0022

10.NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

Johannesburg, 2193

South Africa

11.DATE OF PUBLICATION

Date on the registration certificate of the medicine: 17 February 2006

Date of the most recently revised package insert as approved by council: 06 April 2022