PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

ADCO-ZOLPIDEM HEMITARTRATE 5 mg, film-coated tablets
Each ADCO-ZOLPIDEM HEMITARTRATE 5 mg tablet contains: 5 mg zolpidem hemitartrate.
Contains sugar: Lactose monohydrate 45, 20 mg.

ADCO-ZOLPIDEM HEMITARTRATE 10 mg, film-coated tablets
Each ADCO-ZOLPIDEMHEMITARTRATE 10 mg tablet contains:10 mg zolpidem hemitartrate.
Contains sugar: Lactose monohydrate 90, 40 mg.

Read all of this leaflet carefully before you start taking ADCO-ZOLPIDEM HEMITARTRATE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE is and what it is used for

ADCO-ZOLPIDEM HEMITARTRATE 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.
ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE

Do not take ADCO-ZOLPIDEM HEMITARTRATE

- If you are hypersensitive (allergic) to zolpidem hemitartrate or any of the other ingredients of ADCO-ZOLPIDEM HEMITARTRATE (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 under the age of 18 years.
- If you are pregnant, intend to become pregnant or are breastfeeding.

Warnings and precautions
Take special care with ADCO-ZOLPIDEM HEMITARTRATE:

- The use of ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE or if you feel that you need to take ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE, consult your doctor. When medicines for sleep such as ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE. This can usually be avoided if you get a full night’s sleep (7 to 8 hours) before being active again.
- Some people taking ADCO-ZOLPIDEM HEMITARTRATE, 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 etc.) while not being fully awake after taking ADCO-ZOLPIDEM HEMITARTRATE.
- Use with caution if you have mild to moderate liver problems.
- If you suffer from mental disorders (depression or schizophrenia).
- Next day psychomotor impairment (see also ‘Driving and using
- machines’)
    - You take this medicine less than 7- 8 hours before performing activities that require your alertness.
    - You take a higher dose than recommended.

- You take zolpidem while you are already taking other central nervous system depressants or other medicines that increase zolpidem in your blood, or while drinking alcohol, or while taking illicit substances.

Children and adolescents
Do not give ADCO-ZOLPIDEM HEMITARTRATE to children or adolescents under 18 years of age.

Other medicines and ADCO-ZOLPIDEM HEMITARTRATE
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- 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 surgery)
  - medicines used in the treatment of allergies or hay fever, rashes (antihistamines that cause sleepiness)

The combination of these medicines with ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE.

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

ADCO-ZOLPIDEM HEMITARTRATE with food, drink and alcohol
You should not drink alcohol while taking ADCO-ZOLPIDEM HEMITARTRATE

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, you should not take ADCO-ZOLPIDEM HEMITARTRATE (see Do not take ADCO-ZOLPIDEM HEMITARTRATE).

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 this medicine.

Driving and using machines
ADCO-ZOLPIDEM HEMITARTRATE makes you sleepy, therefore caution should be exercised when operating machinery or driving motor vehicles.
ADCO-ZOLPIDEM HEMITARTRATE has a major influence on the ability to drive and use machines. On the day after taking ADCO-ZOLPIDEM HEMITARTRATE, you should be aware that:

- you may feel drowsy, sleepy, dizzy or confused
- your quick decision-making may be longer
- your vision may be blurred or double
- you may be less alert

A period of at least 8 hours is recommended between taking ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE as it can increase the above-mentioned effects.

ADCO-ZOLPIDEM HEMITARTRATE contains lactose monohydrate
ADCO-ZOLPIDEM HEMITARTRATE 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 this medicinal product.

3. How to take ADCO-ZOLPIDEM HEMITARTRATE

Do not share medicines prescribed for you with any other person.
Always take ADCO-ZOLPIDEM HEMITARTRATE exactly as your doctor has told you. check with your doctor or pharmacist if you are not sure.

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

Elderly
If you are over 65 years of age or have liver problems, the usual dose is 5 mg or half of a tablet (10 mg); this dose should not be exceeded except under special circumstances.
The maximum daily dose is 10 mg in any patient.
ADCO-ZOLPIDEM HEMITARTRATE 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.

If you take more ADCO-ZOLPIDEM HEMITARTRATE 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 and tell them how many tablets have been taken.
If you take too much ADCO-ZOLPIDEM HEMITARTRATE, your consciousness may be impaired, ranging from drowsiness to light coma.

If you forget to take ADCO-ZOLPIDEM HEMITARTRATE
ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE
Keep taking ADCO-ZOLPIDEM HEMITARTRATE until your doctor tells you to stop. Do not stop taking ADCO-ZOLPIDEM HEMITARTRATE 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 ADCO-ZOLPIDEM HEMITARTRATE 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
- 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.
- Sweating

4. Possible side effects

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

If any of the following happen, stop taking ADCO-ZOLPIDEM HEMITARTRATE and tell your doctor immediately or go to the causality department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- Lumpy rash (hives) or nettle rash (urticaria)

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-ZOLPIDEM HEMITARTRATE. 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)
- ADCO-ZOLPIDEM HEMITARTRATE may cause sleep walking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) 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
- Memory difficulties
- Hallucinations
- Agitation
- Nightmares
- Depression

- Tiredness
- Nose, throat or lung infections (respiratory infection)
- Back pain

Less frequent side effects:

- Confusion
- Irritability
- Restlessness
- Aggressiveness
- Delusion
- Libido disorders (changes in sex drive)
- Dependence (need to continue the sleep medicine associated with unpleasant symptoms when the sleep medicine is suddenly stopped)
- Double vision, blurred vision
- Decreased concentration
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Slower breathing (respiratory depression)
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- Itching skin or skin rash
- Excessive sweating
- Unsteadiness, fall (mainly in older patients and when ADCO-
- ZOLPIDEM HEMITARTRATE is not taken in accordance with the prescribing recommendations)
- Muscle weakness, muscle spasms, limp or weak muscles, muscle pain, joint pain

Unknown frequency side effects:

- Rage (anger)
- Abnormal behaviour
- Feeling overly happy or confident (euphoric)
- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis)
- Anxiety
- Confusion
- Tolerance (loss of effectiveness of the sleep medicine)
- Puffy or swollen face, especially around your eyes and mouth, including lips and tongue.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO-ZOLPIDEM HEMITARTRATE.

5. How to store ADCO-ZOLPIDEM HEMITARTRATE

Store all medicines out of reach of children.
Store in the original package at or below 25 °C
Protect from light and moisture.
Keep the container well-closed.
Do not take ADCO-ZOLPIDEM HEMITARTRATE after the expiry date shown on the carton and blister.
Keep the blisters in the outer carton until required for use.

6. Contents of the pack and other information

What ADCO-ZOLPIDEM HEMITARTRATE contains
The active ingredients is zolpidem tartrate.
Each ADCO-ZOLPIDEM HEMITARTRATE 5 mg film-coated tablets contains 5 mg zolpidem hemitartrate.
Each ADCO-ZOLPIDEM HEMITARTRATE 10 mg tablet contains 10 mg zolpidem hemitartrate.
The other ingredients are lactose monohydrate, microcyrstalline cellulose(Avicel PH101), sodium starch glycolate, hydroxypropyl methyl cellulose, magnesium stearate, hypromellose, titanium dioxide (E 171) and macrogol.

What ADCO-ZOLPIDEM HEMITARTRATE looks like and contents of the pack
ADCO-ZOLPIDEM HEMITARTRATE 5 mg tablets are white, oval, biconvex, film-coated tablet, embossed with “ZIM” on one side and “5” on the other side.

ADCO-ZOLPIDEM HEMITARTRATE 10 mg tablets are white, oval, biconvex, film-coated tablet, scored on both sides and debossed with “ZIM” and “10” on one side.

Holder of Certificate of Registration
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Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in
25 March 2025

Registration number (s)
ADCO-ZOLPIDEM HEMITARTRATE 5 mg: 36/2.2/0131
ADCO-ZOLPIDEM HEMITARTRATE 10 mg: 36/2.2/0132

Product name	**Registration number**
Botswana	
ADCO-ZOLPIDEM HEMITARTRATE 10 mg	BOT0801427
Namibia	
ADCO-ZOLPIDEM HEMITARTRATE 10 mg	05/2.2/0138