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-ZOLPIDEM HEMITARTRATE 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
2. What you need to know before you take ADCO-ZOLPIDEM HEMITARTRATE
3. How to take ADCO-ZOLPIDEM HEMITARTRATE
4. Possible side effects
5. How to store ADCO-ZOLPIDEM HEMITARTRATE
6. Contents of the pack and other information

1. What ADCO-ZOLPIDEM HEMITARTRATE is and what it is used for

ADCO-ZOLPIDEM HEMITARTRATE contains a medicine called zolpidem hemitartrate 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, hypromellose, 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, debossed 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
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
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	1C BOT0801427
Namibia	
ADCO-ZOLPIDEM HEMITARTRATE 10 mg	NS5 05/2.2/0138

adcock ingram

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: **S5**

ADCO-ZOLPIDEM HEMITARTRATE 5 mg, filmbedekte tablette
Elke ADCO-ZOLPIDEM HEMITARTRATE 5 mg tablet bevat: 5 mg zolpidemhemitartraat.
Bevat suiker: Laktosemonohidraat 45,20 mg.

ADCO-ZOLPIDEM HEMITARTRATE 10 mg, filmbedekte tablette
Elke ADCO-ZOLPIDEM HEMITARTRATE 10 mg tablet bevat: 10 mg zolpidemhemitartraat.
Bevat suiker: Laktosemonohidraat 90,40 mg.

Lees hierdie hele biljet noukeurig deur voordat u ADCO-ZOLPIDEM HEMITARTRATE begin gebruik
- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of u apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ADCO-ZOLPIDEM HEMITARTRATE is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat ADCO-ZOLPIDEM HEMITARTRATE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ADCO-ZOLPIDEM HEMITARTRATE neem
3. Hoe om ADCO-ZOLPIDEM HEMITARTRATE te neem
4. Moontlike newe-effekte
5. Hoe om ADCO-ZOLPIDEM HEMITARTRATE te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat ADCO-ZOLPIDEM HEMITARTRATE is en waarvoor dit gebruik word
ADCO-ZOLPIDEM HEMITARTRATE bevat 'n medisyne genaamd zolpidemhemitartraat en behoort tot 'n groep medisyne wat hipnotika genoem word. Dit werk deur op u brein in te werk om u te help slaap.
ADCO-ZOLPIDEM HEMITARTRATE word gebruik om slaap aan die gang te sit by volwassenes met ernstige slaapprobleme, ook genoem insomnia, slegs vir 'n kort tydperk.

2. Wat u moet weet voordat u ADCO-ZOLPIDEM HEMITARTRATE neem
Moenie ADCO-ZOLPIDEM HEMITARTRATE neem nie:
- Indien u hipersensitief (allergies) is vir zolpidemhemitartraat of enige van die ander bestanddele van ADCO-ZOLPIDEM HEMITARTRATE (gelys in afdeling 6) (Tekens van 'n allergiese reaksie sluit in: veluitslag, probleme om te sluk of asem te haal, swelling van die lippe, gesig, keel of tong).
- Indien u *myasthenia gravis* het ('n toestand waarin die spiere swak word en maklik moeg word).

- Indien u slaapapnee het ('n toestand waar u tydelik ophou asem haal terwyl u slaap).
- Indien u ernstige longprobleme het.
- Indien u ernstige lewerprobleme het.
- Indien u onder die ouderdom van 18 jaar is.
- Indien u swanger is, van plan is om swanger te raak of borsvoed.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met ADCO-ZOLPIDEM HEMITARTRATE:

- Die gebruik van ADCO-ZOLPIDEM HEMITARTRATE kan lei tot die ontwikkeling van misbruik en/of fisiese en sielkundige afhanklikheid. Die risiko van misbruik en afhanklikheid is groter by pasiënte met 'n geskiedenis van geestesversteurings en/of alkoholmisbruik of misbruik van onwettige middels of medisyne. Lig u gesondheidsorg-verskaffer in indien u al ooit 'n geestesversteuring gehad het, of alkohol of ander medisyne misbruik het, of daaraan verslaaf was.
- Raadpleeg asseblief u dokter indien u agterkom dat u nie kán of wil ophou om ADCO-ZOLPIDEM HEMITARTRATE te neem nie, of indien u voel dat u ADCO-ZOLPIDEM HEMITARTRATE meer gereeld moet neem as wat deur u dokter aan u voorgeskryf is.
- Gebruik versigtig indien u ligte tot matige asemhalings- of borsprobleme het.
- Indien u slaapprobleme voortduur of vererger na 'n kort tydperk van behandeling, raadpleeg u dokter.
- Indien u slaapprobleme terugkeer terwyl u ADCO-ZOLPIDEM HEMITARTRATE neem, raadpleeg u dokter. Wanneer medisyne vir slaap soos ADCO-ZOLPIDEM HEMITARTRATE vir meer as 'n paar weke gebruik word, kan dit hul doeltreffendheid om u te help slaap, verloor. Dit staan bekend as "verdraagsaamheid".
- U kan tydelike geheueverlies (amnesie) hê wanneer u ADCO-ZOLPIDEM HEMITARTRATE neem. Dit kan gewoonlik vermy word indien u 'n volle nag se slaap (7 tot 8 uur) kry voordat u weer aktief is.
- Sommige mense wat ADCO-ZOLPIDEM HEMITARTRATE neem, kan veranderinge in gedrag en denke hê (sien afdeling 4). Indien u of u gesin enige veranderinge in u gedrag opmerk, of indien u enige ongewone of ontstellende gedagtes het, raadpleeg u dokter onmiddellik.
- Indien u ooit 'n geskiedenis van slaapwandeling of ander ongewone gedrag gehad het (soos om te bestuur, eet, 'n oproep te maak of seks te hê, ens.) terwyl u nie heeltemal wakker was nadat u ADCO-ZOLPIDEM HEMITARTRATE geneem het nie.
- Gebruik versigtig indien u ligte tot matige lewerprobleme het.
- Indien u aan geestesversteurings ly (depressie of skisofrenie).
- Psigomotoriese inkorting ervaar die volgende dag (sien ook 'Bestuur en gebruik van masjinerie')
  - U neem hierdie medisyne minder as 7-8 uur voordat u aktiwiteite uitvoer wat u waaksaamheid vereis.
  - U neem 'n hoër dosis as wat aanbeveel word.

- U neem zolpidem terwyl u reeds ander sentrale senuweestelsel-depressante of ander medisyne neem wat zolpidem in u bloed verhoog, of terwyl u alkohol drink, of terwyl u onwettige middels gebruik.

Kinders en adolessente
Moenie ADCO-ZOLPIDEM HEMITARTRATE aan kinders of adolessente jonger as 18 jaar gee nie.

Ander medisyne en ADCO-ZOLPIDEM HEMITARTRATE
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Ander medisyne wat op die brein inwerk, soos:
  - medisyne wat gebruik word vir die behandeling van geestestoestande (antipsigotika, hipnotika, angswerende middels/kalmeermiddels, antidepressante)
  - medisyne wat gebruik word vir sterk pynverligting (narkotiese pynstillers)
  - medisyne wat gebruik word vir die behandeling van stuipaanvalle/stuiptrekkings (antiepileptiese medisyne)
  - verdowingsmiddels (Medisyne wat in chirurgie gebruik word)
  - medisyne wat gebruik word vir die behandeling van allergieë of hooikoors, veluitslag (antihistamiene wat slaperigheid veroorsaak)

Die kombinasie van hierdie medisyne met ADCO-ZOLPIDEM HEMITARTRATE kan u meer lomerig maak as wat dit behoort, en kan die psigomotoriese inkortingseffekte die volgende dag verhoog, insluitend verswakte bestuursvermoë. Daarbenewens kan u eufories wees (toename in welstand) indien narkotiese pynstillers (morfien en opiate) gekombineer word met ADCO-ZOLPIDEM HEMITARTRATE.

- Rifampisien (antibiotika wat gebruik word om infeksies te behandel) aangesien dit die effek van ADCO-ZOLPIDEM HEMITARTRATE op slaap kan verminder.
- Ketokonasool (wat gebruik word om infeksies te behandel) verhoog die effek van ADCO-ZOLPIDEM HEMITARTRATE.
- Fluvoksamien ('n antidepressant-medisyne) aangesien dit die effek van ADCO-ZOLPIDEM HEMITARTRATE kan verhoog. Dit word nie aanbeveel om ADCO-ZOLPIDEM HEMITARTRATE met fluvoksamien te neem nie.
- Siprofloksasien (antibiotika wat gebruik word om infeksies te behandel) aangesien dit die effek van ADCO-ZOLPIDEM HEMITARTRATE kan verhoog. Dit word nie aanbeveel om ADCO-ZOLPIDEM HEMITARTRATE saam met siprofloksasien te neem nie.
- “St John's Wort” ('n kruie-medisyne wat gebruik word vir buierigheid en depressie). Dit word nie aanbeveel om ADCO-ZOLPIDEM HEMITARTRATE saam met “St John's Wort” te neem nie.
- Opioïede (medisyne wat gebruik word vir pynverligting, ook vervat in sommige hoesmedisyne). Gepaardgaande gebruik van ADCO-ZOLPIDEM HEMITARTRATE en opioïede verhoog die risiko van slaperigheid, asemhalingsprobleme, koma en kan lewensgevaarlik wees. As gevolg hiervan moet die gelyktydige gebruik met ADCO-

ZOLPIDEM HEMITARTRATE slegs oorweeg word wanneer ander behandelingsopsies nie moontlik is nie. Lig asseblief u dokter in van alle opioïed-medisyne wat u neem.

ADCO-ZOLPIDEM HEMITARTRATE saam met kos, drank en alkohol
U moet nie alkohol drink terwyl u ADCO-ZOLPIDEM HEMITARTRATE neem nie

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of u baba borsvoed, moet u nie ADCO-ZOLPIDEM HEMITARTRATE neem nie (sien Moenie ADCO-ZOLPIDEM HEMITARTRATE neem nie).

Indien u swanger is of borsvoed, dink u dat u swanger is of is beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik van masjinerie
ADCO-ZOLPIDEM HEMITARTRATE maak u lomerig, daarom moet u versigtig wees wanneer masjinerie gebruik word of motorvoertuie bestuur word.
ADCO-ZOLPIDEM HEMITARTRATE het 'n groot invloed op die vermoë om te bestuur en masjiene te gebruik. Op die dag nadat u ADCO-ZOLPIDEM HEMITARTRATE geneem het, moet u bewus wees dat:

- u lomerig, slaperig, duiselig of verward kan voel
- u vinnige besluitneming langer kan duur
- u visie vaag of dubbel kan wees
- u dalk minder waaksaam is

'n Tydperk van ten minste 8 uur word aanbeveel tussen die neem van ADCO-ZOLPIDEM HEMITARTRATE en om te bestuur, masjinerie te gebruik en te werk op hoogtes om bogenoemde effekte te verminder.
Moenie alkohol drink of ander psigo-aktiewe stowwe neem terwyl u ADCO-ZOLPIDEM HEMITARTRATE neem nie, aangesien dit die bogenoemde effekte kan verhoog.

ADCO-ZOLPIDEM HEMITARTRATE bevat laktosemonohidraat
ADCO-ZOLPIDEM HEMITARTRATE bevat laktosemonohidraat, 'n soort suiker. Indien u deur u dokter meegedeel is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne neem.

3. Hoe om ADCO-ZOLPIDEM HEMITARTRATE te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd ADCO-ZOLPIDEM HEMITARTRATE presies soos u dokter u ingelig het.
Bevestig met u dokter of apteker indien u nie seker is nie.

Volwassenes
Die algemene volwasse dosis ADCO-ZOLPIDEM HEMITARTRATE is 10 mg snags, onmiddellik voor slaaptyd of in die bed. Die dosis van een tablet (10 mg) snags moet nie oorskry word nie.

Bejaardes
Indien u ouer as 65 jaar is of lewerprobleme het, is die algmene dosis 5 mg of die helfte van 'n tablet (10 mg); hierdie dosis moet nie oorskry word nie, behalwe onder spesiale omstandighede.
Die maksimum daaglikse dosis is 10 mg in enige pasiënt.
ADCO-ZOLPIDEM HEMITARTRATE moet slegs vir 'n paar dae tot 2 weke gebruik word, met 'n maksimum van 4 weke, wat die verminderingsproses insluit (geleidelike vermindering van u dosis voordat die behandeling oor 'n tydperk gestaak word).

Indien u meer ADCO-ZOLPIDEM HEMITARTRATE neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum en vertel hulle hoeveel tablette geneem is.
Indien u te veel ADCO-ZOLPIDEM HEMITARTRATE neem, kan u bewussyn benadeel word, wat wissel van slaperigheid tot ligte koma.

Indien u vergeet om ADCO-ZOLPIDEM HEMITARTRATE te neem
ADCO-ZOLPIDEM HEMITARTRATE moet slegs teen slaaptyd geneem word. Indien u vergeet om u tablet teen slaaptyd te neem, moet u dit nie op enige ander tyd neem nie, anders kan u gedurende die dag slaperig, duiselig en verward voel.
Moenie 'n dubbele dosis neem om op te maak vir 'n vergete tablet nie.

Indien u ophou om ADCO-ZOLPIDEM HEMITARTRATE te neem
Hou aan om ADCO-ZOLPIDEM HEMITARTRATE te neem totdat u dokter u inlig om op te hou. Moenie skielik ophou om ADCO-ZOLPIDEM HEMITARTRATE te neem nie, maar lig u dokter in indien u wil stop. U dokter sal u dosis oor 'n tydperk moet verlaag en u tablette dan eers stop. Indien u skielik ophou om ADCO-ZOLPIDEM HEMITARTRATE te neem, kan u slaapprobleme terugkom en u kan 'n 'onttrekkingseffek' kry. Indien dit gebeur, kan u 'n paar van die effekte hieronder ervaar.
Sien dadelik 'n dokter indien u enige van die volgende effekte ervaar:
- angstig, rusteloos, geïrriteerd of verward voel
- hoofpyn
- nagmerries, dinge sien of hoor wat nie werklik is nie (hallusinasies)
- meer sensitief as normaalweg wees vir lig, geraas en aanraking
- verslapte greep op die werklikheid
- voel ver van u liggaam af, of 'marionet-agtig' voel
- gevoelloosheid en tinteling in u hande en voete
- seer spiere
- maagprobleme

- slaapprobleme kom erger terug as voorheen
- in seldsame gevalle kan stuipaanvalle (stuipsametrekkings) ook voorkom.
- Sweet

4. Moontlike newe-effekte

ADCO-ZOLPIDEM HEMITARTRATE kan newe-effekte veroorsaak.
Nie alle newe-effekte wat vir ADCO-ZOLPIDEM HEMITARTRATE aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ADCO-ZOLPIDEM HEMITARTRATE neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak ADCO-ZOLPIDEM HEMITARTRATE en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme kan veroorsaak om te sluk of asem te haal
- Knopperige veluitslag (galbulte) of brandneteluitslag (urtikaria)

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op ADCO-ZOLPIDEM HEMITARTRATE gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- Verkleuring van die vel of oë, pyn in die buik (maag) of 'n opgeblaasde gevoel, erge jeukerigheid, bleek of bloederige stoelgang, uiterste swakheid, naarheid of verlies aan eetlus. Hierdie kan tekens wees van 'n probleem met u lewer.
- Stadiger asemhaling of moeilike asemhaling (respiratoriese depressie)
- ADCO-ZOLPIDEM HEMITARTRATE kan slaapwandel of ander ongewone gedrag veroorsaak (soos bestuur, eet, 'n oproep maak of seks hê, ens.) terwyl u nie heeltemal wakker is nie, waarvan sommige met ernstige beserings geassosieer word.
- Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte:

- Lomerigheid
- Duiseligheid
- Diarree
- Naarheid
- Braking
- Buikpyn
- Hoofpyn
- Verergende slaapprobleme
- Geheue probleme

- Hallusinasies
- Omgekraptheid
- Nagmerries
- Depressie
- Moegheid
- Neus-, keel- of longinfeksies (respiratoriese infeksie)
- Rugpyn

Minder gereelde newe-effekte:
- Verwarring
- Prikkelbaarheid
- Rusteloosheid
- Aggressiwiteit
- Delusies
- Libido-versteurings (veranderinge in seksdrang)
- Afhanklikheid (moet voortgaan met die slaapmedisyne wat verband hou met onaangename simptome wanneer die slaapmedisyne skielik gestaak word)
- Dubbele visie, versteurde visie
- Verminderde konsentrasie
- Ongewone velsensasies soos gevoelloosheid, tinteling, prikkeling, brand of kruiperige gevoel op die vel (parestesie)
- Stadiger asemhaling (respiratoriese depressie)
- Veranderinge in die hoeveelheid lewerensieme – verskyn in die resultate van bloedtoetse
- Jeukerige vel of veluitslag
- Oormatige sweet
- Onbestendigheid, val (hoofsaaklik by ouer pasiënte en wanneer ADCO-ZOLPIDEM HEMITARTRATE nie geneem word in ooreenstemming met die voorskrif-aanbevelings nie)
- Spierswakheid, spierspasmas, slap of swak spiere, spierpyn, gewrigspyn

Newe-effekte van onbekende frekwensie:
- Woede-uitbarsting (kwaad word)
- Abnormale gedrag
- Voel uitermatig gelukkig of selfversekerd (eufories)
- Uit voeling voel met die werklikheid en nie in staat wees om duidelik te dink of te oordeel nie (psigose)
- Angs
- Verwarring
- Verdraagsaamheid (verlies aan doeltreffendheid van die slaapmedisyne)
- Opgeblaasde of geswelde gesig, veral rondom u oë en mond, insluitend lippe en tong.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldings-platform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ADCO-ZOLPIDEM HEMITARTRATE te verskaf.

5. Hoe om ADCO-ZOLPIDEM HEMITARTRATE te bêre
Bêre alle medisyne buite bereik van kinders.
Bêre in die oorspronklike verpakking teen of benede 25 °C
Beskerm teen lig en vogtigheid.
Hou die houer dig toe.
Moenie ADCO-ZOLPIDEM HEMITARTRATE neem ná die vervaldatum wat op die karton en stulpstrook aangedui word nie.
Hou die stulpstroke in die buitenste kartonboksie totdat dit benodig word vir gebruik.

6. Inhoud van die verpakking en ander inligting
Wat ADCO-ZOLPIDEM HEMITARTRATE bevat
Die aktiewe bestanddele is zolpidemtartraat.
Elke ADCO-ZOLPIDEM HEMITARTRATE 5 mg filmbedekte tablet bevat 5 mg zolpidemhemitartraat.
Elke ADCO-ZOLPIDEM HEMITARTRATE 10 mg tablet bevat 10 mg zolpidemhemitartraat.
Die ander bestanddele is laktosemonohidraat, mikrokristallyne sellulose (Avicel PH101), natriumstyselglikolaat, hipromellose, magnesiumstearaat, hipromellose, titaniumdioksied (E 171) en makrogol.

Hoe ADCO-ZOLPIDEM HEMITARTRATE lyk en die inhoud van die verpakking
ADCO-ZOLPIDEM HEMITARTRATE 5 mg tablette is wit, ovaal, bikonvekse, filmbedekte tablette, gegraveer met "ZIM" aan die een kant en "5" aan die ander kant.

ADCO-ZOLPIDEM HEMITARTRATE 10 mg tablette is wit, ovaal, bikonvekse, filmbedekte tablette, gekeep aan beide kante en gegraveer met "ZIM" en "10" aan die een kant.

Houer van Sertifikaat van Registrasie
Adcock Ingram Limited
New Road 1
Erand Gardens
Midrand
1685
Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
25 Maart 2025

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

Produknaam	**Registrasienommer**
Botswana	
ADCO-ZOLPIDEM HEMITARTRATE 10 mg	1C BOT0801427
Namibië	
ADCO-ZOLPIDEM HEMITARTRATE 10 mg	NS5 05/2.2/0138

adcock ingram

344077-03 & 344073-03
05/2025