**SCHEDULING STATUS:** S5

**ZOLPIDEM XR 12,5 ADCO, extended-release tablets**
**Zolpidem tartrate**
**Contains sugar (ZOLPIDEM XR 12,5 ADCO contains 120,85 mg lactose monohydrate per tablet)**

**Read all of this leaflet carefully before you start taking ZOLPIDEM XR 12,5 ADCO**
- 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.
- ZOLPIDEM XR 12,5 ADCO 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 ZOLPIDEM XR 12,5 ADCO is and what it is used for
2. What you need to know before you take ZOLPIDEM XR 12,5 ADCO
3. How to take ZOLPIDEM XR 12,5 ADCO
4. Possible side effects
5. How to store ZOLPIDEM XR 12,5 ADCO
6. Contents of the pack and other information

## 1. What ZOLPIDEM XR 12,5 ADCO is and what it is used for
ZOLPIDEM XR 12,5 ADCO 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.
ZOLPIDEM XR 12,5 ADCO is used to initiate sleep in adults below the age of 65 years with sleeping difficulties, also called insomnia, for a short-term only.

## 2. What you need to know before you take ZOLPIDEM XR 12,5 ADCO
**Do not take ZOLPIDEM XR 12,5 ADCO**
- if you are hypersensitive (allergic) to zolpidem tartrate or any of the other ingredients of ZOLPIDEM XR 12,5 ADCO (listed in section 6).
- if you are a child under 18 years of age.
- if you have sleep apnoea (a condition where you temporarily stop breathing while you sleep).
- if you have myasthenia gravis (a condition in which the muscles become weak and tire easily).
- if you have serious liver problems.
- if you have severe lung problems.
- if you are pregnant or are breastfeeding.

**Warnings and precautions**

**Take special care with ZOLPIDEM XR 12,5 ADCO**

- Use with caution if you have mild to moderate breathing or chest problems.
- You may have temporary memory loss (amnesia) when taking ZOLPIDEM XR 12,5 ADCO. This can usually be avoided if you get a full night's of sleep (7 to 8 hours) before being active again.
- Symptoms like restlessness, irritability, agitation, aggression, delusion, anger, nightmares, hallucinations, abnormal behaviour are known to occur when taking ZOLPIDEM XR 12,5 ADCO. Should these occur stop taking ZOLPIDEM XR 12,5 ADCO and consult your health care provider immediately.
- If you have a history or are experiencing the following symptoms while taking ZOLPIDEM XR 12,5 ADCO: sleep walking, sleep driving, preparing and eating food, making phone calls or having sex, with no memory of these events. Consult your health care provider immediately if you experience any of the above symptoms.
- If your sleep problems return while you are taking ZOLPIDEM XR 12,5 ADCO, consult your doctor. When medicines for sleep such as ZOLPIDEM XR 12,5 ADCO are used for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as tolerance.
- The use of ZOLPIDEM XR 12,5 ADCO may lead to the development of abuse and/or physical and mental dependence. The risk of abuse and dependence is greater in patients with a history of mental disorders and/or alcohol, illegal 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.
- If your sleep problems persist or worsen after a short period of treatment, consult your doctor.
- If you have mild to moderate liver problems.
- Some people taking ZOLPIDEM XR 12,5 ADCO 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 have heart problems.

**Children and adolescents**

Do not give ZOLPIDEM XR 12,5 ADCO to children or adolescents under 18 years of age.

**Other medicines and ZOLPIDEM XR 12,5 ADCO**

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

Tell your doctor or pharmacist if you are currently taking:

- Other medicines that work 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, opioids),

- medicines used for the treatment of seizures/fits (antiepileptic medicines),
- anaesthetics,
- medicines used in the treatment of allergies (antihistamines that cause sleepiness).

The combination of these medicines with ZOLPIDEM XR 12,5 ADCO 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 ZOLPIDEM XR 12,5 ADCO.

- Medicine used to treat fungal infections (ketoconazole) increases the effect of ZOLPIDEM XR 12,5 ADCO.
- The following medicines may increase the effect of ZOLPIDEM XR 12,5 ADCO and it is not recommended to take them together:
  - medicine used to treat depression (fluvoxamine)
  - medicine used to treat bacterial infections (ciprofloxacin).
- The following medicines may decrease the effect of ZOLPIDEM XR 12,5 ADCO and it is not recommended to take them together:
  - medicine used to treat tuberculosis (TB) (rifampicin)
  - herbal medicine used for mood swings and depression (St John's Wort).

**ZOLPIDEM XR 12,5 ADCO with food, drink, and alcohol**

ZOLPIDEM XR 12,5 ADCO should not be administered with or immediately after a meal, for faster onset of sleep.

ZOLPIDEM XR 12,5 ADCO should not be taken with alcohol.

**Pregnancy and breastfeeding**

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 ZOLPIDEM XR 12,5 ADCO.

Do not take ZOLPIDEM XR 12,5 ADCO during pregnancy and breastfeeding (see Do not take ZOLPIDEM XR 12,5 ADCO).

**Driving and using machines**

ZOLPIDEM XR 12,5 ADCO may cause side effects, such as sleepiness, prolonged reaction time, dizziness, blurred/double vision and reduced alertness and can affect your ability to drive a vehicle and use machines the morning after taking the tablet. To minimise this risk, a full night of sleep (7 – 8 hours) is recommended between taking ZOLPIDEM XR 12,5 ADCO and driving a vehicle or operating machines. It is not always possible to predict to what extent ZOLPIDEM XR 12,5 ADCO may interfere with your daily activities. You should not engage in the above activities until you are aware of the measure to which ZOLPIDEM XR 12,5 ADCO affects you.

Do not drink alcohol or take other medicines that enhances the effects of ZOLPIDEM XR 12,5 ADCO while you are taking ZOLPIDEM XR 12,5 ADCO as it can increase the above listed effects.

**ZOLPIDEM XR 12,5 ADCO contains lactose monohydrate**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZOLPIDEM XR 12,5 ADCO.

**ZOLPIDEM XR 12,5 ADCO contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per extended-release tablet, that is to say essentially 'sodium-free'.

## 3. How to take ZOLPIDEM XR 12,5 ADCO

Do not share medicines prescribed for you with any other person.
Always take ZOLPIDEM XR 12,5 ADCO exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult (< 65 years) dose is one tablet of ZOLPIDEM XR 12,5 ADCO at night, immediately before bedtime or in bed.
The maximum dose is 12,5 mg (one tablet of ZOLPIDEM XR 12,5 ADCO) at night. **Do not exceed the maximum dose.**
ZOLPIDEM XR 12,5 ADCO should be taken in a single intake and not taken again during the same night.
ZOLPIDEM XR 12,5 ADCO should only be used for a few days to 2 weeks with a maximum of 4 weeks, which including the tapering off (gradual reduction of your dose before stopping treatment over a period) process.
If you have the impression that the effect of ZOLPIDEM XR 12,5 ADCO is too strong or too weak, tell your doctor or pharmacist.

**If you take more ZOLPIDEM XR 12,5 ADCO than you should**
If you take more ZOLPIDEM XR 12,5 ADCO than you should, your consciousness may be impaired, ranging from sleepiness to 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 ZOLPIDEM XR 12,5 ADCO**
ZOLPIDEM XR 12,5 ADCO must only be taken at bedtime. If you forget to take the tablet before you go to bed, do not take it if you wake up late in the night or very early in the morning. Take ZOLPIDEM XR 12,5 ADCO before bedtime the following day.
Do not take a double dose to make up for forgotten individual doses.

**If you stop taking ZOLPIDEM XR 12,5 ADCO**
Do not stop taking ZOLPIDEM XR 12,5 ADCO immediately. The dose must be reduced gradually over a period. You can experience headaches, muscle pain, extreme anxiety and tension, restlessness, confusion and irritability if you stop taking ZOLPIDEM XR 12,5 ADCO immediately.

## 4. Possible side effects

ZOLPIDEM XR 12,5 ADCO can have side effects.
Not all side effects reported for ZOLPIDEM XR 12,5 ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOLPIDEM XR 12,5 ADCO, please consult your health care provider for advice.
If any of the following happens, stop taking ZOLPIDEM XR 12,5 ADCO 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 ZOLPIDEM XR 12,5 ADCO. 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:

- Amnesia (memory loss),
- hallucination (seeing or hearing things that are not real), depersonalisation (your thoughts and feelings feel as though they belong to someone else),
- changes in the way your heart beats, for example, if you notice it beating faster than normal, abnormal heart rhythms, chest pain, blood clot, heart attack, excess fluid in the lungs,
- sleeping problems that get worse after taking this medicine,
- suicide attempts, suicidal thoughts.

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:*

- Influenza (cough, congestion, runny nose),
- anxiety, slowed speech, disorientation,
- headache, dizziness, drowsiness, memory problems, attention problems, drugged feeling, dry mouth, light headedness, feeling overly happy/confident (euphoric), feeling sluggish,
- visual disturbances, double vision, eye redness,
- sinusitis,
- nausea (feeling sick), constipation, diarrhoea, stomach ache, indigestion, hiccups,
- muscle pain/cramps, neck pain, back pain,
- bladder or kidney infection
- tiredness.

*Less frequent side effects:*

- Lower and upper respiratory tract infections, ear infection with discharge from the ear (inner, middle and outer), shingles (a viral infection) (herpes simplex), abscess,
- anaemia, abnormal blood test results, low white blood cell count, thrombosis (blood clot),

- intestinal infection marked by diarrhoea and cramps, middle ear infection, outer ear infection, abscess, shingles,
- appetite disorder, high blood glucose levels, thirst, gout, high cholesterol, puffy eyes, abnormal blood test results, higher appetite, weight loss,
- depression, confusion, lack of interest, mood swings, binge eating, nightmares, feeling very happy, stress symptoms, a sensation of impending threat, feelings of suffocation, and sensations of floating, spinning or falling when falling asleep,
- hallucination (seeing and hearing things that are not real),
- an extreme, unrealistic feeling of physical and emotional well-being,
- depersonalisation (a state in which one's thoughts and feelings seem unreal or not to belong to oneself),
- unsteadiness/tendency to fall, numbness, pins and needles, a lack of muscle control or coordination of voluntary movements, such as walking or picking up objects, burning sensation, dizziness when standing up, altered taste, muscle spasm, tremor, agitation, trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life, feeling detached, slurred speech, exaggerated mood swings (uncontrollable laughing or crying, or heightened irritability or temper), poor concentration, nervousness, abnormal thinking, memory loss/forgetfulness, illusion, leg cramps, migraine, sleeping (after daytime dosing), yawning, increased sweating, unhealthy pale appearance,
- speech disorder, a state of near-unconsciousness or insensibility, unable to walk in the usual way, aggressive reaction, lack of interest, enthusiasm, or concern, lower sex drive, a belief of altered reality, memory loss, feeling that you're observing yourself from outside your body, a stabbing, burning, and often severe pain due to an irritated or damaged nerve, inflammation of a nerve, damage to the nerves, poor ability to adapt to your environment, panic attacks, weakened muscle movements, personality disorder, sleepwalking, involuntary muscle contractions, fainting, hot flushes, cramping rectal pain with a feeling that bowel needs to be emptied even if you already had complete bowel movement, increased or altered saliva, weakness, loss of movement, impotence (sexual dysfunction),
- foul, salty or metallic taste in your mouth,
- red eyes, blurred vision, altered visual depth perception, tired eyes, eye irritation, eye pain, eye inflammation, conjunctivitis (pink eye), abnormal secretion of tears, seeing flashes of light, increased pressure in the eye, a problem with focusing, an open sore in the eye,
- vertigo (sensation of spinning or swaying), ringing or buzzing noise in both ears,
- rapid heartbeats, low blood pressure (including when getting up from a lying down), position conditions that affect blood flow and the blood vessels in the brain, high blood pressure and worsening of high blood pressure, artery or vein inflammation, varicose veins,
- cough, dry irritated throat, bronchitis (inflammation of the lining of bronchial tubes), laryngitis (throat infection), pneumonia (lung infection), difficulty or shallow breathing, nose bleeds,
- vomiting (being sick), stomach pain, excessive gas in your stomach, frequent bowel movements,a burning sensation in your chest (heartburn) usually after eating which might be worse at night, inflammation of the small intestine, burping, inflammation of the stomach, haemorrhoids, obstruction in the intestines, bleeding from your rectum, tooth cavities,

- blood disorders, including low blood cell count, abnormal lymph node size, unusual large red blood cells, purple-coloured spots and patches that occur on the skin, and in mucus membranes, including the lining of the mouth, porphyria (a rare hereditary blood disease),
- wrinkling of your skin, skin rashes, hives, contact eczema, acne, light sensitivity, skin wrinkles, itching skin, forming of blisters, boils,
- pain in a joint, arthritis (joint inflammation), sciatica (compressed nerve in the lower back causing back, leg and hip pain), osteoarthritis, tendon inflammation,
- painful or difficult urination, bladder infection, passing more or less urine than is normal for you, inability to pass urine, frequent urination at night, kidney infection, kidney pain,
- heavy menstrual flow, itchy and sore in and around your vagina (women), breast pain, painful menstruation, breast tumour,
- abnormal physical weakness or lack of energy, feeling of tiredness, drowsiness, pain, fever, chest discomfort, feeling drunk, influenza-like illness, swelling, falling, general discomfort, trauma, swelling in the face, hot flashes, restless legs, higher tolerance to medicines,
- higher body temperature, higher heart rate, abnormal blood test results.

*Frequency unknown side effects:*
- Sleep walking, restlessness, aggression, delusion, anger, abnormal behaviour, dependence/addiction,
- liver injury,
- muscle weakness.

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 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 ZOLPIDEM XR 12,5 ADCO.

## 5. How to store ZOLPIDEM XR 12,5 ADCO
- Store at or below 30 °C.
- Store all medicines out of reach of children.
- Keep the tablets in the bottle and the blister strip in the outer carton until required for use.
- Do not take ZOLPIDEM XR 12,5 ADCO after the expiry date shown on the bottle or blister.
- 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 ZOLPIDEM XR 12,5 ADCO contains**
The active substance is zolpidem tartrate.

ZOLPIDEM XR 12,5 ADCO: Each tablet contains 12,5 mg zolpidem tartrate.
The other ingredients are colloidal silicon dioxide, FD & C Blue no. 2 aluminium lake (E132), hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry Blue (consisting of FD & C Blue no. 2 aluminium lake (E132), hypromellose, polyethylene glycol, titanium dioxide (E171)), potassium bitartrate, sodium starch glycolate.

**What ZOLPIDEM XR 12,5 ADCO looks like and contents of the pack**
ZOLPIDEM XR 12,5 ADCO: Blue coloured, round, biconvex, film-coated, tablets debossed with E62 on one side and LU on the other side.
Round, opaque white HDPE bottle with a child resistant closure and containing a 1 g silica gel sachet.
Pack sizes: 30 or 100 tablets.

Clear PVC/Aclar film and plain aluminium foil (one side bright and other side dull and lacquered) blister strip, placed in an outer carton.
Pack sizes: 20 tablets (2 blister strips; 10 tablets per blister) or 30 tablets (3 blister strips; 10 tablets per blister)

Not all pack sizes may be marketed.

**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**
20 August 2025

**Registration number**
57/2.2/0188

**PASIËNT INLIGTINGSBILJET**

---

**SKEDULERINGSTATUS:** S5

**ZOLPIDEM XR 12,5 ADCO, tablette met verlengde vrystelling**
**Zolpidemtartraat**
**Bevat suiker (ZOLPIDEM XR 12,5 ADCO bevat 120,85 mg laktosemonohidraat per tablet)**

**Lees hierdie hele biljet noukeurig deur voordat u begin om ZOLPIDEM XR 12,5 ADCO te neem**

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ZOLPIDEM XR 12,5 ADCO is aan u persoonlik voorgeskryf en u moenie 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 ZOLPIDEM XR 12,5 ADCO is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ZOLPIDEM XR 12,5 ADCO neem
3. Hoe om ZOLPIDEM XR 12,5 ADCO te neem
4. Moontlike newe-effekte
5. Hoe om ZOLPIDEM XR 12,5 ADCO te bêre
6. Inhoud van die verpakking en ander inligting


## 1. Wat ZOLPIDEM XR 12,5 ADCO is en waarvoor dit gebruik word

ZOLPIDEM XR 12,5 ADCO bevat 'n medisyne genaamd zolpidemtartraat en behoort tot 'n groep medisyne wat hipnotika genoem word. Dit werk deur op u brein in te werk om u te help slaap. ZOLPIDEM XR 12,5 ADCO word gebruik om slaap slegs vir 'n kort periode te begin by volwassenes onder die ouderdom van 65 jaar, en slaapprobleme, ook genoem insomnia, het.

## 2. Wat u moet weet voordat u ZOLPIDEM XR 12,5 ADCO neem

**Moenie ZOLPIDEM XR 12,5 ADCO neem nie**

- indien u hipersensitief (allergies) is vir zolpidemtartraat of enige van die ander bestanddele van ZOLPIDEM XR 12,5 ADCO (gelys in afdeling 6).
- indien u 'n kind jonger as 18 jaar is.
- indien u slaapapnee het ('n toestand waar u tydelik ophou asem haal terwyl u slaap).
- indien u *myasthenia gravis* het ('n toestand waarin die spiere swak word en maklik moeg word).
- indien u ernstige lewerprobleme het.
- indien u ernstige longprobleme het.
- indien u swanger is of borsvoed.

**Waarskuwings en voorsorgmaatreëls**

**Wees veral versigtig met ZOLPIDEM XR 12,5 ADCO**

- Gebruik versigtig indien u ligte tot matige asemhalings- of borsprobleme het.

- U kan tydelike geheueverlies (amnesie) hê wanneer u ZOLPIDEM XR 12,5 ADCO neem. Dit kan gewoonlik vermy word indien u 'n volle nag se slaap (7 tot 8 uur) inkry voordat u weer aktief is.
- Dit is bekend dat simptome soos rusteloosheid, prikkelbaarheid, geïrriteerdheid, aggressie, delusies, woede, nagmerries, hallusinasies, abnormale gedrag voorkom wanneer ZOLPIDEM XR 12,5 ADCO geneem word. Indien dit gebeur, staak ZOLPIDEM XR 12,5 ADCO en raadpleeg u gesondheidsorgverskaffer onmiddellik.
- Indien u 'n geskiedenis het van, of die volgende simptome ervaar terwyl u ZOLPIDEM XR 12,5 ADCO neem: in u slaap wandel, in u slaap bestuur, kos voorberei en eet, telefoonoproepe maak of seks hê, sonder herinnering aan hierdie gebeure. Raadpleeg u gesondheidsorg-verskaffer onmiddellik indien u enige van die bogenoemde simptome ervaar.
- Indien u slaapprobleme terugkeer terwyl u ZOLPIDEM XR 12,5 ADCO neem, raadpleeg u dokter. Wanneer medisyne vir slaap soos ZOLPIDEM XR 12,5 ADCO vir langer as 'n paar weke gebruik word, kan dit die doeltreffendheid daarvan verloor om u te help slaap. Dit staan bekend as verdraagsaamheid.
- Die gebruik van ZOLPIDEM XR 12,5 ADCO kan lei tot die ontwikkeling van misbruik en/of fisiese en geestelike afhanklikheid. Die risiko van misbruik en afhanklikheid is groter by pasiënte met 'n geskiedenis van geestesversteurings en/of alkohol-, onwettige middel- of medisynemisbruik. Lig u gesondheidsorgverskaffer in indien u al ooit 'n geestesversteuring gehad het, of alkohol of ander medisyne misbruik, of daaraan verslaaf was.
- Indien u slaapprobleme voortduur of vererger na 'n kort tydperk van behandeling, raadpleeg u dokter.
- Indien u ligte tot matige lewerprobleme het.
- Sommige mense wat ZOLPIDEM XR 12,5 ADCO neem, kan veranderinge in gedrag en denke ervaar (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 hartprobleme het.

**Kinders en adolessente**
Moenie ZOLPIDEM XR 12,5 ADCO aan kinders of adolessente jonger as 18 jaar gee nie.

**Ander medisyne en ZOLPIDEM XR 12,5 ADCO**
Lig altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Lig u dokter of apteker in indien u tans neem:
- Ander medisyne wat op die brein werk, soos:
  - medisyne wat gebruik word vir die behandeling van geestestoestande (antipsigotika, hipnotika, angswerende/kalmeermiddels, antidepressante),
  - medisyne wat gebruik word vir sterk verligting van pyn (narkotiese pynstillers, opioïede),
  - medisyne wat gebruik word vir die behandeling van stuipaanvalle (anti-epileptiese medisyne),

- verdowingsmiddels,
- medisyne wat gebruik word vir die behandeling van allergieë (antihistamiene wat slaperigheid veroorsaak).

Die kombinasie van hierdie medisyne met ZOLPIDEM XR 12,5 ADCO kan u meer lomerig maak as wat dit behoort en kan die volgende dag psigomotoriese inkortingseffekte, insluitend verswakte bestuursvermoë, verhoog. Daarbenewens kan u eufories wees (toename van welstandsgevoel) indien narkotiese pynstillers (morfien en opiate) gekombineer word met ZOLPIDEM XR 12,5 ADCO.

- Medisyne wat gebruik word om swaminfeksies te behandel (ketokonasool) verhoog die effek van ZOLPIDEM XR 12,5 ADCO.
- Die volgende medisyne kan die effek van ZOLPIDEM XR 12,5 ADCO verhoog, en dit word aanbeveel om nie tegelykertyd te gebruik nie:
  - medisyne wat gebruik word om depressie te behandel (fluvoksamien)
  - medisyne wat gebruik word om bakteriële infeksies te behandel (siprofloksasien).
- Die volgende medisyne kan die effek van ZOLPIDEM XR 12,5 ADCO verminder en dit word aanbeveel om nie tegelykertyd te gebruik nie:
  - medisyne wat gebruik word om tuberkulose (TB) te behandel (rifampisien)
  - kruiemedisyne wat gebruik word vir buierigheid en depressie (“St John 's Wort”).

**ZOLPIDEM XR 12,5 ADCO saam met kos, drank en alkohol**

ZOLPIDEM XR 12,5 ADCO moet nie saam met, of onmiddellik na 'n maaltyd toegedien word nie, vir vinniger aanvang van slaap.

ZOLPIDEM XR 12,5 ADCO moet nie saam met alkohol geneem word nie.

**Swangerskap en borsvoeding**

Indien u swanger is of borsvoed, dink u kan swanger wees of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u ZOLPIDEM XR 12,5 ADCO neem.

Moenie ZOLPIDEM XR 12,5 ADCO tydens swangerskap en borsvoeding neem nie (sien Moenie ZOLPIDEM XR 12,5 ADCO neem nie).

**Bestuur en gebruik masjiene**

ZOLPIDEM XR 12,5 ADCO kan newe-effekte veroorsaak, soos lomerigheid, verlengde reaksietyd, duiseligheid, versteurde/dubbele visie en verminderde waaksaamheid, en kan u vermoë om 'n voertuig te bestuur en masjinerie die oggend ná die neem van die tablet beïnvloed. Om hierdie risiko te verminder, word 'n volle nag se slaap (7 – 8 uur) aanbeveel tussen die neem van ZOLPIDEM XR 12,5 ADCO en die bestuur van 'n voertuig of die hantering van masjinerie. Dit is nie altyd moontlik om te voorspel in watter mate ZOLPIDEM XR 12,5 ADCO met u daaglikse aktiwiteite kan inmeng nie. U moet nie aan bogenoemde aktiwiteite deelneem voordat u bewus is van die mate waartoe ZOLPIDEM XR 12,5 ADCO u beïnvloed nie. Moenie alkohol drink of ander medisyne neem wat die effekte van ZOLPIDEM XR 12,5 ADCO verhoog terwyl u ZOLPIDEM XR 12,5 ADCO neem nie, aangesien dit die bogenoemde effekte kan verhoog.

**ZOLPIDEM XR 12,5 ADCO bevat laktosemonohidraat**
Indien u deur u dokter meegedeel is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u ZOLPIDEM XR 12,5 ADCO neem.

**ZOLPIDEM XR 12,5 ADCO bevat natrium**
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per verlengde vrystelling tablet, dit is in wese ‘natriumvry’.

## 3. Hoe om ZOLPIDEM XR 12,5 ADCO te neem

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd ZOLPIDEM XR 12,5 ADCO presies soos u dokter u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die gewone volwassene (< 65 jaar) dosis is een tablet ZOLPIDEM XR 12,5 ADCO saans, onmiddellik voor slaaptyd of in die bed.
Die maksimum dosis is 12,5 mg (een tablet ZOLPIDEM XR 12,5 ADCO) saans. **Moenie die maksimum dosis oorskry nie.**
ZOLPIDEM XR 12,5 ADCO moet in 'n enkele inname geneem word en nie weer gedurende dieselfde nag geneem word nie.
ZOLPIDEM XR 12,5 ADCO moet slegs vir 'n paar dae tot 2 weke gebruik word met 'n maksimum van 4 weke, wat die geleidelike afname proses insluit (geleidelike vermindering van u dosis voordat die behandeling oor 'n tydperk gestaak word).
Indien u die indruk het dat die effek van ZOLPIDEM XR 12,5 ADCO te sterk of te swak is, lig u dokter of apteker in.

**Indien u meer ZOLPIDEM XR 12,5 ADCO neem as wat u moes**
Indien u meer ZOLPIDEM XR 12,5 ADCO neem as wat u moes, kan u bewussyn benadeel word, wat wissel van lomerigheid tot koma.
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

**Indien u vergeet om ZOLPIDEM XR 12,5 ADCO te neem**
ZOLPIDEM XR 12,5 ADCO moet slegs voor slaaptyd geneem word. Indien u vergeet om die tablet te neem voordat u gaan slaap, moenie dit neem indien u laat in die nag of baie vroeg in die oggend wakker word nie. Neem ZOLPIDEM XR 12,5 ADCO voor slaaptyd die volgende dag. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

**Indien u ophou om ZOLPIDEM XR 12,5 ADCO te neem**
Moenie dadelik ophou om ZOLPIDEM XR 12,5 ADCO te neem nie. Die dosis moet geleidelik oor 'n tydperk verminder word. U kan hoofpyn, spierpyn, uiterste angs en spanning, rusteloosheid, verwarring en prikkelbaarheid ervaar indien u skielik ophou om ZOLPIDEM XR 12,5 ADCO te neem.

## 4. Moontlike newe-effekte

ZOLPIDEM XR 12,5 ADCO kan newe-effekte hê.
Nie alle newe-effekte wat vir ZOLPIDEM XR 12,5 ADCO aangemeld is, word by hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ZOLPIDEM XR 12,5 ADCO neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, staak ZOLPIDEM XR 12,5 ADCO en raadpleeg u dokter dadelik, 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,
- veluitslag of jeukerigheid,
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op ZOLPIDEM XR 12,5 ADCO gehad. U benodig dalk dringende mediese hulp of hospitalisasie.

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

- Amnesie (geheueverlies),
- hallusinasie (sien of hoor dinge wat nie werklik is nie), depersonalisering (u gedagtes en gevoelens voel asof dit aan iemand anders behoort),
- veranderinge in die manier waarop u hart klop, byvoorbeeld indien u agterkom dat dit vinniger as normaalweg klop, abnormale hartritmes, borspyn, bloedklont, hartaanval, oortollige vloeistof in die longe,
- slaapprobleme wat erger word nadat u hierdie medisyne geneem het,
- selfdoodpogings, selfdoodgedagtes.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Vertel u dokter indien u enige van die volgende opmerk:
*Gereelde newe-effekte:*

- Griep (hoes, geblokte neus, loopneus),
- angs, vertraagde spraak, disoriëntasie,
- hoofpyn, duiseligheid, lomerigheid, geheueprobleme, probleme om aandag te skenk, bedwelmde gevoel, droë mond, lighoofdigheid, te gelukkig/selfversekerd voel (eufories), traag voel,
- gesigsteurnisse, dubbelvisie, rooiheid van die oog,
- sinusitis,
- naarheid (naar gevoel), hardlywigheid, diarree, maagpyn, slegte spysvertering, hik,
- spierpyn/-krampe, nekpyn, rugpyn,
- blaas- of nierinfeksie,
- moegheid.

*Minder gereelde newe-effekte:*

- Infeksies in die onderste en boonste lugweë, oorinfeksie met afskeiding uit die oor (binne, middel en buitenste), gordelroos ('n virusinfeksie) (*herpes simplex*), abses,
- bloedarmoede, abnormale bloedtoetsresultate, lae witbloedseltelling, trombose (bloedklont),
- derminfeksie gekenmerk deur diarree en krampe, middeloorinfeksie, buiteoorinfeksie, abses, gordelroos,
- eetlusversteuring, hoë bloedglukosevlakke, dors, jig, hoë cholesterol, opgeswelde oë, abnormale bloedtoetsresultate, verhoogde eetlus, gewigsverlies,
- depressie, verwarring, gebrek aan belangstelling, buierigheid, oormatig eet, nagmerries, baie gelukkig voel, stres simptome, 'n gevoel van aankomende bedreiging, gevoelens van verstikking, en sensasies van dryf, draai of val wanneer u aan die slaap raak,
- hallusinasie (sien en hoor dinge wat nie werklik is nie),
- 'n uiterste, onrealistiese gevoel van fisiese en emosionele welstand,
- depersonalisering ('n toestand waarin 'n mens se gedagtes en gevoelens onwerklik lyk of voel asof dit nie aan uself behoort nie),
- onbestendigheid/neiging om te val, gevoelloosheid, naalde-en-spelde, 'n gebrek aan spierbeheer of koördinasie van vrywillige bewegings, soos om te loop of voorwerpe op te tel, brandende sensasie, duiseligheid wanneer u opstaan, veranderde smaak, spierspasma, bewing, geïrriteerdheid, probleme om te onthou, nuwe dinge te leer, te konsentreer of besluite te neem wat hul alledaagse lewe beïnvloed, verwyderd voel, onduidelike spraak, oordrewe buierigheid (onbeheerbare lag of huil, of verhoogde prikkelbaarheid of humeur), swak konsentrasie, senuweeagtigheid, abnormale denke, geheueverlies/vergeetagtigheid, illusie, beenkrampe, migraine, slaap (na dosering gedurende die dag), gaap, verhoogde sweet, ongesonde bleek voorkoms,
- spraakversteuring, 'n toestand van byna bewusteloosheid of geen sintuiglike bewustheid nie, nie in staat om op die gewone manier te loop nie, aggressiewe reaksie, gebrek aan belangstelling, entoesiasme of besorgdheid, laer seksdrang, 'n oortuiging van veranderde werklikheid, geheueverlies, gevoel dat u uself van buite u liggaam waarneem, 'n stekerige, brandende en dikwels erge pyn as gevolg van 'n geïrriteerde of beskadigde senuwee, inflammasie van 'n senuwee, skade aan die senuwees, swak vermoë om aan te pas by u omgewing, paniekaanvalle, verswakte spierbewegings, persoonlikheidsversteuring, slaapwandeling, onwillekeurige spiersametrekkings, floute, warm gloede, krampagtige rektale pyn met 'n gevoel dat die derm leeggemaak moet word, selfs al het u reeds ‘n volledige dermbeweging gehad het, verhoogde of veranderde speekselvorming, swakheid, verlies aan beweging, impotensie (seksuele disfunksie),
- onaangename, sout of metaalsmaak in u mond,
- rooi oë, versteurde visie, veranderde visuele dieptepersepsie, moeë oë, oogirritasie, oogpyn, oogontsteking, konjunktivitis (pienk oog), abnormale afskeiding van trane, sien ligflitse, verhoogde druk in die oog, 'n probleem met fokus, 'n oop seer in die oog,
- vertigo (sensasie van draai of swaai), lui of gons geluid in albei ore,
- vinnige hartklop, lae bloeddruk (insluitend wanneer u opstaan vanaf 'n lê-posisie), posisioneringstoestande wat bloedvloei en die bloedvate in die brein beïnvloed, hoë bloeddruk en verergering van hoë bloeddruk, arterie- of aarontsteking, spatare,
- hoes, droë geïrriteerde keel, bronchitis (inflammasie van die voering van bronchiale buise),

laringitis (keelinfeksie), longontsteking (longinfeksie), probleme om asem te haal of vlak asemhaling, neusbloeding,
- braking (naar word), maagpyn, oormatige gas in u maag, gereelde dermbewegings, 'n brandende sensasie in u bors (sooibrand) gewoonlik na ete, wat snags erger kan wees, inflammasie van die dunderm, winde opbreek, inflammasie van die maag, aambeie, obstruksie in die ingewande, bloeding uit u rektum, gaatjies in die tande,
- bloedafwykings, insluitend lae bloedseltelling, abnormale limfkliergrootte, ongewone groot rooibloedselle, perskleurige kolle en kolle wat op die vel voorkom, en in slymvliese, insluitend die voering van die mond, porfirie ('n seldsame oorerflike bloedsiekte),
- plooivorming van u vel, veluitslag, galbulte, kontak-ekseem, aknee, ligsensitiwiteit, velplooie, jeukerige vel, vorming van blase, pitswere,
- pyn in 'n gewrig, artritis (gewrigsontsteking), skiatika (vasgedrukte senuwee in die lae rug wat rug-, been- en heuppyn veroorsaak), osteoartritis, tendon-ontsteking,
- pynlike of moeilike urinering, blaasinfeksie, skei meer of minder urien uit as wat normaal vir u is, onvermoë om te urineer, gereelde urinering in die nag, nierinfeksie, nierpyn,
- swaar menstruele vloei, jeukerig en seer wees in en om u vagina (vroue), borspyn, pynlike menstruasie, borsgewas,
- abnormale fisiese swakheid of gebrek aan energie, gevoel van moegheid, slaperigheid, pyn, koors, ongemak op die bors, dronk voel, griepagtige siekte, swelling, val, algemene ongemak, trauma, swelling in die gesig, warm gloede, rustelose bene, hoër verdraagsaamheid teenoor medisyne,
- hoër liggaamstemperatuur, hoër hartspoed, abnormale bloedtoetsresultate.

*Newe-effekte met onbekende frekwensie:*
- Slaapwandeling, rusteloosheid, aggressie, delusies, woede, abnormale gedrag, afhanklikheid/ verslawing,
- lewerbesering,
- spier swakheid.

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. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (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 ZOLPIDEM XR 12,5 ADCO te verskaf.

## 5. Hoe om ZOLPIDEM XR 12,5 ADCO te bêre

- Bêre teen of benede 30 °C.
- Bêre alle medisyne buite bereik van kinders.
- Hou die tablette in die bottel en die stulpstrook in die buitenste kartonhouer totdat dit benodig word vir gebruik.

- Moenie ZOLPIDEM XR 12,5 ADCO neem ná die vervaldatum wat op die bottel of stulpstrook aangedui word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van die verpakking en ander inligting

**Wat ZOLPIDEM XR 12,5 ADCO bevat**

Die aktiewe bestanddeel is zolpidemtartraat.
ZOLPIDEM XR 12,5 ADCO: Elke tablet bevat 12,5 mg zolpidemtartraat.
Die ander bestanddele is kolloïdale silikondioksied, FD & C Blou no. 2 aluminium-lak (E132), hipromellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, “Opadry” Blou (bestaande uit FD & C Blou no. 2 aluminium-lak (E132), hipromellose, poliëtileenglikol, titaandioksied (E171)), kaliumbitartraat, natriumstyselglikolaat.

**Hoe ZOLPIDEM XR 12,5 ADCO lyk en die inhoud van die verpakking**

ZOLPIDEM XR 12,5 ADCO: Bloukleurige, ronde, bikonvekse, filmbedekte tablette met E62 aan die een kant gedruk en LU aan die ander kant.
Ronde, ondeursigtige wit HDPE-bottel met 'n kinderbestande prop en wat 'n 1 g silikajel-sakkie bevat.
Verpakkingsgroottes: 30 of 100 tablette.

Deursigtige PVC/Aclar-film en gewone aluminiumfoelie (een kant blink en ander kant dof en belak) stulpstrook, geplaas in 'n buitenste kartonboksie.
Verpakkingsgroottes: 20 tablette (2 stulpstroke; 10 tablette per stulpstrook) of 30 tablette (3 stulpstroke; 10 tablette per stulpstrook).
Nie alle verpakkingsgroottes mag dalk bemark word nie.

**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**

20 Augustus 2025

**Registrasienommer**

57/2.2/0188

adcock ingram

281045 07/2025