SCHEDULING STATUS

S5

ADCO ALZAM 0,25 mg, tablets

ADCO ALZAM 0,5 mg, tablets

ADCO ALZAM 1,0 mg, tablets

Alprazolam

Contains sugar: Lactose hydrous 60,0 mg per tablet.

Read all of this leaflet carefully before you start taking ADCO ALZAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADCO ALZAM 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 ALZAM is and what it is used for
2. What you need to know before you take ADCO ALZAM
3. How to take ADCO ALZAM
4. Possible side effects
5. How to store ADCO ALZAM
6. Contents of the pack and other information

1. What ADCO ALZAM is and what it is used for

ADCO ALZAM belongs to a group of medicines known as benzodiazepines.

It is used in the treatment of anxiety disorders, or the short-term relief of symptoms of anxiety, anxiety associated with depression and panic disorders.

2. What you need to know before you take ADCO ALZAM

Do not take ADCO ALZAM:

- if you are allergic (hypersensitive) to alprazolam or other similar benzodiazepine medicines, or to any of the other ingredients of ADCO ALZAM (listed in section 6).
- if you are pregnant or breastfeeding your baby.
- if you suffer from schizophrenia.
- if you have ever suffered any mental illness that required hospital treatment.
- if you have ever felt so depressed that you have thought about taking your own life.
- if you suffer from a disease called myasthenia gravis where you suffer from very weak and tired muscles.
- if you have severe chest problems or breathing difficulties (e.g. chronic bronchitis or emphysema).
- if you have sleep apnoea – this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.
- if you have severe liver problems.
- if you are using ketoconazole and itraconazole.

The safety and efficacy of ADCO ALZAM has not been established in children under the age of 18 years.

Warnings and precautions

Take special care with ADCO ALZAM:

- If you have a history of drug or alcohol abuse or dependence – as dependence on ADCO ALZAM may occur more easily.
- When you stop taking ADCO ALZAM too quickly or abruptly – you may experience withdrawal symptoms like inability to sleep, stomach or muscle cramps, vomiting, sweating, convulsions/seizures.
- If you have epilepsy or a history of seizures – the risk of seizures may be increased when starting or suddenly stopping ADCO ALZAM treatment.
- If you have problems with your lungs, kidneys or liver.
- If you experience memory loss (amnesia). Tell your doctor straight away.
- If you suffer from anxiety with an underlying depressive disorder.

Benzodiazepines, such as ADCO ALZAM, and related products should be used with caution in elderly, due to the risk of sedation and/or musculoskeletal weakness that can promote falls, often with serious consequences in this population.

Children and adolescents

The safety and efficacy of ADCO ALZAM has not been established in children under the age of 18 years.

Other medicines and ADCO ALZAM

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

- Any other medicines to treat anxiety or depression or to help you sleep (e.g. nefazodone, fluvoxamine, fluoxetine, sertraline, imipramine, desipramine).
- Some strong pain killers (e.g. opioids such as - morphine, codeine or propoxyphene).
- Antipsychotic medicines used to treat mental illnesses like schizophrenia.
- Medicines to treat epilepsy.
- Antihistamines for relief of allergies.
- Medicines for treating fungal infections (e.g., ketoconazole, itraconazole).
- Oral contraceptives ('the pill').
- Certain antibiotics (e.g., erythromycin, clarithromycin and troleandomycin).
- Cimetidine (for treating stomach ulcers).
- Diltiazem (used for angina and high blood pressure).
- Digoxin (used to treat various heart conditions).
- Ritonavir or other similar medicines used for treating HIV.

ADCO ALZAM with alcohol

It is important not to drink any alcohol while you are taking ADCO ALZAM, as alcohol increases the effects of ADCO ALZAM.

Pregnancy and breastfeeding

You should not take ADCO ALZAM if you are pregnant or breastfeeding your baby.

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 ADCO ALZAM.

Driving and using machines

ADCO ALZAM may cause drowsiness or dizziness. If you feel drowsy, do not drive or do anything that requires you to be alert.

It is not always possible to predict to what extent ADCO ALZAM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ADCO ALZAM affects you.

ADCO ALZAM contains lactose hydrous

ADCO ALZAM contains lactose hydrous. This should be taken into account if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ADCO ALZAM.

ADCO ALZAM contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet and is essentially 'sodium-free'.

3. How to take ADCO ALZAM

Do not share medicines prescribed for you with any other person.

Always take ADCO ALZAM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of ADCO ALZAM varies from one person to another. Your doctor will decide what is the usual or appropriate dose for your condition.

	USUAL STARTING DOSAGE*	**USUAL DOSAGE RANGE**
Anxiety	0,25 to 0,5 mg given three times daily	0,5 to 4,0 mg daily, given in divided doses
Anxiety associated with depression	0,5 mg given three times daily	1,5 to 4,0 mg daily given in divided doses
Geriatric patients or in the presence of debilitating disease	0,25 mg given two to three times daily	0,5 to 0,75 mg daily, given in divided doses; to be gradually increased if needed and tolerated.
Panic-related disorders	0,5 to 1,0 mg given at bedtime	The dose should be adjusted to patient response. Dosage adjustments should be in increments no greater than 1 mg every 3 to 4 days. Additional doses can be added until a three times daily or four times daily schedule is

		achieved. Maximum of 10 mg daily

Your doctor will tell you how long your treatment with ADCO ALZAM will last. Do not alter the dose yourself without your doctor's advice. Do not stop taking ADCO ALZAM unless told to do so by your doctor. Should you need to stop taking ADCO ALZAM, your doctor will have decided the best method for you. If you have the impression that the effect of ADCO ALZAM is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO ALZAM than you should

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 ADCO ALZAM

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

If you stop taking ADCO ALZAM

Always see your doctor before you stop taking ADCO ALZAM tablets as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' effects which might cause you to become temporarily more anxious or restless or to have difficulty sleeping. These symptoms will go away as your body re-adjusts. If you are worried, your doctor can tell you more about this.

4. Possible side effects

ADCO ALZAM can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and 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 ADCO ALZAM. 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:

- depression, feeling elated or over-excited, which causes unusual behaviour, anger, drug dependence,
- feeling elated or over-excited, which causes unusual behaviour, hallucination (seeing or hearing things that do not exist), feeling agitated or angry, feeling hostile or aggressive, abnormal thoughts, being hyperactive, drug abuse,
- memory loss,
- blurred vision, increased pressure in the eyes,
- drug withdrawal syndrome with symptoms such as feeling uneasy, vomiting, stomach or muscle cramps, sweating, trembling, seizures,
- problems with liver function (this shows up in blood tests), inflammation of the liver, yellowing of the skin and whites of the eyes (jaundice),

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:

- decreased appetite,
- disorientation,
- drowsiness, sleepiness, jerky, uncoordinated movements, dizziness, problems with balance, and unsteadiness,
- constipation, dry mouth, nausea,
- skin irritations.

Less frequent side effects:

- change in weight,
- inability to sleep, nervousness, anxiety,
- problems with co-ordination, trembling or shakiness, lack of energy, headache, imbalance to part of nervous system with symptoms such as fast heart beat and unstable blood pressure (feeling dizzy, light-headed or faint),
- stomach upsets.
- Diarrhoea

Side effects with unknown frequency:

- blood disorders,
- in women, irregular periods or production of too much prolactin (the hormone that stimulates milk production),
- anorexia (an eating disorder),

- irritability, difficulty in concentrating, tiredness,
- slurred speech,
- changes in salivation,
- skin reaction caused by sensitivity to sunlight,
- muscle weakness, twisting or jerking movements,
- difficulty urinating or bladder control problems,
- changes in sex drive (men and women), erectile dysfunction, irregularities with the menstrual cycle,
- swelling of the ankles, feet or fingers.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ADCO ALZAM.

5. How to store ADCO ALZAM

- Store all medicines out of reach of children.
- Store at or below 25 ºC, in a tightly closed container.
- Protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/bottle.
- 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 ADCO ALZAM contains

The active substance is alprazolam 0,25 mg, 0,5 mg or 1,0 mg.

The other ingredients are: dioctyl sodium sulfosuccinate (docusate sodium), lactose hydrous, magnesium stearate, microcrystalline cellulose, pregelatinised starch, FD & C yellow No.6 Lake (C.I. 15985) (0,5 mg tablet), FD & C blue No.2 Lake (C.I. 73015) (1,0 mg tablet)

What ADCO ALZAM looks like and contents of the pack

ADCO ALZAM 0,25 mg: Round, white, biconvex tablets bisected on one side with "WC" and "787" debossed above and below the bisect respectively.

ADCO ALZAM 0,5 mg: Round, peach, biconvex tablets bisected on one side with "WC" and "786" debossed above and below the bisect respectively.

ADCO ALZAM 1,0 mg: Round, pale blue, biconvex tablets bisected on one side with "WC" and "785" debossed above and below the bisect respectively.

30’s, 100’s and 250’s in white polypropylene securitainers or tracer packs or white, round HDPE 90 ml bottle with white polypropylene child resistant closure and heat induction liners in closure.

100’s in white polypropylene securitainers or white, round HDPE 90 ml bottle with red polypropylene child resistant closure and heat induction liners in closure.

Not all pack types and pack sizes will 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

01 August 2023

Registration number

ADCO ALZAM 0,25 mg: 30/2.6/0212

ADCO ALZAM 0,5 mg: 30/2.6/0211

ADCO ALZAM 1,0 mg: 30/2.6/0213

Namibia:

ADCO ALZAM 0,25 mg: NS3 05/2.6/0258

ADCO ALZAM 0,5 mg: NS3 05/2.6/0259

ADCO ALZAM 1,0 mg: NS3 05/2.6/0260

Botswana:

ADCO ALZAM 0,25 mg: S1C BOT1101787

ADCO ALZAM 0,5 mg: S1C BOT1101788

ADCO ALZAM 1,0 mg: S1C BOT1101789

adcock ingram

PIL 31962 / 31963 / 31964 /
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Date of approval: 01 August 2023

PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS

S5

ADCO ALZAM 0,25 mg, tablette

ADCO ALZAM 0,5 mg, tablette

ADCO ALZAM 1,0 mg, tablette

Alprasolaam

Bevat suiker: Laktose gehidreer 60,0 mg per tablet.

Lees hierdie hele voubiljet noukeurig deur voordat u ADCO ALZAM begin neem

- Bewaar hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorg kundige.
- ADCO ALZAM 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 in hierdie voubiljet is

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

1. Wat ADCO ALZAM is en waarvoor dit gebruik word

ADCO ALZAM behoort aan 'n groep medisyne bekend indien bensodiasepiene.

Dit word gebruik in die behandeling van angsversteurings, of die korttermyn-verligting van simptome van angs, angs geassosieer met depressie en paniekversteurings.

Datum van goedkeuring: 01 Augustus 2023

2. Wat u moet weet voordat u ADCO ALZAM neem

Moenie ADCO ALZAM neem nie:

- indien u allergies (hipersensitief) is vir alprasolaam of ander soortgelyke bensodiasepien-medisyne, of vir enige van die ander bestanddele van ADCO ALZAM (gelys in afdeling 6).
- indien u swanger is of u baba borsvoed.
- indien u aan skisofrenie ly.
- indien u al ooit enige geestesongesteldheid gely het wat hospitaalbehandeling vereis het.
- indien u al ooit so depressief gevoel het dat u daaraan gedink het om u eie lewe te neem.
- indien u aan 'n siekte genaamd miastenie gravis ly waar u spiere baie swak en moeg voel.
- indien u ernstige borsprobleme of asemhalingsprobleme het (bv. chroniese brongitis of emfiseem).
- indien u slaapapnee het – dit is 'n toestand waar u asemhaling onreëlmatig raak, selfs vir kort rukkies stop terwyl u slaap.
- indien u ernstige lewerprobleme het.
- indien u ketokonasool en itrakonasool gebruik.

Die veiligheid en doeltreffendheid van ADCO ALZAM is nie by kinders onder die ouderdom van 18 jaar vasgestel nie.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met ADCO ALZAM:

- Indien u 'n geskiedenis van dwelm- of alkoholmisbruik of -afhanklikheid het – aangesien afhanklikheid van ADCO ALZAM makliker kan voorkom.

- Wanneer u ophou om ADCO ALZAM te vinnig of skielik te gebruik – u kan onttrekkingsimptome ervaar soos ‘n onvermoë om te slaap, maag- of spierkrampe, braking, sweet, stuiptrekkings/stuipe.
- Indien u epilepsie het of 'n geskiedenis van stuipaanvalle – die risiko van stuipaanvalle kan verhoog word wanneer ADCO ALZAM behandeling begin of skielik gestaak word.
- Indien u probleme met u longe, niere of lewer het.
- Indien u geheueverlies ervaar. Lig u dokter dadelik in.
- Indien u aan angs ly met 'n onderliggende depressiewe versteuring.

Bensodiasepiene, soos ADCO ALZAM, en verwante produkte moet versigtig by bejaardes gebruik word weens die risiko van sedasie en/of skeletspier swakheid wat die moontlikheid om te val kan bevorder, dikwels met ernstige gevolge in hierdie populasie.

Kinders en adolessente
Die veiligheid en doeltreffendheid van ADCO ALZAM is nie by kinders onder die ouderdom van 18 jaar vasgestel nie.

Ander medisyne en ADCO ALZAM
Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Enige ander medisyne om angs of depressie te behandel of om u te help slaap (bv. nefazodoon, fluvoksamien, fluoksetien, sertralien, imipramien, desipramien).
- Sommige sterk pynstillers (bv. opioïede byvoorbeeld morfien, kodeïen of propoksifeen).
- Antipsigotiese medisyne wat gebruik word om geestesiektes soos skisofrenie te behandel.
- Medisyne om epilepsie te behandel.
- Antihistamiene vir verligting van allergieë.
- Medisyne vir die behandeling van swaminfeksies (bv. ketokonasool, itrakonasool).
- Orale voorbehoedmiddels (‘die pil’).

- Sekere antibiotika (bv. eritromisien, klaritromisien en troleandomisien).
- Simetidien (vir die behandeling van maagsere).
- Diltiasem (gebruik vir angina en hoë bloeddruk).
- Digoksien (gebruik om verskeie harttoestande te behandel).
- Ritonavir of ander soortgelyke medisyne wat gebruik word vir die behandeling van MIV.

ADCO ALZAM met alkohol
Dit is belangrik om geen alkohol te drink terwyl u ADCO ALZAM neem nie, aangesien alkohol die uitwerking van ADCO ALZAM verhoog.

Swangerskap en borsvoeding
U moet nie ADCO ALZAM neem indien u swanger is of u baba borsvoed nie.
Indien u swanger is of borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u ADCO ALZAM neem.

Bestuur van ‘n voertuig en hantering van masjinerie
ADCO ALZAM kan lomerigheid of duiseligheid veroorsaak. Indien u lomerig voel, moenie bestuur of enigiets doen wat vereis dat u wakker moet wees nie.

Dit is nie altyd moontlik om te voorspel tot watter mate ADCO ALZAM met u daaglikse aktiwiteite kan inmeng nie. U moet verseker dat u nie by bogenoemde aktiwiteite betrokke raak voordat u bewus is van die mate waarin ADCO ALZAM u beïnvloed nie.

ADCO ALZAM bevat gehidreerde laktose
ADCO ALZAM bevat gehidreerde laktose. Dit moet in ag geneem word indien u diabetes mellitus het. Indien u deur u dokter ingelig is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u ADCO ALZAM neem.

ADCO ALZAM bevat natrium

Hierdie medisyne bevat minder indien 1 mmol natrium (23 mg) per tablet en is in wese 'natriumvry'.

3. Hoe om ADCO ALZAM te neem

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Neem ADCO ALZAM altyd presies soos u dokter of apteker vir u gesê het. Bevestig met u dokter of apteker indien u nie seker is nie.

Die algemene dosis ADCO ALZAM verskil van persoon tot persoon. U dokter sal besluit wat die algemene of gepaste dosis vir u toestand is.

	ALGEMENE DOSIS OM MEE TE BEGIN*	**ALGEMENE DOSIS GRENSE**
Angs	0,25 tot 0,5 mg toegedien drie keer per dag	0,5 tot 4,0 mg daagliks, toegedien in verdeelde dosisse
Angs geassosieer met depressie	0,5 mg toegedien drie keer per dag	1,5 tot 4,0 mg daagliks toegedien in verdeelde dosisse
Geriatriese pasiënte of in die teenwoordigheid van verswakende siekte	0,25 mg twee tot drie keer daagliks	0,5 tot 0,75 mg daagliks, toegedien in verdeelde dosisse; geleidelik verhoog word indien nodig en verdra word.
Paniek-verwante versteurings	0,5 tot 1,0 mg gegee voor slaaptyd.	Die dosis moet aangepas word volgens reaksie van die pasiënt. Dosisse moet aangepas word in inkremente van nie meer as 1 mg elke 3 tot 4 dae nie. Bykomende dosisse kan bygevoeg word totdat 'n skedule van drie keer per dag of vier

		keer per dag bereik is. Maksimum van 10 mg daagliks

U dokter sal u inlig hoe lank u behandeling met ADCO ALZAM sal duur. Moenie die dosis self verander sonder u dokter se advies nie. Moenie die gebruik van ADCO ALZAM staak nie, tensy u dokter u aangesê het om dit te doen. Indien u moet ophou om ADCO ALZAM te neem, sal u dokter op die beste metode vir u besluit. Indien u die indruk kry dat die effek van ADCO ALZAM te sterk of te swak is, lig u dokter of apteker in.

Indien u meer ADCO ALZAM neem as wat u moes
In die geval van oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om ADCO ALZAM te neem
Moenie 'n dubbele dosis neem om vergete individuele dosisse in te haal nie.

Indien u ophou om ADCO ALZAM te neem
Raadpleeg altyd u dokter voordat u ophou om ADCO ALZAM tablette te neem, aangesien die dosis geleidelik verminder moet word. Indien u ophou om die tablette te neem of die dosis skielik verminder, kan u 'terugslag'-effekte kry wat kan veroorsaak dat u tydelik meer angstig of rusteloos raak, of sukkel om te slaap. Hierdie simptome sal verdwyn soos u liggaam weer aanpas. Indien u bekommerd is, kan u dokter u meer hieroor inlig.

4. Moontlike newe-effekte
ADCO ALZAM kan newe-effekte hê.

Nie alle newe-effekte wat vir ADCO ALZAM aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige nadelige effekte ervaar terwyl u ADCO ALZAM neem, raadpleeg asseblief u gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, hou op om ADCO ALZAM te neem en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeuk,
- flou word.

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

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

- depressie, verheug of oor-opgewonde gevoel, wat ongewone gedrag, woede, dwelmafhanklikheid veroorsaak,
- verheug of oor-opgewonde voel, wat ongewone gedrag veroorsaak, hallusinasie (sien of hoor dinge wat nie bestaan nie), omgekrap of kwaad voel, vyandig of aggressief voel, abnormale gedagtes, hiperaktief wees, dwelmmisbruik,
- geheueverlies,
- versteurde visie, verhoogde druk in die oë,
- middel-onttrekkingsindroom met simptome soos ongemak, braking, maag- of spierkrampe, sweet, bewing, stuipaanvalle,
- probleme met lewerfunksie (dit word opgemerk in bloedtoetse), inflammasie van die lewer, vergeling van die vel en wit van die oë (geelsug),

Hierdie is alles ernstige newe-effekte. U benodig dalk dringende mediese hulp.

Lig u dokter in indien u enige van die volgende opmerk:
Algemene newe-effekte:

- verminderde eetlus,
- disoriëntasie,

- lomerigheid, slaperigheid, rukkerigheid, ongekoördineerde bewegings, duiseligheid, probleme met balans en onstabiliteit,
- hardlywigheid, droë mond, naarheid,
- velirritasies.

Minder algemene newe-effekte:

- verandering in gewig,
- onvermoë om te slaap, senuweeagtigheid, angs,
- probleme met koördinasie, bewing of bewerigheid, gebrek aan energie, hoofpyn, wanbalans in 'n deel van die senuweestelsel, met simptome soos vinnige hartklop en onstabiele bloeddruk (duiselig, lighoofdig voel of floutes),
- maagversteurings.
- diarree

Newe-effekte met onbekende frekwensie:

- bloedafwykings,
- by vroue, onreëlmatige menstruasie of produksie van te veel prolaktien (die hormoon wat melkproduksie stimuleer),
- anoreksie ('n eetversteuring),
- prikkelbaarheid, probleme om te konsentreer, moegheid,
- slepende spraak,
- veranderinge in speekselafskeiding,
- velreaksie veroorsaak deur sensitiwiteit vir sonlig,
- spierswakheid, draai- of rukbewegings,
- probleme met urinering of blaasbeheer-probleme,
- veranderinge in seksdrang (mans en vroue), erektiele disfunksie, onreëlmatighede met die menstruele siklus,
- swelling van die enkels, voete of vingers.

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet 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 vorm “6.04 Adverse Drug Reaction Reporting Form”, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ADCO ALZAM te verskaf.

5. Hoe om ADCO ALZAM te bêre

- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 25 ºC, in 'n diggeslote houer.
- Beskerm teen lig.
- Moenie in 'n badkamer stoor nie.
- Moenie na die vervaldatum gebruik soos op die etiket/bottel aangedui 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 ADCO ALZAM bevat

Die aktiewe bestanddeel is alprasolaam 0,25 mg, 0,5 mg of 1,0 mg.

Die ander bestanddele is: dioktielnatriumsulfosuksinaat (dokusaatnatrium), gehidreerde laktose, magnesiumstearaat, mikrokristallyne sellulose, pregelatiniseerde stysel, FD & C geel No.6 kleursel (C.I. 15985) (0,5 mg tablet), FD & C blou No.2 kleursel (C.I. 73015) (1,0 mg tablet)

Hoe ADCO ALZAM lyk en inhoud van die verpakking

ADCO ALZAM 0,25 mg: Ronde, wit, bikonvekse tablette met verdeellyn aan die een kant met "WC" en "787" onderskeidelik bo en onder die verdeellyn gegraveer.

Datum van goedkeuring: 01 Augustus 2023

ADCO ALZAM 0,5 mg: Ronde, perske, bikonvekse tablette met verdeellyn aan die een kant met "WC" en "786" onderskeidelik bo en onder die verdeellyn gegraveer.
ADCO ALZAM 1,0 mg: Ronde, ligblou, bikonvekse tablette met verdeellyn aan die een kant met "WC" en "785" onderskeidelik bo en onder die verdeellyn gegraveer.

30's, 100'e en 250's in wit polipropileen-sekuriteitshouers of merk-pakkies of wit, ronde HDPE 90 ml-bottel met wit polipropileen-kinderbestande prop en hitte-induksievoerings in die prop.

100'e in wit polipropileen-sekuriteitshouers of wit, ronde HDPE 90 ml-bottel met rooi polipropileen-kinderbestande prop en hitte-induksievoerings in prop.

Nie alle verpakkingstipes en verpakkingsgroottes sal bemark word nie.

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

Hierdie voubiljet is mees onlangs hersien op
01 Augustus 2023

Registrasienommer
ADCO ALZAM 0,25 mg: 30/2.6/0212
ADCO ALZAM 0,5 mg: 30/2.6/0211
ADCO ALZAM 1,0 mg: 30/2.6/0213

Namibië:

ADCO ALZAM 0,25 mg: NS3 05/2.6/0258

ADCO ALZAM 0,5 mg: NS3 05/2.6/0259

ADCO ALZAM 1,0 mg: NS3 05/2.6/0260

Botswana:

ADCO ALZAM 0,25 mg: S1C BOT1101787

ADCO ALZAM 0,5 mg: S1C BOT1101788

ADCO ALZAM 1,0 mg: S1C BOT1101789

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PIL 31962 / 31963 / 31964 /
31965 / 31966 / 31967 08/2024

Datum van goedkeuring: 01 Augustus 2023