PATIENT INFORMATION LEAFELET

SCHEDULING STATUS

S5

CLOBAZAM 10 ADCO, 10 mg (tablets)
CLOBAZAM 20 ADCO, 20 mg (tablets)
Clobazam
CLOBAZAM 10 ADCO contains sugar, 92 mg lactose monohydrate
CLOBAZAM 20 ADCO contains sugar, 184 mg lactose monohydrate

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

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

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

CLOBAZAM ADCO contains the active substance clobazam.
CLOBAZAM ADCO is used to treat anxiety in neurotic patients and for pre-operative medication.
CLOBAZAM ADCO can also be effective in relieving acute symptoms of alcohol withdrawal syndrome.

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

Do not take CLOBAZAM ADCO:

- if you are hypersensitive (allergic) to clobazam or any of the other ingredients of CLOBAZAM ADCO (listed in section 6)
- if you have a history of drug or alcohol dependence
- if you suffer from an illness that causes muscle weakness (called ‘myasthenia gravis’)
- if you have breathing problems
- if you stop breathing for short periods during sleep (called ‘sleep apnoea syndrome’)
- if you have severe liver problems
- if you are in your first trimester of pregnancy or breastfeeding your baby
- if the patient is under 3 years.

Warnings and precautions

Take special care with CLOBAZAM ADCO:

- if you experience any memory loss, please inform your doctor.
- if you have existing muscle weakness or experience any muscle weakness while being treated.
- if you have existing depression or aggression problems.
- if you have ever become dependent upon another drug or alcohol. Alcohol should not be taken during treatment with CLOBAZAM ADCO as there is an increased risk of experiencing side effects.
- if you experience any skin reaction during treatment with CLOBAZAM ADCO.
- if you have chronic or acute breathing problems.
- if you have kidney or liver problems.
- if you are over 65 or debilitated. This is due to the increased sensitivity to adverse reactions in the elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of fall that may result in serious injury.
- if you are a poor CYP2C19 metaboliser.
- if you are drinking alcohol during treatment.
- if you are using any opioids (pain medication) or any other benzodiazepines.
- if you are using any barbiturates (to treat anxiety or sleep disorders), antihistamines (to treat allergies), narcotics (to induce sleep) or other central nervous depressants (to treat anxiety, panic attacks, seizures, insomnia (trouble to sleep), etc.).

The medicines prescribed to reduce seizures have been associated with a rare but serious reaction called Drug Reaction with Eosinophilia and Systemic Symptoms, or DRESS.
This serious sensitivity is a reaction of the immune system that can cause severe swelling (inflammation) throughout the body, or injury to organs, including the liver, kidneys, lungs, heart, or pancreas. It can lead to hospitalisation and damage or failure of these organs and may progress to death, especially if treatment is delayed.
Do not stop taking CLOBAZAM ADCO without first talking to your healthcare professional. Stopping CLOBAZAM ADCO suddenly can cause uncontrolled seizures.
Call your healthcare professional and seek immediate medical attention if you develop any of the following symptoms at any time while taking CLOBAZAM ADCO:

- Fever
- Swollen lymph nodes
- Sore throat
- Skin rash (may or may not be present)
- Swelling of your face or eyes
- Painful sores in the mouth or around the eyes
- Trouble swallowing or breathing
- Yellowing of your skin or eyes
- Unusual bruising or bleeding
- Severe fatigue and weakness
- Shortness of breath or exercise intolerance

- Severe muscle pain

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

Tell your doctor if you are taking any of the following medicines:
- Antipsychotics (such as chlorpromazine, haloperidol, clozapine and pimozide).
- Hypnotics, anxiolytics/sedative (medicines that work on the central nervous system to relieve anxiety, aid sleep, or have a calming effect).
- Antidepressant agents (such as Monoamine Oxidase Inhibitors (MAOIs) or tricyclic anti-depressants such as trazodone, or Selective Serotonin Re-uptake Inhibitors (SSRIs) such as fluvoxamine or paroxetine).
- Narcotic analgesics and opioids (medicines containing codeine, dihydrocodeine, morphine, fentanyl, oxycodone and, methadone).
- Anti-convulsant medicines (such as phenytoin, carbamazepine, stiripentol or valproic acid).
- Anaesthetics (medicine that is administered during an operation).
- Sedative antihistamines (such as chlorphenamine, promethazine or diphenhydramine).
- Lithium (used for a mental illness called ‘manic-depressive illness’ (mood changes between a state of high excitability or exaggerated emotions and depression)).
- Muscle relaxants (such as baclofen) and nitrous oxide (laughing gas).
- CYP2C19 inhibitors (such as fluconazole (used to treat fungal conditions), fluvoxamine (SSRI, used to treat depression) and ticlopidine (an antiplatelet medication used in patients with an increased risk of stroke).
- CYP2D6 substrates such as Dextromethorphan (used to relieve dry, irritating coughs), pimozide (used to treat severe mental illness), paroxetine (SSRI, used to treat depression), nebivolol (used to treat high blood pressure).

CLOBAZAM ADCO with food and drink
Be careful how much alcohol you drink. Due to the combined effect of CLOBAZAM ADCO and alcohol it can increase the effects of CLOBAZAM ADCO e.g., sedation.

Pregnancy, breastfeeding, and fertility
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 CLOBAZAM ADCO.
CLOBAZAM ADCO is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception.
Since CLOBAZAM ADCO is found in the breastmilk, CLOBAZAM ADCO should not be given to breastfeeding mothers.

Fertility
No human data available.

Driving and using machines
CLOBAZAM ADCO may cause sedation, memory loss, impaired concentration and impaired muscular function which may adversely affect your ability to drive or use machines.
It is not always possible to predict to what extent CLOBAZAM ADCO may interfere with your daily activities. You should ensure that you do not engage in the driving of a vehicle or use of machines until you are aware of the measure to which CLOBAZAM ADCO affects you.

CLOBAZAM 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 this medicine.

3. How to take CLOBAZAM ADCO
Do not share medicines prescribed for you with any other person.
Always take CLOBAZAM ADCO exactly as your doctor has instructed you with an adequate amount of liquid. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on your starting dose.
The normal adult dose ranges between 10 – 30 mg daily. Doses of 20 mg and above should preferably be given at bedtime or as divided doses.
Treatment will usually start with the lowest recommended dose and the maximum dose should not be exceeded.
Use in children
The daily dose should be halved for children.
Elderly people
For elderly, debilitated and light-weight patients, the daily dose should be halved.

The overall duration of treatment should not be more than 8 – 12 weeks, including a tapering off process.
If you doctor extends treatment beyond this period, it should not take place without re-evaluation of your status.
Your doctor will tell you how long your treatment with CLOBAZAM ADCO will last. Do not stop treatment early because you may experience headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. If you have the impression that the effect of CLOBAZAM ADCO is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOBAZAM ADCO than you should
In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of CLOBAZAM ADCO
Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLOBAZAM ADCO
If you suddenly stop taking CLOBAZAM ADCO you may experience headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.
Your doctor may suggest you reduce the dose gradually before stopping treatment.

4. Possible side effects
CLOBAZAM ADCO can have side effects.
Not all side effects reported for CLOBAZAM ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLOBAZAM ADCO, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking CLOBAZAM ADCO 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 (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOBAZAM 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:
- respiratory depression (a breathing disorder characterized by slow and ineffective breathing),
- respiratory failure particularly in patients with pre-existing compromised respiratory function e.g., in patients with bronchial asthma or brain damage,
- photosensitivity reaction (an immune system reaction that is triggered by sunlight causing itchy patches or redness),
- urticaria (also known as hives, is an outbreak of swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly),
- Stevens-Johnson syndrome (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters),
- toxic epidermal necrolysis (symptoms include a painful, red area that spreads quickly, the skin may peel without blistering and fever),
- hypothermia (when your body loses heat faster than it can produce heat).

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,
- irritability,
- aggression,

- restlessness,
- Depression (pre-existing depression may be unmasked)
- medicine tolerance (when your body adapts to the continued presence of the medicine and doesn't respond to the medicine as well anymore),
- agitation (a state of anxiety or nervous excitement),
- somnolence (a strong desire to sleep and a feeling of drowsiness),
- sedation,
- dizziness,
- disturbance in attention,
- slow speech/dysarthria (slurred speech)/speech disorder,
- headache,
- tremor,
- ataxia (impaired balance or coordination),
- dry mouth,
- nausea,
- constipation,
- fatigue, especially at the beginning of treatment.

Less frequent side effects

- abnormal behaviour,
- confessional state (confused thinking and reduced awareness of surroundings),
- anxiety (intense and persistent worry and fear about everyday),
- delusion (believing things that isn't true),
- nightmare,
- loss of libido (sexual drive),
- emotional poverty,
- amnesia (memory loss that may be associated with abnormal behaviour),
- memory impairment (changes in your memory),
- anterograde amnesia (loss of the ability to recall the recent past but long-term memories are still intact),
- depression of mood and affect
- lethargy
- increased motor activity
- decreased motor activity
- paradoxical reactions (inconsistent or contradictory) such as an excess
- excitability with rage
- diplopia (double vision),
- rash
- weight increase,
- increased possibility of tripping or falling, especially in elderly patients.
- fall

Unknown frequency

- dependence (becoming dependent of CLOBAZAM ADCO),
- initial insomnia (problem falling asleep and staying asleep),
- anger,
- hallucination (seeing things that isn't real),
- psychotic disorder (a mental disorder characterised by a disconnection from reality),
- poor sleep quality,
- suicidal ideation (to think or plan suicide),
- cognitive disorder (disorders that affect cognitive abilities including learning, memory, perception and problem solving),
- altered state of consciousness (particularly in elderly patients, may be combined with respiratory disorders),
- nystagmus (involuntary movement of the eye causing the eye to rapidly move from side to side),
- gait disturbance (change in the way you walk),
- muscle spasms,
- muscle weakness,
- slow response to stimuli (slow reaction time).

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, 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 CLOBAZAM ADCO.

5. How to store CLOBAZAM ADCO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Store at or below 25 °C.
Store in the original container
Do not use after the expiry date stated on the label.
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 CLOBAZAM ADCO contains
The active substance(s) is 10 mg clobazam in CLOBAZAM 10 ADCO and 20 mg clobazam in CLOBAZAM 20 ADCO.
The other ingredient(s) are:

colloidal silicon dioxide, corn starch, hydroxy propyl cellulose, lactose monohydrate, magnesium stearate, talc.

What CLOBAZAM ADCO looks like and contents of the pack
CLOBAZAM 10 ADCO tablets are presented as white to off white, oval shaped, uncoated tablets with functional score on one side and “C” and “M” debossed on the other side.
CLOBAZAM 20 ADCO tablets are presented as white to off white, oval shaped, uncoated tablets with functional score on one side and “C” and “L” debossed on the other side.

100’s count bottle pack for CLOBAZAM 10/20 ADCO
40 ml HDPE container, utilizing 33 mm child resistant (CR) closure with induction sealing wad. Puritan cotton coil 9 grm/yard.
1000’s count bottle pack for CLOBAZAM 10 ADCO
250 ml HDPE containers, utilizing 53 mm continuous thread (CT) Screw cap closure with induction sealing wad. Puritan cotton coil 9 grm/yard.
1000’s count bottle pack for CLOBAZAM 20 ADCO
400 ml HDPE containers, utilizing 53 mm continuous thread (CT) Screw cap closure with induction sealing wad. Puritan cotton coil 9 grm/yard.

Holder of Certificate of Registration
Adcock Ingram Limited
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Customer Care: 0860 ADCOCK / 232625

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Registration/Application number
CLOBAZAM 10 ADCO: 55/2.6/0546
CLOBAZAM 20 ADCO: 55/2.6/0547

SKEDULERINGSTATUS

S5

CLOBAZAM 10 ADCO, 10 mg (tablette)
CLOBAZAM 20 ADCO, 20 mg (tablette)
Klobasaam
CLOBAZAM 10 ADCO bevat suiker, 92 mg laktosemonohidraat
CLOBAZAM 20 ADCO bevat suiker, 184 mg laktosemonohidraat

Lees die hele voubiljet noukeurig deur voordat u CLOBAZAM ADCO begin neem

- Bewaar hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u enige verdere vrae het, raadpleeg u dokter, apteker, verpleër of ander gesondheidsorg kundige.
- CLOBAZAM ADCO 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 CLOBAZAM ADCO is en waarvoor dit gebruik word
2. Wat u moet weet voordat u CLOBAZAM ADCO neem
3. Hoe om CLOBAZAM ADCO te neem
4. Moontlike newe-effekte
5. Hoe om CLOBAZAM ADCO te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat CLOBAZAM ADCO is en waarvoor dit gebruik word

CLOBAZAM ADCO bevat die aktiewe bestanddeel klobasaam.
CLOBAZAM ADCO word gebruik vir die behandeling van angs by neurotiese pasiënte en vir pre-operatiewe medikasie.
CLOBAZAM ADCO kan ook effektief wees om akute simptome van alkoholonttrekkingsindroom te verlig.

2. Wat u moet weet voordat u CLOBAZAM ADCO neem

Moenie CLOBAZAM ADCO neem nie:

- indien u hipersensitief (allergies) is vir klobasaam of enige van die ander bestanddele van CLOBAZAM ADCO (gelys in afdeling 6)
- indien u 'n geskiedenis van dwelm- of alkoholafhanklikheid het
- indien u aan 'n siekte ly wat spierswakheid veroorsaak (genoem 'myasthenia gravis')
- indien u asemhalingsprobleme het
- indien u ophou asemhaal vir kort periodes tydens slaap (genoem 'slaapapnee-sindroom')

- indien u ernstige lewerprobleme het
- indien u in u eerste trimester van swangerskap is of u baba borsvoed
- indien die pasiënt jonger as 3 jaar is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met CLOBAZAM ADCO:

- indien u enige geheueverlies ervaar, stel asseblief u dokter in kennis.
- indien u bestaande spierswakheid het of enige spierswakheid ervaar terwyl u behandel word.
- indien u bestaande depressie- of aggressieprobleme het.
- indien u ooit van 'n ander dwelm of alkohol afhanklik geword het. Alkohol moet nie tydens behandeling met CLOBAZAM ADCO geneem word nie, aangesien daar 'n verhoogde risiko is om newe-effekte te ervaar.
- indien u enige velreaksie ervaar tydens behandeling met CLOBAZAM ADCO.
- indien u chroniese of akute asemhalingsprobleme het.
- indien u nier- of lewerprobleme het.
- indien u ouer as 65 jaar of verswak is. Dit is omdat daar ‘n verhoogde sensitiwiteit vir nadelige reaksies by bejaardes is, soos lomerigheid, duiseligheid en spierswakheid. Daar is ook 'n verhoogde risiko van val wat tot ernstige besering kan lei.
- indien u 'n swak CYP2C19 metaboliseerder is.
- indien u alkohol drink tydens behandeling.
- indien u enige opioïede (pynmedikasie) of enige ander bensodiasepiene gebruik.
- indien u enige barbiturate gebruik (om angs of slaapversteurings te behandel), antihistamiene (om allergieë te behandel), verdowingsmiddels (om slaap te veroorsaak) of ander sentrale senuwee-depressante (om angs, paniekaanvalle, aanvalle, insomnia (probleme om te slaap) te behandel), ens.

Die medisyne wat voorgeskryf word om stuipaanvalle te verminder, is geassosieer met 'n seldsame maar ernstige reaksie genaamd Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome, of GRESS.
Hierdie ernstige sensitiwiteit is 'n reaksie van die immuunstelsel wat ernstige swelling (inflammasie) regdeur die liggaam kan veroorsaak, of besering aan organe, insluitend die lewer, niere, longe, hart of pankreas. Dit kan lei tot hospitalisasie en skade of versaking van hierdie organe en kan tot die dood vorder, veral indien behandeling vertraag word.
Moenie ophou om CLOBAZAM ADCO te neem sonder om eers u gesondheidsorg kundige te raadpleeg nie. Indien u CLOBAZAM ADCO skielik staak, kan dit onbeheerde stuipaanvalle veroorsaak.
Kontak u gesondheidsorg kundige en soek onmiddellike mediese hulp indien u enige van die volgende simptome op enige tydstip ontwikkel terwyl u CLOBAZAM ADCO neem:

- Koors
- Geswelde limfknope

- Seer keel
- Veluitslag (mag teenwoordig wees, of nie)
- Swelling van u gesig of oë
- Pynlike sere in die mond of rondom die oë
- Sukkel om te sluk of asem te haal
- Vergeling van u vel of oë
- Ongewone kneusing of bloeding
- Erge moegheid en swakheid
- Kortasem of oefen-intoleransie
- Erge spierpyn

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

Lig u dokter in indien u enige van die volgende medisyne gebruik:
- Antipsigotika (soos chloorpromasien, haloperidol, klosapien en pimosied).
- Hipnotika, angsmiddels/kalmeermiddels (medisyne wat op die sentrale senuweestelsel werk om angs te verlig, slaap aan te help of 'n kalmerende effek te hê).
- Antidepressante (soos monoamienoksidase-inhibeerders (MAOI's) of trisikliese antidepressante soos trasodoon, of selektiewe serotonien heropname-inhibeerders (SSHI's) soos fluvoksamien of paroksetien).
- Narkotiese pynstillers en opioïede (medisyne wat kodeïen, dihidrokodeïen, morfien, fentaniel, oksikodoon en metadoon bevat).
- Anti-konvulsante (soos fenitoïen, karbamasepien, stiripentol of valproaatsuur).
- Narkosemiddels (medisyne wat tydens 'n operasie toegedien word).
- Kalmerende antihistamiene (soos chloorfenamien, prometasien of difenhidramien).
- Litium (gebruik vir 'n geestesongesteldheid wat 'manies-depressiewe siekte' genoem word (bui verander tussen 'n toestand van hoë prikkelbaarheid of oordrewe emosies en depressie)).
- Spierverslappers (soos baklofeen) en stikstofoksied (laggas).
- CYP2C19-remmers (soos flukonasool (wat gebruik word om swamtoestande te behandel), fluvoksamien (SSHI, gebruik om depressie te behandel) en tiklopidien ('n antiplaatjie-medikasie wat gebruik word by pasiënte met 'n verhoogde risiko van beroerte).
- CYP2D6-substrate soos Dekstrometorfaan (gebruik om droë, irriterende hoes te verlig), pimosied (gebruik vir die behandeling van ernstige geestesongesteldheid), paroksetien (SSHI, gebruik om depressie te behandel), nebivolol (gebruik om hoë bloeddruk te behandel).

CLOBAZAM ADCO met voedsel en drank

Wees versigtig hoeveel alkohol u drink. As gevolg van die gekombineerde effek van CLOBAZAM ADCO en alkohol kan dit die effekte van CLOBAZAM ADCO verhoog, bv. sedasie.

Swangerskap, borsvoeding en vrugbaarheid
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 CLOBAZAM ADCO neem.
CLOBAZAM ADCO word nie aanbeveel tydens die eerste trimester van swangerskap en by vroue van vrugbare potensiaal wat nie voorbehoeding gebruik nie.
Aangesien CLOBAZAM ADCO in die borsmelk voorkom, moet CLOBAZAM ADCO nie aan borsvoedende moeders gegee word nie.

Vrugbaarheid
Geen menslike data beskikbaar nie.

Bestuur van ‘n voertuig en hantering van masjinerie
CLOBAZAM ADCO kan sedasie, geheueverlies, verswakte konsentrasie en verswakte spierfunksie veroorsaak wat u vermoë om ‘n voertuig te bestuur of masjiene te hanteer nadelig kan beïnvloed.
Dit is nie altyd moontlik om te voorspel tot watter mate CLOBAZAM ADCO met u daaglikse aktiwiteite kan inmeng nie. U moet verseker dat u nie betrokke raak by die bestuur van 'n voertuig of die hantering van masjinerie totdat u bewus is van die mate waarin CLOBAZAM ADCO u raak nie.

CLOBAZAM ADCO bevat laktosemonohidraat
Indien u deur u dokter ingelig is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne gebruik.

3. Hoe om CLOBAZAM ADCO te neem
Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.
Neem altyd CLOBAZAM ADCO presies soos u dokter u voorgeskryf het met 'n voldoende hoeveelheid vloeistof. U moet u dokter of apteker raadpleeg indien u nie seker is nie.

U dokter sal u aanvangsdosis bepaal.
Die normale dosis vir volwassenes wissel tussen 10 en 30 mg daagliks. Dosisse van 20 mg en hoër moet verkieslik voor slapenstyd of as verdeelde dosisse gegee word.
Behandeling sal gewoonlik met die laagste aanbevole dosis begin en die maksimum dosis moet nie oorskry word nie.
Gebruik by kinders
Die daaglikse dosis moet vir kinders gehalveer word.
Bejaardes

Vir bejaarde, verswakte en liggewig pasiënte moet die daaglikse dosis gehalveer word.

Die algehele duur van behandeling moet nie meer as 8 – 12 weke wees nie, insluitend 'n verlagingsproses.
Indien u dokter die behandeling na hierdie tydperk verleng, moet dit nie plaasvind sonder 'n herevaluering van u status nie.
U dokter sal u inlig hoe lank u behandeling met CLOBAZAM ADCO sal duur. Moenie behandeling vroeg staak nie, want u kan hoofpyn, spierpyn, uiterste angs, spanning, rusteloosheid, verwarring en prikkelbaarheid ervaar. Indien u die indruk het dat die effek van CLOBAZAM ADCO te sterk of te swak is, lig u dokter of apteker in.

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

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

Indien u ophou om CLOBAZAM ADCO te neem
Indien u skielik CLOBAZAM ADCO staak, kan u hoofpyn, spierpyn, uiterste angs, spanning, rusteloosheid, verwarring en prikkelbaarheid ervaar.
U dokter kan voorstel dat u die dosis geleidelik verminder voordat die behandeling gestaak word.

4. Moontlike newe-effekte
CLOBAZAM ADCO kan newe-effekte hê.
Nie alle newe-effekte wat vir CLOBAZAM ADCO aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige nadelige effekte ervaar terwyl u CLOBAZAM ADCO neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, staak CLOBAZAM ADCO 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,
- floute (duiseligheid).

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op CLOBAZAM ADCO 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:

- respiratoriese depressie ('n asemhalingsversteuring wat gekenmerk word deur stadige en oneffektiewe asemhaling),
- respiratoriese versaking veral by pasiënte met bestaande ingeperkte respiratoriese funksie, bv. by pasiënte met brongiale asma of breinskade,
- fotosensitiwiteitsreaksie ('n immuunstelselreaksie wat veroorsaak word deur sonlig wat jeukerige kolle of rooiheid veroorsaak),
- urtikaria (ook bekend as galbulte, is 'n uitbreking van geswelde, ligrooi knoppe of plake (opwellings) op die vel wat skielik verskyn),
- Stevens-Johnson-sindroom (begin met griepagtige simptome, gevolg deur 'n pynlike rooi of perserige uitslag wat versprei en blase maak),
- toksiese epidermale nekrolise (simptome sluit in 'n pynlike, rooi area wat vinnig versprei, die vel kan afdop sonder blase en koors),
- hipotermie (wanneer u liggaam vinniger hitte verloor as wat dit hitte kan produseer).

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,
- prikkelbaarheid,
- aggressie,
- rusteloosheid,
- depressie (bestaande depressie kan ontmasker word)
- medisyneverdraagsaamheid (wanneer u liggaam aanpas by die voortdurende teenwoordigheid van die medisyne en nie meer so goed op die medisyne reageer nie),
- agitasie ('n toestand van angs of senuwee-opwinding),
- slaperigheid ('n sterk begeerte om te slaap en 'n gevoel van lomerigheid),
- sedasie,
- duiseligheid,
- versteuring in aandag,
- stadige spraak/disartrie (onduidelike spraak)/spraakversteuring,
- hoofpyn,
- bewing,
- ataksie (verswakte balans of koördinasie),
- droë mond,
- naarheid,
- hardlywigheid,
- moegheid, veral aan die begin van behandeling.

Minder algemene newe-effekte

- abnormale gedrag,
- konfessionele toestand (verwarde denke en verminderde bewustheid van die omgewing),
- angs (intense en aanhoudende bekommernis en vrees oor alledaagse),
- waan-toestand (glo dinge wat nie waar is nie),
- nagmerrie,
- verlies van libido (seksuele drang),
- emosionele armoede,
- geheueverlies wat met abnormale gedrag geassosieer kan word,
- geheue inkorting (veranderinge in u geheue),
- anterograde geheueverlies (verlies aan die vermoë om die onlangse verlede te herroep, maar langtermynherinneringe is steeds ongeskonde),
- depressie van bui en affekte
- lusteloosheid
- verhoogde motoriese aktiwiteit
- verminderde motoriese aktiwiteit
- paradoksale reaksies (inkonsekwent of teenstrydig) soos in oormaat
- opgewondenheid met woede
- diplopie (dubbelvisie),
- veluitslag
- gewigstoename,
- verhoogde moontlikheid om te struikel of te val, veral by bejaarde pasiënte.
- om te val

Onbekende frekwensie

- afhanklikheid (word afhanklik van CLOBAZAM ADCO),
- aanvanklike slapeloosheid (probleem om aan die slaap te raak en aan die slaap te bly),
- woede,
- hallusinasie (sien dinge wat nie werklik is nie),
- psigotiese versteuring ('n geestesversteuring wat gekenmerk word deur 'n ontkoppeling van die werklikheid),
- slegte kwaliteit slaap,
- selfdoodgedagtes (om aan selfdood te dink of te beplan),
- kognitiewe versteuring (afwykings wat kognitiewe vermoëns beïnvloed, insluitend leer, geheue, persepsie en probleemoplossing),
- veranderde bewussynstoestand (veral by bejaarde pasiënte, kan gekombineer wees met respiratoriese afwykings),

- nistagmus (onwillekeurige beweging van die oog wat veroorsaak dat die oog vinnig van kant tot kant beweeg),
- stapversteuring (verandering in die manier waarop u loop),
- spierspasmas,
- spierswakheid,
- stadige reaksie op stimuli (stadige reaksietyd).

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, lig u dokter, apteker of verpleër in. Dit sluit enige moontlike newe-effekte in wat nie in hierdie voubiljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via Med Safety Toep (Medsafety X SAHPRA) en eAanmedlingsplatform (who-umc.org) wat gevind kan word op SAHPRA se webwerf. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van hierdie CLOBAZAM ADCO te verskaf.

5. Hoe om CLOBAZAM ADCO te bêre
BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Bêre teen of benede 25 °C.
Bêre in die oorspronklike houer
Moenie gebruik na die vervaldatum soos op die etiket 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 CLOBAZAM ADCO bevat
Die aktiewe bestanddeel(e) is 10 mg klobasaam in CLOBAZAM 10 ADCO en 20 mg klobasaam in CLOBAZAM 20 ADCO.
Die ander bestanddeel(e) is:
kolloïdale silikondioksied, mieliestysel, hidroksiepropielsellulose, laktosemonohidraat, magnesiumstearaat, talk.

Hoe CLOBAZAM ADCO lyk en inhoud van die verpakking
CLOBAZAM 10 ADCO tablette word aangebied as wit tot naaswit, ovaalvormige, onbedekte tablette met ‘n funksionele breeklyn aan die een kant en “C” en “M” ingedruk aan die ander kant.
CLOBAZAM 20 ADCO tablette word aangebied as wit tot naaswit, ovaalvormige, onbedekte tablette met ‘n funksionele breeklyn aan die een kant en “C” en “L” ingedruk aan die ander kant.

100's tel bottel verpakking vir CLOBAZAM 10/20 ADCO

40 ml HDPE-houer, maak gebruik van ‘n 33 mm kinderbestande (KB) prop met induksie verseëling. Puriteinse katoenspoel 9 g/jaart.

1000's tel bottel verpakking vir CLOBAZAM 10 ADCO

250 ml HDPE-houers, maak gebruik van ‘n 53 mm deurlopende draad (DD) skroefprop sluiting met induksie verseëling. Puriteinse katoenspoel 9 g/jaart.

1000's tel bottel verpakking vir CLOBAZAM 20 ADCO

400 ml HDPE-houers, gebruik 53 mm deurlopende draad (CT) skroefdop sluiting met induksie verseëling. Puriteinse katoenspoel 9 g/jaart.

Houer van Sertifikaat van Registrasie

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

Hierdie voubiljet is mees onlangs hersien op

25 Januarie 2025

Registrasie-/Aansoeknommer

CLOBAZAM 10 ADCO: 55/2.6/0546
CLOBAZAM 20 ADCO: 55/2.6/0547

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