SCHEDULING STATUS: S3

METFORMIN 500 XR ADCO, 500 mg prolonged release tablet
Metformin hydrochloride
Sugar free

METFORMIN 1000 XR ADCO, 1 000 mg prolonged release tablet
Metformin hydrochloride
Sugar free

Read all of this leaflet carefully before you start taking METFORMIN XR ADCO

- 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.
- METFORMIN XR 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 METFORMIN XR ADCO is and what it is used for

METFORMIN XR ADCO contains the active ingredient metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides which helps reduce high blood sugar levels.

METFORMIN XR ADCO does not stimulate insulin secretion and therefore the unwanted effects of an over reduction of blood sugar will not be produced.

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you have diabetes, your pancreas does not make enough insulin or your body is not able to properly use the insulin it produces. This leads to a high level of glucose in your blood. METFORMIN XR ADCO tablets helps to lower your blood glucose to as normal a level as possible.

METFORMIN XR ADCO is used for the treatment of type 2 diabetes mellitus in adults, when diet and exercise alone have not been enough to control blood glucose (sugar). METFORMIN XR ADCO can be given alone or can be taken with other oral antidiabetic medicines or with insulin.

2. What you need to know before you take METFORMIN XR ADCO
Do not take METFORMIN XR ADCO:

- if you are hypersensitive (allergic) to (metformin hydrochloride) or any of the other ingredients of METFORMIN XR ADCO (listed in section 6),
- if you have severe complications of your diabetes such as diabetic ketoacidosis (a metabolic state resulting from a serious lack of insulin) or diabetic pre-coma (when complications are left untreated). Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual, fruity smell,
- if you have severely weakened kidney function or kidney failure,
- if you have a short term conditions that may affect your kidney function e.g., dehydration, severe infection, shock, or if you have had injections of contrast mediums that contains iodine through the veins,
- if you have short or long term conditions that may cause a lack of oxygen to your tissues such as heart or breathing/lung failure, a recent heart attack, shock,
- if you have had a recent heart attack,
- if you have previously had inflammation of your pancreas,
- if you suffer from a liver condition, or use excessive amounts of alcohol,
- if you are pregnant.

Warnings and precautions
Take special care with METFORMIN XR ADCO:

- If you have serious kidney problems, cardiorespiratory illness (range of conditions that affect the heart and lungs) or sepsis (body's extreme response to an infection), the risk for developing a complication such as lactic acidosis is higher. Lactic acidosis is a rare, but serious and life threatening complication that can occur when lactic acid builds up in the blood stream faster than it can be removed.
- If you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. You should stop taking metformin and talk to your doctor for further instructions.
- If you show symptoms of lactic acidosis such as acidotic dyspnoea (hyperventilation), abdominal / stomach pain, muscle cramps, asthenia (a general feeling of not being well with severe tiredness and hypothermia), reduced body temperature and heartbeat followed by a state of coma (unconsciousness), the

use of METFORMIN XR ADCO should be stopped and should urgently be treated in a hospital environment.

- If you take other medicines which can lower the kidney's capacity to function properly for a short period of time (such as blood pressure reducing medicines, diuretics (water pills) and NSAIDs (non-steroidal anti-inflammatory drugs). During the treatment with METFORMIN XR ADCO, your doctor should monitor your kidney functioning more frequently.
- If you have risk factors for the development of lactic acidosis such as uncontrolled diabetes, serious infections, prolonged fasting or high amounts of alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
- If you are using METFORMIN XR ADCO as long-term treatment, your vitamin B_{12} levels should be monitored yearly to assess for the development of megaloblastic anaemia (abnormal, immature red blood cells).
- If you have heart failure or kidney disease, continuous monitoring is needed. You must not use METFORMIN XR ADCO if you have unstable heart failure.
- If you are older than 75 years, treatment with METFORMIN XR ADCO should not be started to lower the risk or slow down the development of type 2 diabetes.
- If you are to be injected with a contrast medium that contains iodine, the use of metformin should be stopped for a period before and after the procedure. Only when your kidney function is stable may metformin be restarted again.
- If you need to have major surgery, METFORMIN XR ADCO should be discontinued 48 hours before and some time after the procedure. Your doctor will decide when you should stop and when to restart treatment with METFORMIN XR ADCO.
- If you are taking other blood sugar lowering tablets (e.g., sulphonylurea or meglitinides), or insulin.
- If you are starting treatment with METFORMIN XR ADCO and insulin, you might have to be admitted to hospital as you might be at risk for developing low blood glucose levels (until the correct ratio of the two medicines have been determined),
- If you are overweight: you should continue with your energy-restricted diet and be regularly monitored. You should continue your diet with a regular distribution of carbohydrate intake throughout the day.
- If you see the tablet shells in your stools. This is normal and will not cause you harm.

Other medicines and METFORMIN XR ADCO

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

You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of METFORMIN XR ADCO. It is especially important to mention the following:

- When you drink large amounts of alcohol and /or use alcohol-containing medications (e.g., elixirs or cough syrups).
- If you need to have an injection of contrast mediums that contains iodine into a vein, when you need an X-ray or a scan. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN XR ADCO.
- Medicines used to treat pain and inflammation such as NSAID (e.g., ibuprofen) and COX-2-inhibitors (e.g., celecoxib)
- Certain medicines for the treatment of high blood pressure such as ACE inhibitors and angiotensin II receptor antagonists (e.g., enalapril or valsartan) or diuretics (water pills) especially loop diuretics (e.g., furosemide).
- Medicines to treat asthma such as beta-2 agonists (e.g., salbutamol or terbutaline).
- Corticosteroids to treat a variety of conditions, including severe inflammation of the skin or in asthma.
- Anticoagulants (medicines used to prevent clotting of the blood).
- Sulphonylurea (medicines that are used to help control your blood glucose levels).
- METFORMIN XR ADCO may reduce the uptake of vitamin B_{12} from your gastro-intestinal tract. The dose of METFORMIN XR ADCO may need to be adjusted.
- If you are taking verapamil (for the treatment of high blood pressure), rifampicin (an antibiotic used to treat tuberculosis), cimetidine (medicines used to treat heartburn or stomach ulcers), dolutegravir (an anti-viral), ranolazine (treats heart related chest pain), trimethoprime (antibiotic), isavuconazole (antifungal), rizotinib, olaparib and vandetanib (chemotherapy medicines used for certain types of cancer). These medicines may increase the amount of METFORMIN XR ADCO in your blood, especially if you have reduced kidney function.

METFORMIN XR ADCO with food and drink

Avoid excessive alcohol intake while taking METFORMIN XR ADCO since this may increase the risk of lactic acidosis (see section 2, Warnings and precautions).

Pregnancy and 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 this medicine.

You should not take METFORMIN XR ADCO during pregnancy and breastfeeding.

No data on the influence of fertility is available.

Driving and using machines:
It is not always possible to predict to what extent METFORMIN XR ADCO may interfere with your daily actitivies. You should ensure that you do not engage in activites requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware ofthe measure to which METFORMIN XR ADCO affects you.

METFORMIN XR ADCO on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines. However, take special care if you take METFORMIN XR ADCO together with other medicines used to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take METFORMIN XR ADCO
Do not share medicines prescribed for you with any other person:
Always take METFORMIN XR ADCO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

METFORMIN XR ADCO is for oral use only.

METFORMIN XR 500 ADCO:
The usual starting dose is one tablet daily taken with the evening meal. Your doctor may adjust your dose after 10 to 15 days.
The maximum recommended dosage is usually not more than four tablets daily.

METFORMIN XR 1000 ADCO:
The usual starting dose is one tablet daily taken with the evening meal at a maximum recommended dose of 2 tablets per day.
METFORMIN XR 1000 ADCO is intended as maintenance therapy for patients currently treated with either 1 000 mg or 2 000 mg of metformin hydrochloride.

If you take more METFORMIN XR ADCO 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 have taken more METFORMIN XR ADCO than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat.

If you experience some of these symptoms, you should seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking METFORMIN XR ADCO immediately and contact a doctor or the nearest hospital straight away.

If you forget to take METFORMIN XR ADCO
Do not take a double dose to make up for forgotten individual dose. Take the dose as soon as you remember.

4. Possible side effects
METFORMIN XR ADCO can have side effects.
Not all side effects reported for METFORMIN XR ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METFORMIN XR ADCO, please consult your health care provider for advice.
If any of the following happens, stop taking METFORMIN XR ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe skin reactions such as erythema, a type of hypersensitivity reaction with fever, itching and skin lesions, pruritus (itching) and urticaria (hives or rash of the skin).

These are all very serious side effects. If you have them, you may have had a serious reaction to METFORMIN XR ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequent side effects:

- taste disturbance,
- nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. These side-effects occur most frequently during start of therapy and resolve spontaneously in most cases. A slow increase of the dose may also reduce unwanted effects affecting the bowels.

Less frequent side effects:

- decrease of the absorption of a nutrient namely vitamin B_{12} with decrease of blood levels during long-term use of METFORMIN XR ADCO. This decrease in absorption should be considered if you present with megaloblastic anaemia (a deficiency of folic acid or Vitamin B_{12}),
- lactic acidosis (a condition where lactic acid build up in the bloodstream faster than it can be removed) (see section 2, Warnings and precautions).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the 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 METFORMIN XR ADCO.

5. How to store METFORMIN XR ADCO

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What METFORMIN XR ADCO contains
The active substance is metformin hydrochloride.

The other ingredients for METFORMIN XR 500 ADCO are carboxymethylcellulose (sodium CMC) 9M31F PH, hypromellose K 100M, magnesium stearate.

The other ingredients for METFORMIN XR 1000 ADCO are carmellose sodium, hypromellose K 100M, magnesium stearate, povidone K 90.

What METFORMIN XR ADCO looks like and contents of the pack
METFORMIN XR 500 ADCO:
Prolonged release tablets.
White to off white capsule shaped, biconvex, bevelled edge tablet, with occasionally mottled appearance, debossed with "TL001" on one side and plain on other side.

Contents of the pack:

- 10 X 10 prolonged release tablets are packed in clear, transparent, non-toxic PVC/PVDC film on a printed aluminium foil blister pack with a heat seal lacquer.

The blisters are further packed into a carton with a leaflet.

METFORMIN XR 1000 ADCO:
Prolonged release tablets.
White to off white oval, biconvex, bevelled edge, uncoated tablet with occasionally mottled appearance, debossed 'TL089' on one side and plain on other side.

Contents of the pack:

- 6 x 10 prolonged release tablets are packed in blister strips composed of plain aluminium foil and clear, transparent, non-toxic PVC/PVDC film with text matter printed on dull surface of aluminium (with NC coating) and heat seal lacquer coating on other side (silver coloured).

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
Not applicable

Registration number
METFORMIN 500 XR ADCO: 56/21.2/0728
METFORMIN 1000 XR ADCO: 56/21.2/0473

SKEDULERINGSTATUS: S3

METFORMIN 500 XR ADCO, 500 mg verlengde vrystelling-tablet
Metformienhidrochloried
Suikervry

METFORMIN 1000 XR ADCO, 1 000 mg verlengde vrystelling-tablet
Metformienhidrochloried
Suikervry

Lees die voubiljet noukeurig voordat u METFORMIN XR ADCO begin gebruik
- Hou hierdie voubiljet. U mag dit weer moet lees.
- Vra asseblief u dokter, apteker, verpleegster of ander gesondheidsorgverskaffer as u enige verdere vrae het.
- METFORMIN XR ADCO is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle skaad, al het hulle dieselfde simptome as u.

Wat in hierdie voubiljet is

1. Wat METFORMIN XR ADCO is en waarvoor dit gebruik word
METFORMIN XR ADCO bevat die aktiewe bestanddeel metformien, 'n medisyne om diabetes te behandel.
Dit behoort tot 'n groep medisynes wat biguaniede genoem word wat help om hoë bloedsuikervlakke te verlaag.

METFORMIN XR ADCO stimuleer nie insulien-afskeiding nie en daarom sal die ongewenste uitwerking van oor-verlaging van bloedsuiker nie plaasvind nie.

Insulien is 'n hormoon wat in die pankreas vervaardig word en wat u liggaam help om glukose (suiker) uit die bloed te onttrek. U liggaam gebruik glukose om energie te produseer of vir toekomstige gebruik te stoor.

As u diabetes het vervaardig u pankreas nie genoeg insulien nie of u liggaam is nie in staat om die insulien wat dit vervaardig behoorlik te gebruik nie. Dit lei tot 'n hoë

vlak glukose in u bloed. METFORMIN XR ADCO tablette help om u bloedglukose tot ’n vlak wat so na aan normaal as moontlik is te verlaag.
METFORMIN XR ADCO word gebruik vir die behandeling van tipe 2 diabetes mellitus by volwassenes wanneer dieet en oefening alleen nie genoeg om om u bloedglukose (-suiker) te beheer nie. METFORMIN XR ADCO kan op sy eie of saam met ander anti-diabetiese medisyne of insulien gebruik word.

2. Wat u moet weet voordat u METFORMIN XR ADCO gebruik
Moenie METFORMIN XR ADCO gebruik nie:

- as u hipersensitief (allergies) is vir metformienhidrochloried of enige van die ander bestanddele van METFORMIN XR ADCO (in afdeling 6 gelys),
- as u ernstige komplikasies met u diabetes, soos diabetiese ketoasidose (’n metaboliese toestand wat ’n ernstige tekort aan insulien veroorsaak) of diabetiese pre-koma (wanneer komplikasies onbehandeld gelaat word). Ketoasidose is ’n toestand waar stowwe wat ‘ketoon-liggaampies’ genoem word, in die bloed ophoop en wat tot diabetiese pre-koma kan lei. Simptome sluit maagpyn, vinnige en diep asemhaling, lomerigheid of u asem ontwikkel ’n ongewone vrugtige reuk, in,
- as u ernstige verswakte nierfunksie of nierversaking het,
- as u enige korttermyn toestande het wat u nierfunksie kan beïnvloed, bv. dehidrasie, erge infeksie, skok, of as u inspuitings met kontrasmiddels wat jodium bevat deur u are gehad het,
- as u kort- of langtermyn toestande het wat ’n tekort aan suurstof na u weefsels, soos die hart, of asemhalings-/longversaking, ’n onlangse hartaanval of skok kan veroorsaak,
- as u ’n onlangse hartaanval gehad het,
- as u vantevore inflammasie van die pankreas gehad het,
- as u aan ’n lewertoestand ly, of oormatige hoeveelhede alkohol gebruik,
- as u swanger is.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met METFORMIN XR ADCO:

- As u ernstige nierprobleme, kardiorespiratoriese siekte (reeks toestande wat die hart en longe beïnvloed) of sepsis (die liggaam se uiterste reaksie op infeksie), is die risiko om ’n komplikasie soos melksuur-asidose te kry hoër. Melksuur-asidose is ’n skaars, maar ernstig en lewensbedreigende toestand wat kan voorkom wanneer melksuur vinniger in die bloed opbou as wat dit verwyder kan word.
- As u ’n toestand het wat met dehidrasie geassosieer kan word (beduidende verlies van liggaamsvloeistowwe) soos erge braking, diarree, koors, blootstelling aan hitte of as u minder vloeistof drink as normaal. U moet gebruik van metformien staak en met u dokter praat vir verdere instruksies.
- As u simptome van melksuur-asidose soos asidotiese dispnee (hiperventilasie), buik/maagpyn, spierkrampe, astenie (’n algemene gevoel van siek wees met erge

moegheid en hipotermie), verlaagde liggaamstemperatuur en hartklop gevolg deur ’n staat van koma (bewusteloosheid), moet die gebruik van METFORMIN XR ADCO gestaak word en u moet dringende behandeling in ’n hospitaal-omgewing kry.
- As u ander medisyne vir ’n kort periode gebruik wat die niere se kapasiteit om te funksioneer kan inperk (soos medisyne om bloeddruk te verlaag, diuretika (waterpille) en NSAIDs (nie-steroïde anti-inflammatoriese medisynes). U dokter moet u nierfunksie meer gereeld monitor tydens gebruik van METFORMIN XR ADCO.
- As u risikofaktore vir die ontwikkeling van melksuur-asidose soos onbeheerde diabetes, ernstige infeksie, langdurige vas of inname van groot hoeveelhede alkohol, dehidrasie, lewerprobleme en enige mediese toestand waar ’n deel van die liggaam ’n verminderde toevoer van suurstof kry (soos ’n akute, erge hartsiekte).
- As u METFORMIN XR ADCO as langtermyn behandeling gebruik, moet u vitamien B_{12} vlakke jaarliks gemonitor word om te bepaal of u megaloblastiese anemie (abnormale, onderontwikkelde rooi bloedselle) ontwikkel.
- As u hartversaking of niersiekte het is voortdurende monitering nodig. U moenie METFORMIN XR ADCO gebruik as u onstabiele hartversaking het nie.
- As u ouer as 75 jaar is, moet behandeling met METFORMIN XR ADCO nie begin word om die risiko te verminder of die ontwikkeling of risiko van tipe 2 diabetes te vertraag nie.
- As u met ’n kontrasmiddel wat jodium bevat ingespuit moet word, moet die gebruik van metformien vir ’n tydperk voor en na die prosedure gestaak word. Behandeling met metformien kan slegs hervat word wanneer u nierfunksie stabiel is.
- As u ’n groot operasie moet ondergaan moet gebruik van METFORMIN XR ADCO 48 uur voor en vir ’n tydperk na die prosedure gestaak word. U dokter sal besluit wanneer u behandeling met METFORMIN XR ADCO moet staak en hervat.
- As u ander tablette vir die verlaging van bloedsuiker (bv. sulfonielureum of meglitiniede), of insulien gebruik.
- As u behandeling met METFORMIN XR ADCO saam met insulien begin, mag u in die hospitaal opgeneem moet word, want u kan ’n risiko loop vir die ontwikkeling van lae glukose-vlakke (totdat die korrekte verhouding van die twee medisynes bepaal is),
- As u oorgewig is: u moet aanhou met u energie-beperkte dieet en gereeld gemonitor word. U moet voortgaan met u dieet met ’n gereelde verspreiding van koolhidraat-inname deur die dag.
- As u die tablet-doppies in u stoelgang sien. Dit is normaal en sal u nie skaad nie.

Ander medisyne en METFORMIN XR ADCO

Vertel altyd u gesondheidsorgverskaffer as u ander medisyne gebruik.

(Dit sluit alle aanvullende en tradisionele medisyne in.)
U mag meer gereelde bloedglukose- en nierfunksie-toetse nodig hê, of u dokter mag die dosis van METFORMIN XR ADCO aanpas. Dit is veral belangrik om die volgende te noem:

- Wanneer u groot hoeveelhede alkohol en/of alkohol-bevattende medikasies (bv. eliksers of hoesstroop) gebruik.
- As u ’n inspuiting van kontrasmiddels wat jodium bevat in u aar moet kry, wanneer u ’n X-straal op skandering moet kry. U dokter sal besluit wanneer u behandeling met METFORMIN XR ADCO moet staak en hervat.
- Medisyne wat vir behandeling van pyn en inflammasie gebruik word, soos NSAIDs (bv. ibuprofeen) en COX-2-inhibeerders (bv. celecoxib)
- Sekere medisynes vir die behandeling van hoë bloeddruk soos ACE-inhibeerders en angiotensien II-reseptorantagoniste (bv. enalapril of valsartan) of diuretika (waterpille) spesifiek lus diuretika (bv. furosemied).
- Medisynes om asma te behandel soos beta-2-agoniste (bv. salbutamol of terbutalien).
- Kortikosteroïede om ’n verskeidenheid toestande te behandel, wat inflammasie van die vel en asma insluit.
- Antikoagulante (medisynes wat gebruik word om bloedklonte te verhoed).
- Sulfonielureums (medisynes wat gebruik word om te help om u bloedglukosevlakke te beheer).
- METFORMIN XR ADCO kan die opname van vitamien B_{12} uit u gastroïntestinale kanaal verminder. Die dosis van METFORMIN XR ADCO mag aangepas moet word.
- As u verapamil (vir die behandeling van hoë bloeddruk), rifampicin (’n antibiotika wat gebruik word om tuberkulose te behandel), cimetidine (medisyne wat gebruik word om sooibrand en maagsere te behandel), dolutegravir (’n antivirale middel), ranolazine (behandel hartverwante borspyn), trimethoprime (antibiotika), isavuconazole (anti-swam middel), rizotinib, olaparib en vandetanib (chemoterapeutiese medisyne gebruik vir behandeling van sekere tipes kanker) gebruik. Hierdie medisyne kan die hoeveelheid van METFORMIN XR ADCO in u bloed verhoog, veral as u verminderde nierfunksie het.

METFORMIN XR ADCO met kos en drank
Vermy oormatige alkohol-inname terwyl u METFORMIN XR ADCO gebruik want dit kan die risiko van melksuur-asidose verhoog (sien afdeling 2, Waarskuwings en voorsorgmaatreëls).

Swangerskap en borsvoeding
Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies as u swanger is of borsvoed, dink u kan dalk swanger wees of beplan om ’n baba te hê, voordat u hierdie medisyne gebruik.
U moenie METFORMIN XR ADCO tydens swangerskap of borsvoeding gebruik nie.

Geen data oor die invloed op vrugbaarheid is beskikbaar nie.

Bestuur en bedryf van masjinerie:
Dit is nie altyd moontlik om te voorspel tot watter mate METFORMIN XR ADCO u daaglikse aktiwiteite kan beïnvloed nie. U moet verseker dat u nie enige aktiwiteite beoefen wat geestelike paraatheid, oordeel en/of klankkoördinasie en sig vereis nie, bv. bestuur, ry, vlieg, seil of masjinerie/toerusting bedryf totdat u bewus is van die mate waartoe METFORMIN XR ADCO u beïnvloed nie.

METFORMIN XR ADCO op sy eie veroorsaak nie hipoglukemie (’n bloedglukosevlak wat te laag is) nie. Dit beteken dat dit nie u vermoë om te bestuur of masjinerie te bedryf beïnvloed nie. Neem nogtans spesiale sorg as u METFORMIN XR ADCO saam met ander medisynes vir die behandeling van diabetes wat hipoglukemie kan veroorsaak (soos sulfonielureums, insulien, meglitinides) gebruik. Simptome van hipoglukemie sluit swakheid, duiseligheid, toename in sweet, vinnige hartklop, versteuring van sig of moeite om te konsentreer in. Moenie bestuur of masjinerie bedryf as u hierdie simptome begin ervaar nie.

3. Hoe om METFORMIN XR ADCO te gebruik
Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie:
Gebruik METFORMIN XR ADCO altyd presies soos u dokter of apteker voorgeskryf het. Bevestig met u dokter of apteker as u onseker is.

METFORMIN XR ADCO is slegs vir mondelikse gebruik.

METFORMIN XR 500 ADCO:
Die gewone aanvangsdosis is een tablet daagliks met aandete. U dokter mag u dosis na 10 tot 15 dae aanpas.
Die maksimum aanbevole dosis is gewoonlik nie meer as vier tablette per dag nie.

METFORMIN XR 1000 ADCO:
Die gewone aanvangsdosis is een tablet daagliks met aandete. Die maksimum aanbevole dosis is 2 tablette per dag.
METFORMIN XR 1000 ADCO is bedoel as onderhoudsterapie vir pasiënte wat tans met 1 000 mg of 2 000 mg metformienhidrochloried behandel word.

As u meer METFORMIN XR ADCO gebruik as wat u moet
Raadpleeg u dokter of apteker in die geval van oordosering. As nie een van hulle beskikbaar is nie, kontak u naaste hospitaal of gifsentrum.
As u meer METFORMIN XR ADCO gebruik as wat u moes, kan u melksuur-asidose ervaar. Simptome van melksuur-asidose is nie-spesifiek, soos braking, maagpyn

(abdomale pyn) met spierkrampe, ’n algemene siek gevoel of net nie lekker voel nie met erge moegheid, en moeite om asem te haal. Verdere simptome is verlaagde liggaamstemperatuur en hartklop.

U moet onmiddellik mediese hulp kry as u sommige van hierdie simptome ervaar, want melksuur-asidose kan tot koma lei. Staak gebruik van METFORMIN XR ADCO en kontak ’n dokter of naaste hospitaal onmiddellik.

As u vergeet om METFORMIN XR ADCO te gebruik
Moenie ’n dubbel dosis neem om op te maak vir vergete individuele dosisse nie. Neem die dosis sodra u onthou.

4. Moontlike newe-effekte
METFORMIN XR ADCO kan newe-effekte hê.
Nie alle newe-effekte wat vir METFORMIN XR ADCO aangemeld is word in hierdie voubiljet ingesluit nie. As u algemene gesondheid verswak of u ervaar enige nadelige effekte tydens gebruik van METFORMIN XR ADCO, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.
Staak gebruik van METFORMIN XR ADCO en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal as enige van die volgende gebeur:

- Ernstige velreaksies soos eriteem, ’n tipe hipersensitiewe reaksie met koors, jeuking en velletsels, pruritis (jeuking) en urtikaria (galbulte of uitslag van die vel).

Hierdie is almal baie ernstige newe-effekte. As u hulle ervaar, kon u ’n ernstige reaksie tot METFORMIN XR ADCO gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

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

- verandering in smaak,
- naarheid, braking, diarree, abdomale pyn en verlies van eetlus. Hierdie newe-effekte kom mees algemeen by aanvang van behandeling voor en verdwyn vanself in meeste gevalle. ’n Geleidelike verhoging van die dosis kan ook nadelige effekte wat die buik beïnvloed verminder.

Minder gereelde newe-effekte:

- afname in die opname van ’n voedingstof genaamd vitamien B_{12} met afname van bloedvlakke gedurende langtermyn gebruik van METFORMIN XR ADCO. Hierdie afname in opname moet oorweeg word as u megaloblastiese anemie (’n tekort aan foliensuur of Vitamien B_{12}) toon,
- melksuur-asidose (’n toestand waar melksuur vinniger in die bloedstroom opbou as wat dit verwyder kan word (sien afdeling 2, Waarskuwings en voorsorgmaatreëls).

Lig asseblief u dokter of apteker in as u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegster as u newe-effekte ervaar. Dit sluit enige moontlike newe-effekte wat nie in hierdie voubiljet genoem word nie, in. U kan newe-effekte ook by SAHPRA aanmeld via die 6.04 Adverse Drug Reaction Reporting Form, aanlyn gevind onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan u help om meer inligting te verskaf oor die veiligheid van METFORMIN XR ADCO.

5. Hoe om METFORMIN XR ADCO te bêre
- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of laer as 25 °C.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) afspoel nie.
- Gee alle ongebruikte medisyne aan u apteker terug.

6. Inhoud van pak en ander inligting
Wat METFORMIN XR ADCO bevat
Die aktiewe bestanddeel is metformienhidrochloried.

Die ander bestanddele van METFORMIN XR 500 ADCO is karboksimetielsellulose (natrium CMC) 9M31F PH, hipromellose K 100M, magnesiumstearaat.

Die ander bestanddele van METFORMIN XR 1000 ADCO is karmellose natrium, hipromellose K 100M, magnesiumstearaat, povidoon K 90.

Hoe METFORMIN XR ADCO lyk en inhoud van pak
Verlengde vrystellingstablette.
Wit tot naaswit kapsule, bikonveks gevormde tablet met afgeronde rand, somtyds met gevlekte voorkoms, met “ADCO 001” op een kant gedruk en met niks op die ander kant nie.

Inhoud van die pak
- 10 X 10 verlengde vrystellingstablette, verpak in helder, deurskynende, nie-giftige PVC/PVDC film op ’n bedrukte aluminium foelie stulpverpakking met ’n hitte seël lak.

Die stulpverpakkings is verder in ’n kartondosie met ’n voubiljet verpak.

METFORMIN XR 1000 ADCO:

Verlengde vrystellingstablette.
Wit tot naaswit ovaal, bikonveks gevormde tablet met afgeronde rand, onbedekte tablet, somtyds met gevlekte voorkoms, met ‘1089’ op een kant gedruk en met niks aan die ander kant.

Inhoud van die pak:

- 6 x 10 verlengde vrystellingstablette in stulpverpakkings wat uit aluminium foelie en helder, deurskynende, nie-giftige PVC/PVDC film saamgestel is met teks op die dowwe oppervlak van die aluminium gedruk (met NC deklaag) en hitte seël lak aan die ander kant (silwerkleurig).

Nie alle pakgroottes word noodwendig bemark nie

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1685
Klantediens: 0860 ADCOCK/232625

Laaste hersieningsdatum van voubiljet
Nie beskikbaar nie

Registrasienommer
METFORMIN 500 XR ADCO: 56/21.2/0728
METFORMIN 1000 XR ADCO: 56/21.2/0473

adcock ingram

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