

METFORMIN BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

[S3]

METFORMIN 500 BIOTECH, 500 mg, film-coated tablet
METFORMIN 850 BIOTECH, 850 mg, film-coated tablet
Metformin hydrochloride
Contains sugar (lactose monohydrate).
METFORMIN 500 BIOTECH contains 10,8 mg and
METFORMIN 850 BIOTECH contains 14,4 mg per film-coated tablet.

Read all of this leaflet carefully before you start taking METFORMIN BIOTECH

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

1. What METFORMIN BIOTECH is and what it is used for

METFORMIN BIOTECH contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

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 BIOTECH helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking METFORMIN BIOTECH over a long period of time also helps to lower the risk of complications associated with diabetes. METFORMIN BIOTECH is associated with either a stable body weight or modest weight loss.

METFORMIN BIOTECH is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

Adults and children over 12 years of age can take METFORMIN BIOTECH on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

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

- if you are hypersensitive (allergic) to metformin or any of the other ingredients of METFORMIN BIOTECH (listed in section 6).
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. 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 reduced kidney function.
- if you lost too much water from your body (dehydration), such as due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see Warnings and precautions).
- if you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see Warnings and precautions).
- if you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream.
- if you are treated for acute heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see Warnings and precautions).
- if you have liver problems.
- if you drink a lot of alcohol.
- if you are pregnant or breastfeeding your infant.

Warnings and precautions

Take special care with METFORMIN BIOTECH:

Risk of lactic acidosis

METFORMIN BIOTECH may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), 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).

Stop taking METFORMIN BIOTECH for a short time 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. Talk to your doctor for further instructions.

Stop taking METFORMIN BIOTECH and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
 - stomach-ache (abdominal pain)
 - muscle cramps
 - a general feeling of not being well with severe tiredness
 - difficulty in breathing
 - reduced body temperature and heartbeat
- Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with METFORMIN BIOTECH, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

If you need to have major surgery, you must stop taking METFORMIN BIOTECH during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN BIOTECH.

You should continue your diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

The usual laboratory tests for diabetes monitoring should be performed regularly.

Tell your doctor if you suffer from a blood disease that is caused by a deficiency of vitamin B12 and folic acid.

METFORMIN BIOTECH on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take METFORMIN BIOTECH together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Children and adolescents

Do not use in children younger than 12 years of age.

Other medicines and METFORMIN BIOTECH

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

- iodinated contrast medicines.
- medicines which increase urine production (diuretics).
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma).
- medicines that may change the amount of METFORMIN BIOTECH in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- medicines used to treat clotting (anticoagulants).
- other medicines used to treat diabetes.

METFORMIN BIOTECH with alcohol

Avoid excessive alcohol intake while taking METFORMIN BIOTECH since this may increase the risk of lactic acidosis (see Warnings and precautions).

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 healthcare provider for advice before taking this medicine.

Do not take METFORMIN BIOTECH if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent METFORMIN BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which METFORMIN BIOTECH affects you.

METFORMIN BIOTECH 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 BIOTECH together with other medicines 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.

METFORMIN BIOTECH 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 METFORMIN BIOTECH

Do not share medicines prescribed for you with any other person. Always take METFORMIN BIOTECH exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take METFORMIN BIOTECH with or after a meal. This will avoid you having side effects affecting your digestion.

The usual dose is METFORMIN 850 BIOTECH twice a day or METFORMIN 500 BIOTECH three times a day.

If you are elderly your doctor will adjust the dose based on renal function.

If you are older than 12 years your doctor will prescribe a dose according to your blood glucose measurements.

Do not crush or chew the tablets. Swallow each tablet with a glass of water. If you take one dose a day, take it in the morning (breakfast). If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner). If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the evening (dinner).

Your doctor will tell you how long your treatment with METFORMIN BIOTECH will last. Do not stop treatment early because you feel better. If you have the impression that the effect of METFORMIN BIOTECH is too strong or too weak, tell your doctor or pharmacist.

If you take more METFORMIN BIOTECH 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 METFORMIN BIOTECH

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

If you stop taking METFORMIN BIOTECH

Do not stop taking METFORMIN BIOTECH without talking to your doctor first. Your blood sugar levels will be uncontrolled if you stop taking METFORMIN BIOTECH.

4. Possible side effects

METFORMIN BIOTECH can have side effects. Not all side effects reported for METFORMIN BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METFORMIN BIOTECH, please consult your healthcare provider for advice.

If any of the following happens, stop taking METFORMIN BIOTECH 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 METFORMIN BIOTECH. 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:

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see Warning and precautions)
- 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:

- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- bellyache (abdominal pain)
- loss of appetite

These side effects most often happen at the beginning of the treatment with METFORMIN BIOTECH. It helps if you spread the doses over the day and if you take METFORMIN BIOTECH with or straight after a meal.

- changes in taste.
- low vitamin B12 levels in the blood.

Less frequent side effects:

- abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes).
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

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. 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 BIOTECH.

5. How to store METFORMIN BIOTECH

Store all medicines out of reach of children.
Store at or below 25° C in a well-closed container.
Do not remove tablets from original packaging until required for use.
Protect from light and moisture.
Do not use after the expiry date stated on the label / carton / 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 METFORMIN BIOTECH contains

- The active substance is metformin hydrochloride.
METFORMIN 500 BIOTECH contains 500 mg metformin hydrochloride.
METFORMIN 850 BIOTECH contains 850 mg metformin hydrochloride.
- *The other ingredients are:*
Tablet core: colloidal silicon dioxide, copolyvidone, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.
Tablet coating: Opadry white OY- L-28900 consisting of: lactose monohydrate, macrogol 4 000, methylhydroxypropylcellulose, titanium dioxide (E171).

What METFORMIN BIOTECH looks like and contents of the pack

METFORMIN 500 BIOTECH: White, biconvex oblong film coated tablets, with a both sided score notch. One side engraved "M/500". The surface is faultless. L: 17,0 to 17,4 mm, B: 7,0 to 7,4 mm, H: 5,2 to 6,6 mm.

METFORMIN 850 BIOTECH: White, oblong film coated tablets. upside with "snap-tab" downside convex and engraved "M/850" and faultless surface. L: 19,0 to 19,4 mm, B: 8,0 to 8,4 mm.

METFORMIN 500 BIOTECH:

PRP (Patient Ready Pack): Plain laminated pouch made up of outer side metalised polyethylene terephthalate (PET) and inner side white opaque polyethylene (PE). Open from bottom side and zip lock with perforation on top side.

Pack size: 28, 56 and 84's
White, opaque HDPE container with white, opaque screw type cap with induction sealing wad.
Pack size: 56, 84 and 100's
Clear PVC/Aluminium blisters.
Pack size: 30, 60 and 90's

METFORMIN 850 BIOTECH:

PRP (Patient Ready Pack): Plain laminated pouch made up of outer side metalised polyethylene terephthalate (PET) and inner side white opaque polyethylene (PE). Open from bottom side and zip lock with perforation on top side.

Pack size: 28, 56 and 84's
White, opaque HDPE container with white, opaque screw type cap with induction sealing wad.
Pack size: 56, 84 and 100's
Clear PVC/Aluminium blisters.
Pack size: 30, 60 and 90's
Not all strengths or pack sizes may be marketed at the same time.

Holder of Certificate of Registration

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METFORMIN 500 BIOTECH: 35/21.2/0093
METFORMIN 850 BIOTECH: 35/21.2/0094

METFORMIN BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

[53]

METFORMIN 500 BIOTECH, 500 mg, firلمbedekte tablet
METFORMIN 850 BIOTECH, 850 mg, filmbedekte tablet
Metformienhidrochloried
Bevat suiker (laktosemonohidraat).
METFORMIN 500 BIOTECH bevat 10,8 mg en
METFORMIN 850 BIOTECH bevat 14,4 mg per filmbedekte tablet.

Lees hierdie pamflet versigtig deur voordat jy begin om METFORMIN BIOTECH te neem

- Bewaar hierdie pamflet. Jy mag dit dalk weer moet deurlees.
- Indien jy verdere vrae het, vra asseblief vir jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- METFORMIN BIOTECH is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat METFORMIN BIOTECH is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy METFORMIN BIOTECH neem
3. Hoe om METFORMIN BIOTECH te neem
4. Moontlike nuwe-effekte
5. Hoe om METFORMIN BIOTECH te bewaar
6. Inhoud van die pak en ander inligting

1. Wat METFORMIN BIOTECH is en waarvoor dit gebruik word

METFORMIN BIOTECH bevat metformien, 'n medisyne om diabetes (suikersiekte) te behandel. Dit behoort aan 'n groep medisyne wat biguaniede genoem word.

Indien jy diabetes het, maak jou pankreas nie genoeg insulien nie of jou liggaam is nie in staat om die insulien wat dit produseer behoorlik te gebruik nie. Dit lei tot 'n hoë vlak van glukose in jou bloed. METFORMIN BIOTECH help om jou bloedglukose tot so normaal as moontlik te verlaag.

Indien jy 'n oorgewig volwassene is, help die neem van METFORMIN BIOTECH oor 'n lang tydperk ook om die risiko van komplikasies wat met diabetes geassosieer word, te verlaag. METFORMIN BIOTECH word geassosieer met óf 'n stabiele liggaamsgewig óf beskeie gewigsverlies.

METFORMIN BIOTECH word gebruik om pasiënte met tipe 2-diabetes (ook genoem 'nie-insulienafhanklike diabetes') te behandel wanneer dieet en oefening alleen nie genoeg was om jou bloedglukosevlakke te beheer nie. Dit word veral in oorgewig pasiënte gebruik.

Volwassenes en kinders ouer as 12 jaar kan METFORMIN BIOTECH op sy eie of saam met ander medisyne gebruik om diabetes te behandel (medisyne wat deur die mond of insulien geneem word).

2. Wat jy moet weet voordat jy METFORMIN BIOTECH neem

Moenie METFORMIN BIOTECH neem nie:

- indien jy hipersensitief (allergies) is vir metformien of enige van die ander bestanddele van METFORMIN BIOTECH (gelys in afdeling 6),
- indien jy onbeheerde diabetes het, met byvoorbeeld ernstige hiperglukemie (hoë bloedglukose), naarheid, braking, diarree, vinnige gewigsverlies, melksuurasedose (sien "Risiko van melksuurasedose "hieronder) of ketoasidose. Ketoasidose is 'n toestand waarin stowwe wat 'ketoonliggame' genoem word, in die bloed ophoop en wat tot diabetiese pre-koma kan lei. Simptome sluit in maagpyn, vinnige en diep asemhaling, slaperigheid of jou asem wat 'n ongewone vrugtige reuk ontwikkel.
- indien jy ernstig verminderde nierfunksie het,
- indien jy te veel water uit jou liggaam verloor het (dehidrasie), soos as gevolg van langdurige of erge diarree, of as jy verskeie kere in 'n ry opgegooi het. Dehidrasie kan lei tot nierprobleme, wat jou in gevaar kan stel vir melksuurasedose (sien Waarskuwings en voorsorgmaatreëls).
- indien jy 'n ernstige infeksie het, soos 'n infeksie wat jou long of brongiale stelsel of jou nier aantas. Erge infeksies kan lei tot nierprobleme, wat jou in gevaar kan stel vir melksuurasedose (sien Waarskuwings en voorsorgmaatreëls).
- indien jy 'n ondersoek soos X-straal of skandering moet ondergaan wat die inspuiting van kontrasmedisyne wat jodium bevat in jou bloedstroom behels.
- indien jy behandel word vir akute hartversaking of onlangs 'n hartaanval gehad het, ernstige probleme met jou sirkulasie het (soos skok) of asemhalingsprobleme het. Dit kan lei tot 'n gebrek aan suurstoftoevoer na weefsel wat jou in gevaar kan stel vir melksuurasedose (sien Waarskuwings en voorsorgmaatreëls).
- indien jy lewerprobleme het.
- indien jy baie alkohol drink.
- indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met METFORMIN BIOTECH:

Risiko van melksuurasedose

METFORMIN BIOTECH kan 'n baie seldsame, maar baie ernstige nuwe-effek veroorsaak wat melksuurasedose genoem word, veral as jou niere nie behoorlik werk nie. Die risiko om melksuurasedose te ontwikkel word ook verhoog met onbeheerde diabetes, ernstige infeksies, langdurige vas of alkoholinnam, dehidrasie (sien verdere inligting hieronder), lewerprobleme en enige mediese toestande waarin 'n deel van die liggaam 'n verminderde toevoer van suurstof het (soos akute ernstige hartsiekte).

Hou op om METFORMIN BIOTECH vir 'n kort tydjie te neem as jy 'n toestand het wat geassosieer kan word met dehidrasie (aansienlike verlies aan liggaamsvloeistowwe) soos erge braking, diarree, koors, blootstelling aan hitte of as jy minder vloeistof drink as normaalweg. Praat met jou dokter vir verdere instruksies.

Hou op om METFORMIN BIOTECH te neem en kontak onmiddellik 'n dokter of die naaste hospitaal as jy van die simptome van melksuurasedose ervaar, aangesien hierdie toestand tot koma kan lei.

Simptome van melksuurasedose sluit die volgende in:

- braking
 - maagpyn (abdominale pyn)
 - spierkrampe
 - 'n algemene gevoel van onwel met erge moegheid
 - moeilike asemhaling
 - verlaagde liggaamstemperatuur en hartklop
- Melksuurasedose is 'n mediese noodgeval en moet in 'n hospitaal behandel word.

Tydens behandeling met METFORMIN BIOTECH sal jou dokter jou nierfunksie ten minste een keer per jaar of meer gereeld nagaan as jy bejaard is en/ of as jy verslegtende nierfunksie het.

Indien jy 'n groot operasie moet ondergaan, moet jy ophou om METFORMIN BIOTECH tydens en vir 'n geruime tyd na die prosedure te neem. Jou dokter sal besluit wanneer jy moet stop en wanneer om jou behandeling met METFORMIN BIOTECH weer te begin.

Jy moet jou dieet voortsit met 'n gereelde verspreiding van koolhidraat-inname gedurende die dag. Oorgewig pasiënte moet voortgaan met hul energie-beperkte dieet.

Die gewone laboratoriumtoetse vir diabetesmonitering moet gereeld uitgevoer word.

Vertel jou dokter as jy aan 'n bloedsiekte ly wat veroorsaak word deur 'n tekort aan vitamien B12 en foliensuur.

METFORMIN BIOTECH op sy eie veroorsaak nie hipoglukemie ('n bloedglukosevlak wat te laag is nie). As jy egter METFORMIN BIOTECH saam met ander medisyne gebruik om diabetes te behandel wat hipoglukemie kan veroorsaak (soos sulfonilureumderivate, insulien, meglitiniede), is daar 'n risiko van hipoglukemie. As jy simptome van hipoglukemie ervaar soos swakheid, duiseligheid, verhoogde sweet, vinnige hartklop, sigafwykings of konsentrasieprobleme, help dit gewoonlik om iets wat suiker bevat te eet of te drink.

Kinders en adolessente

Moet nie by kinders jonger as 12 jaar gebruik nie.

Ander medisyne en METFORMIN BIOTECH

- Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)
- jodiumhoudende kontrasmedisyne.
 - medisyne wat urienproduksie verhoog (diuretika).
 - sekere medisyne vir die behandeling van hoë bloeddruk (ACE-inhibeerdere en angiotensien II-reseptorantagoniste).
 - medisyne wat gebruik word om pyn en inflammasie te behandel (NSAID en COX-2-inhibeerdere, soos ibuprofen en selekoksib).
 - kortikosteroïede (word gebruik om 'n verskeidenheid toestande te behandel, soos ernstige inflammasie van die vel of asma).
 - medisyne wat die hoeveelheid METFORMIN BIOTECH in jou bloed kan verander, veral as jy verminderde nierfunksie het (soos verapamil, rifampisien, simetidine, dolutegravir, ranolasion, trimetoprim, vandetanib, isavukonasool, krizotinib, olaparib).
 - medisyne wat gebruik word om stolling te behandel (antikoagulate).
 - ander medisyne wat gebruik word om diabetes te behandel.

METFORMIN BIOTECH met alkohol

Vermi oormatige alkoholinnam terwyl jy METFORMIN BIOTECH neem aangesien dit die risiko van melksuurasedose kan verhoog (sien Waarskuwings en voorsorgmaatreëls).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

Moenie METFORMIN BIOTECH neem as jy swanger is of jou baba borsvoed nie.

Bestuur en gebruik van masjiene

Dit is nie altyd moontlik om te voorspel tot watter mate METFORMIN BIOTECH jou daaglikse aktiwiteite kan inmeng nie. Jy moet verseker dat jy nie bestuur of masjinerie bestuur nie totdat jy bewus is van die mate waarin METFORMIN BIOTECH jou beïnvloed.

METFORMIN BIOTECH op sy eie veroorsaak nie hipoglukemie ('n bloedglukosevlak wat te laag is nie). Dit beteken dat dit nie jou vermoë om te bestuur of masjiene te gebruik sal beïnvloed nie. Wees egter veral versigtig as jy METFORMIN BIOTECH saam met ander medisyne gebruik om diabetes te behandel wat hipoglukemie kan veroorsaak (soos sulfonilureumderivate, insulien, meglitiniede). Simptome van hipoglukemie sluit in swakheid, duiseligheid, verhoogde sweet, vinnige hartklop, sigafwykings of konsentrasieprobleme. Moenie bestuur of masjiene gebruik as jy hierdie simptome begin voel nie.

METFORMIN BIOTECH bevat laktosemonohidraat

Indien jou dokter jou vertel het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne neem.

3. Hoe om METFORMIN BIOTECH te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem METFORMIN BIOTECH altyd presies soos jou dokter of apteker vir jou gesê het. Gaan praat met jou dokter of apteker as jy nie seker is nie.

Neem METFORMIN BIOTECH met of na 'n maaltyd. Dit sal verhoed dat jy nuwe-effekte het wat jou spysvertering beïnvloed.

Die gewone dosis is METFORMIN 850 BIOTECH twee keer per dag of METFORMIN 500 BIOTECH drie keer per dag.

Indien jy bejaard is, sal jou dokter die dosis aanpas op grond van nierfunksie.

Indien jy ouer as 12 jaar is, sal jou dokter 'n dosis volgens jou bloedglukosemetings voorskryf.

Moenie die tablette vergruis of kou nie. Sluk elke tablet met 'n glas water. Indien jy een dosis per dag neem, neem dit soggens (ontbyt). As jy twee verdeelde dosisse per dag neem, neem dit soggens (ontbyt) en aand (aandete). As jy drie verdeelde dosisse per dag neem, neem dit soggens (ontbyt), middagete (middagete) en saans (aandete).

Jou dokter sal jou vertel hoe lank jou behandeling met METFORMIN BIOTECH sal duur. Moenie behandeling vroeg staak nie omdat jy beter voel nie. As jy die indruk het dat die effek van METFORMIN BIOTECH te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer METFORMIN BIOTECH neem as wat jy moet

Indien die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om METFORMIN BIOTECH te neem

Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

Indien jy ophou om METFORMIN BIOTECH te neem

Moenie ophou om METFORMIN BIOTECH te neem sonder om eers met jou dokter te praat nie. Jou bloedsuikervlakke sal onbeheers wees as jy ophou om METFORMIN BIOTECH te neem.

4. Moontlike nuwe-effekte

METFORMIN BIOTECH kan nuwe-effekte hê.
Nie alle nuwe-effekte wat vir METFORMIN BIOTECH aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of indien jy enige nadelige effekte ervaar terwyl jy METFORMIN BIOTECH neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om METFORMIN BIOTECH te neem en vertel jou dokter dadelik of gaan na die ongevallende afdeling by jou 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,
- uitslag of jeuk,
- floute.

Hierdie is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op METFORMIN BIOTECH gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter dadelik of gaan na die ongevallende afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- melksuurasedose. Dit is 'n baie seldsame maar ernstige komplikasie, veral as jou niere nie behoorlik werk nie. Simptome van melksuurasedose is nie-spesifiek (sien Waarskuwing en voorsorgmaatreëls)
- Hierdie is alles ernstige nuwe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde nuwe-effekte:

- siek gevoel (naarheid)
 - siek wees (braking)
 - diarree
 - maagpyn (abdominale pyn)
 - verlies aan aptyt/ eetlus
- Hierdie nuwe-effekte kom meestal voor aan die begin van die behandeling met METFORMIN BIOTECH. Dit help as jy die dosisse oor die dag versprei en as jy METFORMIN BIOTECH met of direk na 'n maaltyd neem.
- veranderinge in smaak.
 - lae vitamien B12 vlakke in die bloed.

Minder gereelde nuwe-effekte:

- abnormaliteite in leverfunksietoetse of hepatitis (inflammasie van die lever; dit kan moegheid, verlies aan eetlus, gewigsverlies, met of sonder vergeling van die vel of wit van die oë veroorsaak).
- velreaksies soos rooiheid van die vel (eriteem), jeuk of 'n jeukerige uitslag (korwe).

Indien jy enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van nuwe-effekte

Indien jy nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aan SAHPRA aanmeld deur die vorm “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn gevind kan word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van METFORMIN BIOTECH te verskaf.

5. Hoe om METFORMIN BIOTECH te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar teen of benede 25° C in 'n diggeslote houer.
Moenie tablette uit oorspronklike verpakking verwyder totdat dit benodig word vir gebruik nie.
Beskerm teen lig en vog.
Moet nie gebruik na die vervaldatum soos aangedui op die etiket/ karton/ bottel nie.
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat METFORMIN BIOTECH bevat

- Die aktiewe stof is metformienhidrochloried.
METFORMIN 500 BIOTECH bevat 500 mg metformienhidrochloried.
METFORMIN 850 BIOTECH bevat 850 mg metformienhidrochloried.
- *Die ander bestanddele is:*
Tabletkern: kolloïdale silikoondioksied, kopoliïdooon, magnesiumstearaat, mikrokristallïene sellulose, natriumstyselglikolaat.
Tabletbedekking: Opadry wit OY- L-28900 wat bestaan uit: laktosemonohidraat, makrogol 4 000, metielhidroksiopropiëlsellulose, titaandioksied (E171).

Hoe METFORMIN BIOTECH lyk en die inhoud van die pak

Hoe METFORMIN BIOTECH lyk en die inhoud van die verpakking
METFORMIN 500 BIOTECH: Wit, bikonvekse langwerpige filmbedekte tablette, met 'n kerf aan beide kante. Een kant gegraveer "M/500". Die oppervlak is glad. L: 17,0 tot 17,4 mm, B: 7,0 tot 7,4 mm, H: 5,2 tot 6,6 mm.

METFORMIN 850 BIOTECH: Wit, langwerpige filmbedekte tablette. onderstebo met "snap-tab" onderkant konvek en gegraveerde "M/850" en gladde oppervlak. L: 19,0 tot 19,4 mm, B: 8,0 tot 8,4 mm.

METFORMIN 500 BIOTECH:

PRP (Pasiënt Gereed Pak): Gewone gelamioneerde sakkie wat bestaan uit gemetalliseerde poliëtleentereftalaat (PET) aan die buitekant en wit ondeursigtige poliëtleen (PE) aan die binnekant. Maak oop van onderkant en ritssluiting met gate aan bokant.
Pakgrootte: 28, 56 en 84's
Wit, ondeursigtige HDPE-houer met wit, ondeursigtige skroef tipe dop met induksie verseëling.
Pakgrootte: 56, 84 en 100's
Deursigtige PVC/Aluminium stulpstrok.
Pakgrootte: 30, 60 en 90's

METFORMIN 850 BIOTECH:

PRP (Pasiënt Gereed Pak): Gewone gelamioneerde sakkie wat bestaan uit gemetalliseerde poliëtleentereftalaat (PET) aan die buitekant en wit ondeursigtig poliëtleen (PE) aan die binnekant. Maak oop van onderkant en ritssluiting met gate aan bokant.
Pakgrootte: 28, 56 en 84's
Wit, ondeursigtige HDPE-houer met wit, ondeursigtige skroef tipe dop met induksie verseëling.
Pakgrootte: 56, 84 en 100's
Deursigtige PVC/Aluminium stulpstrok.
Pakgrootte: 30, 60 en 90's
Nie alle sterktes en of pakgroottes word gelyktydig bemark nie.

Houer van die Sertifikaat van Registrasie

Biotech Laboratories (Edms) Bpk
Grondvloer, Blok K Wes, Central Park
16^{de} Weg 400, Randjespark, Midrand, 1685
Suid-Afrika

Hierdie pamflet is laas hersien

31 Augustus 2023

Registrasienuommer

METFORMIN 500 BIOTECH: 35/21.2/0093
METFORMIN 850 BIOTECH: 35/21.2/0094