Approved Patient Information Leaflet for Medicines for Human Use:

METFORMIN ASCENDIS 500/850

SCHEDULING STATUS: S3

METFORMIN ASCENDIS 500 Film-coated tablets

Metformin hydrochloride

lactose monohydrate 66,60 mg

METFORMIN ASCENDIS 850 Film-coated tablets

Metformin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking

METFORMIN ASCENDIS

- 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 ASCENDIS 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 ASCENDIS is and what it is used for

2. What you need to know before you take METFORMIN ASCENDIS

3. How to take METFORMIN ASCENDIS

4. Possible side effects

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

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

METFORMIN ASCENDIS indicated in treating non-insulin dependent diabetes particularly in overweight patients, when dietary management and exercise alone does not control blood glucose level.

In children over 12 years of age and adolescents with type 2 diabetes, METFORMIN ASCENDIS may be used as alone or in combination with insulin.

In overweight adult, taking METFORMIN ASCENDIS over a long period of time also helps to lower the risk of complications associated with diabetes.

2. What you need to know before you take METFORMIN ASCENDIS

Do not take METFORMIN ASCENDIS

- if you are hypersensitive (allergic) to metformin hydrochloride or any of the other ingredients of METFORMIN ASCENDIS (listed in section 6).
- If you have kidney problems such as kidney failure of kidney disease or condition which may alter kidney function such as:
  - dehydration (significant loss of water from the body),
  - severe infection,
  - shock,

- if you have liver disease
- if you suffer from heart attack or heart failure, severe breathing problems, a past history of lactic acidosis, diabetic coma, ketoacidosis
- if you drink a lot of alcohol

Make sure you ask your doctor for advice, 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
- you need to have major surgery

You must stop taking METFORMIN ASCENDIS for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Warnings and precautions

Special care should be taken with METFORMIN ASCENDIS

- Risk of lactic acidosis

  METFORMIN ASCENDIS may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidney 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).

If any of the above apply to you, talk to your doctor for further instructions.

Stop taking METFORMIN ASCENDIS 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 ASCENDIS 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.

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

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

During treatment with METFORMIN ASCENDIS, 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.

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

Children and adolescents

The diagnosis of type 2 diabetes mellitus should be confirmed before treatment with metformin is started. A careful follow-up of the effect of metformin on these parameters in metformin-treated children, especially prepubescent children is recommended.

Other medicines and METFORMIN ASCENDIS

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

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking METFORMIN ASCENDIS before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN ASCENDIS.

Tell your doctor if you taking, have recently taken or might take any medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of METFORMIN ASCENDIS. It is especially important to mention the following:

- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2 inhibitors, such as ibuprofen and celecoxib)

- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- beta-2 agonist such as salbutamol or terbutaline (used to treat asthma)
- 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 ASCENDIS in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole, crizotinib, olaparib)
- Other medicines used to treat diabetes.

METFORMIN ASCENDIS with iodinated contrasts agents

It should be discontinue prior to, or at the time of the imaging procedure and not restarted until 48 hours after provided that renal function has been re-evaluated and found to be stable.

METFORMIN ASCENDIS with alcohol

Avoid excessive alcohol intake while taking METFORMIN ASCENDIS since this may increase the risk of lactic acidosis.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking METFORMIN ASCENDIS.

Speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels. This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

METFORMIN ASCENDIS 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 ASCENDIS 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.

It is not always possible to predict to what extent METFORMIN ASCENDIS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which METFORMIN ASCENDIS affects them.

METFORMIN ASCENDIS contains lactose monohydrate

If you have been told by your healthcare provider that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take METFORMIN ASCENDIS

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

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

It is important that METFORMIN ASCENDIS tablets be taken in divided doses with meals.

Adults:

Initially, one 500 mg tablet three times a day or one 850 mg or 1000 mg tablet twice a day with or after food. After 10 to 15 days, the dose should be adjusted, according to blood glucose measurements. A slow increase in dose may decrease side effects affecting the stomach. The maximum daily dose is 3000 mg.

Children and adolescents:

METFORMIN ASCENDIS can be used in children from 12 years of age and adolescents. The usual starting dose is 500 mg or 850 mg once daily, given during meals or after meals. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of metformin is 2000 mg daily, taken as 2 or 3 divided doses.

Elderly: METFORMIN ASCENDIS dose in the elderly should be adjusted based on renal function.

Duration of administration

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

Method of administration

- You should take METFORMIN ASCENDIS in divided dosed with meals.
- Take the tablets with a sufficient quantity of liquid (e.g. one glass of water)
- Take METFORMIN ASCENDIS once a day, every day, at about the same time each day.

If you take more METFORMIN ASCENDIS than you should

If you have taken more METFORMIN ASCENDIS that 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 ASCENDIS immediately and contact a doctor or the nearest hospital straight away.**

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 ASCENDIS

Do not take a double dose to make up for forgotten individual doses. Take the next dose at the usual time.

4. Possible side effects

METFORMIN ASCENDIS can have side effects.

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

If any of the following happens, stop taking METFORMIN ASCENDIS 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 very serious side effects. If you have them, you may have had a serious reaction to METFORMIN ASCENDIS. You may need urgent medical attention or hospitilisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- vomiting
- stomach ache (abdominal pain)
- muscle pain
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite
- Change in taste
- Decrease or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin)

Less frequent side effects:

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

Side effects with frequency unknown:

- Lactic acidosis (vomiting, stomach ache, muscle cramps, a general feeling of not being well with severe tiredness, difficulty in breathing, reduced body temperature and heartbeat).

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. 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 ASCENDIS**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store METFORMIN ASCENDIS

Store all medicines out of reach of children

- Store at or below 25 °C.
- Store in the original package to protect from light and moisture.
- Keep the blisters in the carton until required for use.

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 ASCENDIS contains

METFORMIN ASCENDIS 500 mg:

- The active substance is metformin hydrochloride. Each film-coated tablet contains metformin hydrochloride 500 mg.
- The other ingredients are:

  Tablet core: colloidal silicon dioxide, gelatine, lactose monohydrate, magnesium stearate, sodium starch glycolate

Tablet coating: isopropyl alcohol, opadry white (consisting of hypromellose titanium dioxide, ethylcellulose, diethyl pththalate).

METFORMIN ASCENDIS 850 mg:

- The active substance is metformin hydrochloride. Each film-coated tablet contains metformin hydrochloride 850 mg.
- The other ingredients are:

  Tablet core: colloidal silicon dioxide, magnesium stearate, maize starch, povidone K-30, sodium starch glycolate

  Tablet coating: opadry white (consisting of hypromellose, purified talc, titanium dioxide, propylene glycol, polyethylene glycol/macrogol).

What METFORMIN ASCENDIS looks like and contents of the pack

METFORMIN ASCENDIS 500 are biconvex, white, film-coated tablets with a slight distinctive odour.

METFORMIN ASCENDIS 500 is supplied as 10 Tablets packed in aluminium and clear PVC blister strips. Ten blister strips are packed in an outer carton.

Alternatively, 14 tablets are packed in aluminium and clear PVC blister strips.

Two/four/six/eight blister strips are packed in an outer carton or 28, 56 or 84 tablets are packed in Patient Ready Pack Pouches (for state tender purposes only).

500 tablets are packed in white HDPE containers with white PP child resistant caps or white HDPE screw-on caps.

METFORMIN ASCENDIS 850 are biconvex, white, film-coated round tablets.

METFORMIN ASCENDIS 850 is supplied as 10 Tablets packed in aluminium and clear PVC blister strips. Six blister strips are packed in an outer carton.

Alternatively, 14 tablets are packed in aluminium and clear PVC blister strips.

Two/four/six blister strips are packed in an outer carton or 28, 56 or 84 tablets are packed in Patient Ready Pack Pouches (for state tender purposes only).

300 tablets are packed in white HDPE containers with white PP child resistant caps or white HDPE screw-on caps.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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