SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

1.1 Product Name: Metformin Hydrochloride 1000 mg film coated Tablets

1.2 Strength: 1000 mg

1.3 Pharmaceutical Dosage Form: Film coated Tablets

2. Qualitative and quantitative composition

2.1 Qualitative Declaration

Name of active ingredient(s)*
Metformin Hydrochloride
Povidone
Magnesium stearate
Purified water
Ready to use coating agent clear
Purified water

2.2 Quantitative Declaration

Name of active ingredient(s)*
Metformin Hydrochloride
Povidone
Magnesium stearate
Purified water
Ready to use coating agent clear
Purified water

3. Pharmaceutical form

Tablets

4. Clinical particulars

4.1 Therapeutic indications

Metformin Hydrochloride 1000 mg film-coated tablets contains metformin, a medicine to treat diabetes.1t belongs to group of medicines called biguanide.

Insulin is hormone produced by the pancreas that makes your body to take in glucose (sugar) from the blood. Your body use glucose to produce energy or to store it in future use. If you have diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. Metformin helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking Metformin Hydrochloride 1000 mg film-coated tablets over a long period of time also helps to lower the risk of complications associated with diabetes. Metformin Hydrochloride 1000 mg film-coated tablets is associated with either a stable body weight or modest weight loss.

Metformin Hydrochloride 1000 mg film-coated tablets 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 can take Metformin Hydrochloride 1000 mg film-coated tablets on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin). Children 10 years and over and adolescents can take Metformin Hydrochloride 1000 mg film-coated tablets on its own or together with insulin.

4.2 Posology and method of administration

Metformin Hydrochloride 1000 mg film coated tablet is 1000 mg:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have reduced kidney function, your doctor may prescribe a lower dose.

Metformin Hydrochloride 1000 mg film-coated tablets cannot replace the benefits of a healthy lifestyle. Continue to follow any advice about diet that your doctor has given you and get some regular exercise.

Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin Hydrochloride 1000 mg film-coated tablets' once a day. The maximum daily dose is 2000 mg

taken as 2 or 3 divided doses. Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited. Adults usually start with 500 mg or 850 mg Metformin Hydrochloride 1000 mg film-coated tablets' two or three times a day. The maximum daily dose is 3000 mg token as 3 divided doses.

* Tablets containing 500 mg . 850 and 1000 mg active substance metformin hydrochloride are also available, for individual dose adjustment.

If you take insulin too, your doctor will tell you how to start taking Metformin Hydrochloride 1000 mg film-coated tablets.

If you have reduced kidney function, your doctor may prescribe a lower dose.

Monitoring

Your doctor will perform regular blood glucose tests and will adapt your dose of Metformin Hydrochloride 1000 mg film-coated tablets to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an elderly.

- Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an elderly or if your kidneys are notworking normally.

If you have taken too much Metformin Hydrochloride 1000 mg film-coated tablets, contact your doctor the nearest hospital immediately.

A Metformin Hydrochloride 1000 mg film-coated tablets overdose of will not cause excessively low blood sugar levels. However, it increases the risk of over-acidification with lactic acid in the blood with lactic acid.

Over-acidification symptoms are listed at the end of sub-chapter "Do not take Metformin Hydrochloride 1000 mg film-coated tablets". Muscle pain with cramps, deep and rapid breathing, loss of consciousness and coma can develop within hours. This requires immediate emergency admission to hospital

If you forget to take Metformin Hydrochloride 1000 mg film-coated tablets

If you forget to take a dose, skip that dose and take your next dose at the next prescribed time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Metformin Hydrochloride 1000 mg film-coated tablets

Stopping Metformin Hydrochloride 1000 mg film-coated tablets treatment without your doctor's consent can cause your blood sugar level to rise uncontrollably. This will increase the risk of long term damage occurring e.g. to the eyes, kidney and vessels.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Method of administration : Oral, Swallow the tablets whole and with a glass of water with or after meals.

4.3 Contraindications

Renal or hepatic failure, alcoholism, NIDDM complicated by severe ketosis and acidosis, diabetic precoma and coma, patients undergoing surgery, after severe trauma or during infections, chronic obstructive pulmonary disease, coronary heart disease, cardiac failure, peripheral vascular disease, pregnancy, hypoglycemia and know hypersensitivity to Metformin.

4.4 Special warnings and precautions for use

Risk of lactic acidosis

Metformin 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). If any of the above apply to you, talk to your doctor for further instructions.
Stop taking Metformin Hydrochloride 1000 mg film-coated tablets fora 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 Hydrochloride 1000 mg film-coated tablets 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.

Metformin Hydrochloride 1000 mg film-coated tablets on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin Hydrochloride 1000 mg film-coated tablets together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonyl urea, 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.

If you need to have major surgery you must stop taking Metformin Hydrochloride 1000 mg film-coated tablets during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin Hydrochloride 1000 mg film-coated tablets.

During treatment with Metformin Hydrochloride 1000 mg film-coated tablets, 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.

4.5 Interaction with other medicinal products and other forms of interaction

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 Hydrochloride 1000 mg film-coated tablets before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Metformin Hydrochloride 1000 mg film-coated tablets.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dose of Metformin Hydrochloride 1000 mg film-coated tablets.

It is especially important to mention the following:

corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)

beta-2 agonists such as salbutamol or terbutaline (used to treat asthma)

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)

medicines that may change the amount of Metformin Hydrochloride 1000 mg film-coated tablets in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)

medicines to lower blood sugar levels such as insulin or those taken orally Taking these medicines together with Metformin Hydrochloride 1000 mg film-coated tablets could cause your blood sugar levels to become too low.

Avoid excessive alcohol intake while taking Metformin Hydrochloride 1000 mg film-coated tablets since this may increase the risk of lactic acidosis.

4.6 Fertility, pregnancy and lactation

During pregnancy, you need insulin to treat your diabetes. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

4.7 Effects on ability to drive and use machines

Metformin Hydrochloride 1000 mg film-coated tablets 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 Hydrochloride 1000 mg film-coated tablets together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonyl ureas, 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.

4.8 Undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Metformin may cause a very rare (may affect up to 1 in 10,000 people), but very serious side effect called lactic acidosis (see section "Warnings and precautions. If this happens you must stop taking Metformin Hydrochloride 1000 mg film-coated tablets and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

Other possible side effects

Very common, may affect more than 1 in 10 people.

nausea

vomiting

diarrhoea

abdominal pain

loss of appetite

These complaints mainly occur when beginning of therapy and spontaneously disappear in most cases. To prevent these complaints take the tablets with or after meals and in 2 to 3 doses daily.

Common,may affect upto 1 in 10 people

- change in taste

Very rare, may affect upto 1 in 10,000 people

reduction in the vitamin B12 uptake in the intestine when treated fora long-term period with Metformin Hydrochloride 1000 mg film-coated tablets

skin reddening

itching

itchy rash

abnormalities in liver function tests or liver inflammation; this may cause:

tiredness

loss of appetite

weight loss

yellowing of the skin or whites of the eyes.

Stop taking Metformin Hydrochloride 1000 mg film-coated tablets and tell your doctor straight away if this occurs.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix Y. By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

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5. Pharmacological properties

5.1 Pharmacodynamic properties

Metformin hydrochloride is an anti hyperglycemic agent which improves glucose tolerance in NIDDM (type 2 diabetes mellitus) subjects, lowering both basal and postprandial plasma glucose. Its pharmacological mechanisms of action are different from those of sulfonylureas. Metformin decrease hepatic glucose production and improves insulin sensitivity (increases peripheral glucose uptake and utilization). Unlike sulfonylureas, metformin does not produce hypoglycemia in either diabetic or non diabetic subjects and does not cause hyper insulinemia. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and day-long plasma insulin levels may actually decrease.

5.2 Pharmacokinetic properties

Absorption and Bioavailability : Following a single oral dose of sustained release Metformin, Cmax is achieved with a median value of 7 hours and a range of 4 hours to 8 hours. After repeated administration of a sustained release formulation, Metformin does not accumulate in plasma. Although the extent of absorption of sustained release Metformin increases by approximately 50% when given with food, there is no effect of food on Cmax and T max of Meformin.

Distribution

The apparent volume of distribution (V/F) of Metformin following single oral doses of 850 mg is 654±375 L. Metformin is negligibly bound to plasma proteins. At usual clinical

doses and dosing schedules, steady state plasma concentrations of Metformin are reached within 24-48 hours and are generally < 1 mg/ml.

Metabolism and Elimination

Metformin is excreted unchanged in the urine and does not undergo hepatic metabolism or biliary excretion. Renal clearance is approximately 3.5 times greater than creatinine clearance, which indicates that tubular secretion is the major route of Metformin elimination. Following oral administration, approximately 90% of the absorbed drug is eliminated via the renal route within the first 24 hours, with a plasma elimination half-life of approximately 17.6 hours.

SPECIAL POPULATIONS:

Patients with type 2 *diabetes and Gender:* There are no reported differences in pharmacokinetics of Metformin hydrochloride between patients with type 2 diabetes and normal subjects when analyzed according to gender.

Renal insufficiencv:

In patients with decreased renal function (based on measured creatinine Clearance), the plasma and blood half-life of Metformin Hydrochloride is prolonged and the renal clearance is decreased in proportion to the decrease in creatinine clearance. This increased level may lead to condition of lactic acidosis.

Hepatic insufficiencv:

No pharmacokinetic studies of Metformin hydrochloride have been conducted in patients with hepatic insufficiency.

Geriatrics:

Reported data from controlled pharmacokinetic studies of Metformin hydrochloride in healthy elderly subjects suggest that total plasma clearance is decreased, the half-life is prolonged and Cmax is increased, compared to healthy young subjects. From this data, it appears that the change in Metformin hydrochloride pharmacokinetics with aging is primarily accounted for by a change in renal function.

Pediatrics:

No pharmacokinetic studies of Metformin hydrochloride in pediatric patients have been conducted.

5.3 Preclinical safety data

Not available.

6. Pharmaceutical particulars

6.1 List of excipients

Povidone, Magnesium Stearate, Hydroxypropylmethyl cellulose, Macrogol6000, Macrogol400

6.2 Incompatibilities

None

6.3 Shelf life

36 Months

6.4 Special precautions for storage:

Keep out of reach of children.
Protect from light and moisture.
Store below 30°C in a dry place

6.5 Nature and contents of container

The tablets are packed in transparent PV'C/PV'dC &Aluminium foil blister packs of 30 ‘s tablets in a carton.

6.6 Special precautions for disposal and other handling: Not applicable.

7 Marketing Authorization Holder:

Mega lifesciences Public company Ltd.

8. Marketing Authorization Number(S):

09110/10899/NMR/2023

9. Date of first authorization/renewal of the authorization:
Nov 16, 2023

10. Date of revision of the text:

Nov 16, 2023