SPMC

Metformin Tablets BP 500 mg

Metformin Tablets BP 850 mg

Pharmacology

Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not cause hypoglycaemia. Metformin reduces basal hyperinsulinemia, and in combination with insulin, reduces insulin requirement. Metformin exerts its anti hyperglycaemic effect via multiple mechanisms: Metformin reduces hepatic glucose production. Metformin facilitates peripheral glucose uptake and utilization, in part by increasing insulin action. Metformin alters glucose turnover in the gut: Uptake from circulation is increased and absorption from food is decreased. Additional mechanisms attributed to the gut include an increase in release of glucagon-like peptide 1 (GLP-1) and a decrease of bile acid resorption. Metformin alters the gut microbiome. Metformin can improve the lipid profile in hyperlipidemic individuals. In clinical studies, use of metformin was associated with either a stable body weight or modest weight loss. Metformin is an adenosine monophosphate-protein-kinase (AMPK) activator and increases the transport capacity of all types of membrane glucose transporters (GLUTs).

Indications

- Type 2 diabetes mellitus (non-insulin-dependent diabetes mellitus), particularly in overweight or obese patients, when adequate glycaemic control has not been achieved through diet and exercise alone.
- In adults, Metformin 500 mg tablets may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.
- In children from 10 years of age and adolescents, Metformin 500 mg tablets may be used as monotherapy or in combination with insulin.
- A reduction in diabetic complications has been demonstrated in overweight adults with type 2 diabetes treated with Metformin as first-line therapy following failure of dietary measures.

Contraindications

- Hypersensitivity to Metformin or to any of the excipients listed in section Composition.
- Diabetic pre-coma.
- Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis)
- Severe renal failure (GFR <30 mL/min)
- Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock.
- Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock.
- Hepatic insufficiency, acute alcohol intoxication, alcoholism.

Special Warnings and Precautions

- Lactic acidosis is a rare but serious metabolic complication associated with Metformin accumulation, particularly in the presence of renal impairment, cardiorespiratory illness, sepsis, dehydration, hepatic insufficiency, excessive alcohol intake, ketosis, prolonged fasting, or hypoxic conditions.

Immediate Medical Attention Required: In the event of suspected lactic acidosis, Metformin should be discontinued immediately and the patient should be referred for urgent medical assessment and appropriate hospital management, as lactic acidosis may progress to coma.

Symptoms of Lactic Acidosis: Vomiting, Abdominal pain, Muscle cramps, A general feeling of being unwell with severe tiredness, Difficulty breathing, Reduced body temperature and heartbeat, Lactic acidosis is a medical emergency and requires hospital treatment.

- Metformin should be temporarily discontinued during episodes of severe dehydration (e.g., severe diarrhoea, vomiting, fever, or reduced fluid intake).
- Renal function (GFR) should be assessed before initiation of therapy and monitored regularly thereafter. Metformin is contraindicated in patients with GFR <30 mL/min.
- Use caution when initiating concomitant medications that may impair renal function, including antihypertensives, diuretics, and NSAIDs.
- Metformin is not recommended in individuals with known or suspected mitochondrial disorders (e.g., MELAS syndrome or MIDD) due to an increased risk of lactic acidosis and neurological complications.
- Patients with stable chronic heart failure may receive Metformin with regular monitoring of cardiac and renal function. Metformin is contraindicated in acute or unstable heart failure.
- Metformin should be discontinued prior to or at the time of administration of iodinated contrast media and restarted only after renal function has been reassessed and confirmed as stable.
- Metformin should be discontinued at the time of surgery under general, spinal, or epidural anaesthesia and restarted no earlier than 48 hours post-procedure, provided renal function is stable and oral nutrition has resumed.
- In paediatric patients, the diagnosis of type 2 diabetes mellitus should be confirmed before treatment initiation. Careful monitoring of growth and pubertal development is recommended during long-term treatment.
- Regular monitoring of glycaemic control and routine diabetes-related laboratory parameters is recommended throughout treatment.
- Metformin may reduce serum vitamin B12 levels, particularly with long-term use. Monitoring should be considered in patients with risk factors for vitamin B12 deficiency or when deficiency is suspected.
- Metformin monotherapy does not usually cause hypoglycaemia; however, caution is advised when used in combination with insulin or other antidiabetic agents associated with hypoglycaemia.
- This medicinal product is essentially sodium-free, containing less than 1 mmol (23 mg) sodium per film-coated tablet.

Children and Adolescents

Clinical experience in children aged 10–12 years is limited; therefore, treatment in this age group should be undertaken with caution.

Adverse Drug Reaction

Like all medicines, this medicine can cause side effects, although not everyone experiences them.

Very rare (up to 1 in 10,000 people) & very serious side effects)

Lactic acidosis

Very Common Side Effects (may affect more than 1 in 10 people)

Nausea, Vomiting, Diarrhoea, Abdominal pain, Loss of appetite

These side effects most commonly occur at the beginning of treatment with Metformin. Taking doses throughout the day and administering the medicine with or immediately after meals may help reduce these effects.

Common Side Effects (may affect up to 1 in 10 people)

Changes in taste, Decreased or low vitamin B12 levels in the blood

Symptoms of low vitamin B12 levels may include: Extreme tiredness (fatigue), A sore and red tongue (glossitis), Pins and needles (paraesthesia), Pale or yellow skin.

Liver Problems

Abnormal liver function test results, Hepatitis (inflammation of the liver)

symptoms may include: Tiredness, Loss of appetite, Weight loss. Yellowing of the skin or the whites of the eyes

Skin Reactions

Redness of the skin (erythema, Itching, Itchy rash (hives)

Additional Side Effects in Children and Adolescents

Limited data indicate that adverse events in children and adolescents are similar in nature and severity to those reported in adults.

Reporting of suspected adverse reactions

Suspected adverse reactions should be reported to the NMRA through the national pharmacovigilance reporting system. Furthermore, suspected adverse reactions should be reported via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

Driving and Using Machines

Use of Metformin alone is not expected to affect the ability to drive or operate machines. Special caution is required when Metformin is taken together with other medicines used to treat diabetes that may cause hypoglycaemia, such as sulphonylureas, insulin, or meglitinides.

Interactions

Concomitant medications should be reviewed. Additional monitoring of glycaemic control and renal function, and dose adjustment of Metformin where appropriate, may be required.

Concomitant Medications Requiring Special Consideration:

- Diuretics
- NSAIDs and COX-2 inhibitors, such as Ibuprofen and Celecoxib
- ACE inhibitors and angiotensin II receptor antagonists
- Beta-2 agonists such as salbutamol or Terbutaline
- Corticosteroids (used for various conditions, including severe skin inflammation and asthma)
- Medicines that may alter the amount of Metformin in the blood, particularly in cases of reduced kidney function, such as Verapamil, Rifampicin, Cimetidine, Dolutegravir, Ranolazine, Trimethoprim, Vandetanib, Isavuconazole, Crizotinib, and Olaparib
- Other antihyperglycaemics

Metformin with Alcohol

Caution is advised with excessive alcohol intake during Metformin therapy, as it may increase the risk of lactic acidosis (see Warnings and Precautions).

Posology & Method of Administration

Posology:

Adults with normal renal function (GFR≥90 mL/min)

Monotherapy and combination with other oral antidiabetic agents: The usual starting dose is 500 mg or 850 mg Metformin hydrochloride 2 or 3 times daily given during 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 hydrochloride is 3 g daily, taken as 3 divided doses. If transfer from another oral antidiabetic agent is intended: discontinue the other agent and initiate Metformin at the dose indicated above.

Combination with insulin: Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Metformin hydrochloride is given at the usual starting dose of 500 mg or 850 mg 2 or 3 times daily, while insulin dosage is adjusted on the basis of blood glucose measurements.

Elderly: Due to the potential for decreased renal function in elderly subjects, the Metformin dosage should be adjusted based on renal function. Regular assessment of renal function is necessary (see section 4.4).

Renal impairment: A GFR should be assessed before initiation of treatment with Metformin containing products and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

GFR mL/min	Total maximum daily dose (to be divided into 2-3 daily doses)	Additional considerations
60-89	3000 mg	Dose reduction may be considered in relation to declining renal function.
45-59	2000 mg	Factors that may increase the risk of lactic acidosis (see section 4.4) should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum dose.
30-44	1000 mg	
<30	-	Metformin is contraindicated.

Paediatric population

Monotherapy and combination with insulin:

- Metformin Tablets can be used in children from 10 years of age and adolescents. The usual starting dose is 500 mg or 850 mg metformin hydrochloride once daily, given during 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 hydrochloride is 2 g daily, taken as 2 or 3 divided doses.

Method of Administration:

- Metformin therapy is intended to complement, and not replace, appropriate lifestyle modifications. Continued adherence to recommended dietary measures, regular physical activity, and weight management strategies remains essential for achieving and maintaining optimal glycaemic control and overall metabolic health.
- To improve gastrointestinal tolerability, metformin should be administered during or after meals. Tablets should be swallowed whole with a glass of water and should not be crushed, broken, or chewed.
- The dosing schedule should be followed as prescribed. For once-daily administration, the dose should be taken with breakfast. For twice-daily administration, doses should be taken with breakfast and the evening meal. For three-times-daily administration, doses should be taken with breakfast, lunch, and the evening meal.
- Determine renal function before treatment & at least annually (at least twice a year in patients with additional risk factors for renal impairment or if deterioration suspected).

- In adult patients taking up to 2 g daily of the standard release Metformin may start with the same daily dose of Metformin modified release, not suitable if dose of standard release tablets more than 2 g daily.
- Patients and their carers should be informed of the risk of lactic acidosis and told to seek immediate medical attention if symptoms such as dyspnoea, muscle cramps, abdominal pain, hypothermia or asthenia occur.

When Metformin Should Be Temporarily Discontinued:

- An examination such as an X-ray or scan involving the injection of iodine-containing contrast medicines into the bloodstream is required.
- Major surgery is required - Treatment with Metformin must be stopped for a certain period before and after the examination or surgery. Alternative treatment should be provided. Compliance with medical instructions is essential.

Hepatic Impairment

Withdraw if tissue Hypoxia likely.

Renal Impairment

In Adults: avoid if eGFR is less than 30 ml/ min/1.73m^2.

In children: avoid if estimated Glomerular filtration rate is less than 30 ml/ min/1.73m^2.

Pregnancy and Breast-feeding

In pregnant women or those planning pregnancy, the need for treatment modification and appropriate monitoring of glycaemic control should be considered. Use of metformin during breastfeeding is not recommended.

Overdose

Taking more Metformin than prescribed may result in lactic acidosis.

Missed Dose

If a dose is missed, the next dose should be taken at the usual scheduled time. A double dose must not be taken to make up for the missed dose.

Storage Presentations

Instructions:

Keep this medicine out of the sight and reach of children. Store below 30°C and keep the bottle tightly closed. **Shelf life** 24 months. Do not use after the expiry date shown on the package.

Presentation:

Metformin tablet BP 500 mg:

White, circular, double-convex, film coated tablets with "SPMC" letters embossed on one side and score mark on the other side.

Bulk - 500's & 1000's, Blister - 200's

Metformin tablet BP 850 mg:

White, oval shape film coated tablets, engraved "SPMC" letters on one side.

Bulk - 500's

Composition

Metformin tablet BP 500 mg: Each film coated tablet contains Metformin Hydrochloride 500 mg as DC granules.

Metformin tablet BP 850 mg: Each film coated tablet contains Metformin Hydrochloride 850 mg.

Excipients: Maize Starch, Microcrystalline Cellulose, Povidone K 30, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Purified Talc, Magnesium Stearate, Hydroxypropyl cellulose, Polyethylene Glycol, Glycerol, Titanium Dioxide, Ethyl Alcohol.

Manufacturer & Marketing Authorization Holder:

State Pharmaceuticals Manufacturing Corporation
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