



METFORMIN TABLET 500MG

Metformin Hydrochloride (500mg)

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What SW Metformin Tablet 500mg is used for

It is used as treatment to control high blood sugar which is not responsive to diet alone or diet plus treatment with sulphonylurea.

How SW Metformin Tablet 500mg works

The active ingredient in the medicine is metformin hydrochloride. Metformin HCl works in lowering the production of glucose in liver by three way mechanisms which known in reduction of hepatic glucose production, increasing insulin sensitivity in muscle and uptake in peripheral tissue and also delay of intestinal glucose absorption. Metformin has favourable effects on lipid metabolism. This shown at therapeutic doses in controlled of medium or long term clinical studies that metformin reduce the level of total cholesterol, LDL cholesterol and triglycerides.

Before you use SW Metformin Tablet 500mg

- When you must not use it

Do not take SW Metformin Tablet 500mg if you:-

- have liver problem.
- have severely reduced kidney function.
- have lactic acidosis [too much lactic acid in the blood (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 of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).
- have heart problem or congestive heart failure.
- have low blood pressure.
- have diabetes mellitus with excessive acid level in body.
- have infectious disease or tissue death problem.

- are hypersensitivity to metformin HCl or any ingredients listed at the end of this leaflet.
- taking high amount or heavy drinker of alcohol

Pregnancy and breastfeeding

You should check with your doctor if you are pregnant or think you may be pregnant, planning to become pregnant or if you are breastfeeding. Metformin able to excrete into placenta which the concentration can be the same level of the dose intake by the mother.

Metformin is also found excreted into human breastmilk. It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks.

- Before you start to use it

Please consult your doctor or pharmacist if you are/have:

- heart disease.
- going for surgery or after surgery
- take medicine containing iodinated contrast agents (dyes) through injections.
- anaemia or neuropathy due to vitamin B12 deficiency.

Risk of lactic acidosis

SW Metformin Tablet 500mg 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, liver problems and any medical conditions in which a part of the body has a reduce 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 SW Metformin Tablet 500mg 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 SW Metformin Tablet 500mg 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

Lactic acidosis is a medical emergency and must be treated in a hospital.

Risk of kidney function

During treatment with SW Metformin Tablet 500mg, 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.

Children and adolescents

The diagnosed of type 2 diabetes should be confirmed before treatment with metformin is initiated. Although there is no effects of metformin on growth and puberty of children, however need to be used in caution especially used in children aged between 10 -12 years.

- Taking other medicines

There are few medicines which may interact with SW Metformin Tablet 500mg. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- iodinated contrast agents (dyes).
- medicine used to treat diabetes such as insulin, glitinides and sulfonylureas.
- large amounts of alcohol drinker or medicines contain alcohol with metformin.
- medicine for high blood pressure such as ACE inhibitors (such as enalapril, perindopril, quinapril), water tablet (diuretic) and beta-blockers and NSAIDs (pain relief).
- medicines contains steroids.
- Organic cation transporters (co-administration of metformin with verapamil, rifampicin or cimetidine).

How to use SW Metformin Tablet 500mg

- How much to use

You should take SW Metformin Tablet 500mg exactly as advised by your doctor or pharmacist. Dosage requirements are variable and must be individualized on the basis of the disease and the response of the individual.

Oral administration.

- Adult
One or combination therapy with other oral antidiabetic agents
Start with one tablet 2 or 3 times daily, take

during or after meals. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurement.

Your doctor or pharmacist may slowly increase the dose based on the gastro intestinal tolerability. The maximum recommended dose is 3g daily, taken as 3 divided tablets dose.

Combination with insulin

SW Metformin Tablet 500mg and insulin can be use combine as therapy for blood glucose control. The dose can start off with one tablet 2 – 3 times daily and insulin dosage is adjusted on the basis of blood glucose measurements.

Elderly

SW Metformin Tablet 500mg should be adjusted based on renal function. Your doctor may suggest for regular assessment of renal function if necessary due to the potential for decreased renal function.

Renal impairment

Your doctor may assess Glomerular filtration rate (GFR) in your blood before prescribe any medication contain metformin or after as frequent to monitor progression of kidney function especially if you are in the elderly age.

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 should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum
30-44	1000 mg	
<30	-	Metformin is contraindicated

• Children

One or combination therapy with insulin

The start off dose for children from 10 years old and adolescents is 500 or 850mg daily, taken during or after meals. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurement.

Your doctor or pharmacist may slowly increase the dose based on the gastro intestinal tolerability. The maximum recommended dose is 2g daily, taken as 2 or 3 divided tablets dose.

- When to use it

Use SW Metformin Tablet 500mg when needed and according to doctor's prescription.

- How long to use it

It is important to take SW Metformin Tablet 500mg as long as your doctor prescribes.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea and vomiting, anorexia (fear of gaining weight), weight loss, increased of acid level in stomach, unconsciousness and excessive of fluid in lungs and also lactic acidosis too.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking SW Metformin Tablet 500mg.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give SW Metformin Tablet 500mg to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how SW Metformin Tablet 500mg affects you.

Side effects

Like all medicines, SW Metformin Tablet 500mg can cause side effects, although not everybody gets them. The side effects may include;

- Gastrointestinal disorders: Very common
 - Nausea, vomiting, abdominal pain, loss of appetite.
- Nervous system disorders: Common
 - Taste altered/disturbance.
- Metabolism and nutrition disorders: Common (may affect up to 1 in 10 people):
 - Decreased 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). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Very rare

- Lactic acidosis (refer to Risk of lactic acidosis, in section **Before you use SW Metformin Tablet 500mg**)
- Liver & biliary system disorders: Very rare
 - Abnormalities in liver function tests or hepatitis (inflammation of the liver).
- Skin and tissue disorder: Very rare
 - Skin reaction such as redness on the skin, itchiness, hives.

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

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of SW Metformin Tablet 500mg

- Storage

Store at or below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines which no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Round, standard convex, white film-coated tablet with single score on one side only.

- Ingredient(s)

- Active Ingredient

- Metformin HCl

- Inactive Ingredients

- Lactose
- Corn Starch
- Magnesium Stearate
- Hydroxypropyl Methylcellulose
- Titanium dioxide
- Calcium Carbonate (light)
- Talcum powder
- Polyvinylpyrrolidone K90
- Kollidon 90F
- Isopropyl Alcohol
- Polyethylene Glycol 6000

- MAL number

MAL19900397AZ

Manufacturer & Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
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Date of revision

22/04/2026

Serial number:

NPRA(R2/2)260421/00050