



METFORMIN TABLET

Metformin Hydrochloride (250/500/850mg)

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What SW Metformin Tablet 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 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

– When you must not use it

Do not take SW Metformin Tablet 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 during surgery.
- are hypersensitivity to metformin HCL or any ingredients listed at the end of this leaflet.

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. It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks.

– Before you start to use it

Risk of lactic acidosis

SW Metformin Tablet 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 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 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 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, 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 metformin efficacy and safety in children below 12 did not differ in the older children, your doctor may outweigh any potential risks.

– Taking other medicines

There are few medicines which may interact with SW Metformin Tablet. 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.
- medicines contains steroids.

How to use SW Metformin Tablet

– How much to use

You should take SW Metformin Tablet exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Oral administration

Dosage requirements are variable and must be individualized on the basis of the disease and the response of the individual.

The initial recommended dosage is 500mg thrice a day or 850mg twice daily with meal and may gradually increase to 3gm maximum daily.

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 dose.
30-44	1000 mg	
<30	-	Metformin is contraindicated.

- When to use it

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

- How long to use it

It is important to take SW Metformin Tablet 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.

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.

- 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 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advice.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, SW Metformin Tablet can cause side effects, although not everybody gets them. The side effects may include reduction of Vitamin B12 absorption, nausea and vomiting, anorexia (fear of gaining weight), weight loss, increased of acid level in stomach, unconsciousness and excessive of fluid in lungs. Besides this increases of lactic acidosis and ketoacidosis may increase 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 reduce supply of oxygen (such as acute severe heart disease).

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 calling Tel: 03-78835549, or visiting the website npra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of SW Metformin Tablet

- 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 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

- Corn Starch
- Lactose
- Magnesium Stearate
- Hydroxypropyl methylcellulose
- Ethyleneglycol monoethyl ether
- Titanium dioxide
- Calcium Carbonate (light)
- Talcum

- MAL number

MAL05072022AZ
MAL19900397AZ
MAL07010930ASZ
MAL06051294AZ

Manufacturer

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Product Registration Holder

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26/09/2018

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