

PART III: PATIENT MEDICATION INFORMATION

**Pr METFORMIN
Metformin Hydrochloride Tablets**

This leaflet is part III of a three-part "Product Monograph" published when METFORMIN was approved for sale in Canada and is designed specifically for Consumers. Read this leaflet carefully before you start taking METFORMIN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment, and ask if there is any new information about METFORMIN.

ABOUT THIS MEDICATION

What is METFORMIN used for?

METFORMIN (metformin hydrochloride) is used, in addition to diet and exercise, to improve blood sugar levels in adults with type 2 diabetes.

How does METFORMIN work?

People with type 2 diabetes are not able to make enough insulin or respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, amputations, and blindness. Diabetes is also closely linked to heart disease. The main goal of treating diabetes is to lower your blood sugar to a normal level.

High blood sugar can be lowered by diet and exercise, by a number of medicines taken by mouth, and by insulin shots. While you take your diabetes medicine, continue to exercise and follow the diet advised for your diabetes, by your doctor.

No matter what your recommended diabetes management plan is, studies have shown that maintaining good blood sugar control can prevent or delay complications of diabetes, such as blindness.

METFORMIN helps to control your blood sugar. Although the mode of action of METFORMIN is not fully understood, it is believed to help your body respond better to the insulin it makes naturally by:

- decreasing the amount of sugar your liver makes, and
- decreasing the amount of sugar your intestines absorb.

What are the ingredients in METFORMIN?

Medicinal ingredient:

The medicinal ingredient in METFORMIN is metformin hydrochloride.

Nonmedicinal ingredients:

METFORMIN tablets contain the following non-medicinal ingredients:

Trade dress "M 500" and "M 850": povidone K 90 and magnesium stearate. The film-coating contains: hypromellose, titanium dioxide (E 171) and macrogol 4000.

METFORMIN comes in the following dosage forms:

METFORMIN (metformin hydrochloride) is formulated into 500 mg and 850 mg film-coated tablets for oral administration.

500 mg and 850 mg: bottles of 100 and 500 tablets.

Do not use METFORMIN if:

- You have unstable and/or insulin-dependent (Type I) diabetes mellitus.
- You have acute or chronic metabolic acidosis (including diabetic ketoacidosis, with or without coma, history of ketoacidosis with or without coma)
- You have a history of lactic acidosis (too much lactic acid in the blood)
- You drink a lot of alcohol
- You have severe liver dysfunction or liver disease
- You have kidney disease or impairment
- You are going to have an x-ray procedure with injection of iodinated contrast materials
- You have a severe infection or trauma
- Prior to surgery and during your recovery phase
- You suffer from severe dehydration (have lost a lot of water from your body)
- You are hypersensitive or allergic to metformin hydrochloride or any ingredient in the formulation or component of the container
- You are pregnant or planning to become pregnant
- You are breastfeeding
- You have cardiovascular collapse (abrupt failure of blood circulation) or cardiorespiratory insufficiency

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions

METFORMIN may rarely cause a serious, life-threatening condition called lactic acidosis (see Lactic Acidosis section below).

You should not drink a lot of alcohol if you take METFORMIN (see Lactic Acidosis section below).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take METFORMIN. Talk about any health conditions or problems you may have.

Lactic Acidosis

METFORMIN may rarely cause a serious, life-threatening condition called lactic acidosis.

You should not take METFORMIN due to greater risk for lactic acidosis if you:

- have kidney problems or a history of kidney disease
- are 80 years or older and you have NOT had your kidney function tested
- are seriously dehydrated (have lost a lot of water from your body)
- have liver disease
- have metabolic acidosis (e.g. diabetic ketoacidosis)
- drink a lot of alcohol (regularly drink alcohol or sometimes drink a lot of alcohol, binge drinking)
- have an x-ray procedure with injection of dyes (contrast agents)
- prior to surgery and during your recovery phase
- develop a serious medical condition, such as heart attack, severe infection, or a stroke

Due to greater risk for lactic acidosis, you should talk to your doctor if you take METFORMIN and if you:

- develop or experience a worsening of heart disease and particularly heart failure

Signs and symptoms of lactic acidosis include: discomfort, muscle pain, difficult or fast breathing, extreme tiredness, weakness, upset stomach, stomach pain, feeling cold, low blood pressure or slow heartbeat.

If any of the above side effects occur, consult your doctor immediately.

Other warnings you should know about:

You should not take METFORMIN if you:

- are pregnant or planning to become pregnant
- are breastfeeding
- have vitamin B-12 deficiency or anemia
- have any known hypersensitivity or allergy to the medicinal or nonmedicinal ingredients

Do not start or stop any medicine without the approval of your healthcare professional.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following drugs may interact with METFORMIN and require careful monitoring of your dose or condition:

- other diabetes drugs such as glyburide
- furosemide
- nifedipine
- cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin)
- certain “blood thinners” (phenprocoumon or other antivitamin K anticoagulants)

- diuretics, especially loop diuretics, that may increase the risk of lactic acidosis due to their potential to decrease renal function
- drugs that tend to produce hyperglycemia (high blood sugar) and may lead to a loss of blood sugar control. Some example of drugs that can increase the blood sugar include:
 - Thiazide and other diuretics (water pills)
 - Corticosteroids
 - Phenothiazines
 - Thyroid products
 - Estrogens or estrogens plus progestogen
 - Oral contraceptives
 - Phenytoin
 - Nicotinic Acid
 - Sympathomimetics
 - Calcium channel blocking drugs
 - Isoniazid
 - Beta-2-agonists
- ACE inhibitors drugs may lower blood glucose and the combination with METFORMIN should be carefully monitored.

Before using any drugs or herbal products, consult your healthcare professional.

PROPER USE OF THIS MEDICATION

How to take METFORMIN:

METFORMIN tablets are to be taken orally (by mouth).

Usual dose:

Your doctor will tell you how much medicine to take and when to take it. Follow the directions provided by your doctor for using this medicine. Taking this medicine with food will decrease symptoms such as nausea and vomiting.

Tablets may be split for ease of swallowing. Tablets should not be split to provide a lower dosage. Both halves of a split tablet are to be taken.

Overdose:

In general, an overdose may lead to increased symptoms as described under “SIDE EFFECTS AND WHAT TO DO ABOUT THEM” including stomach discomfort, nausea, vomiting, diarrhea, drowsiness, weakness, dizziness, malaise and headache.

A serious, life-threatening condition called lactic acidosis may also occur (see WARNINGS AND PRECAUTIONS, Lactic Acidosis).

If you think you have taken too much METFORMIN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take METFORMIN tablets, do not take a double dose to make up for forgotten individual doses. Take the next dose at the usual time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

What are possible side effects from using METFORMIN?

These are not all the possible side effects you may feel when taking METFORMIN. If you experience any side effects not listed here, contact your healthcare professional. Please also see WARNINGS AND PRECAUTIONS.

Common side effects of METFORMIN include:

- diarrhea
- nausea
- upset stomach
- abdominal bloating
- gas
- loss of appetite

These side effects generally go away after you take the medicine for a while. Taking your medicine with meals can help reduce these side effects. Tell your doctor if the side effects bother you a lot, last for more than a few weeks, come back after they've gone away, or start later in therapy. You may need a lower dose or need to stop taking the medicine for a short period or for good.

After you are on the same dose for several days or weeks, if any of these symptoms come back, tell your doctor immediately. A late recurrence of stomach symptoms may be due to a serious medical condition (lactic acidosis).

METFORMIN rarely causes hypoglycemia (low blood sugar) by itself. However, hypoglycemia can happen if you do not eat enough, if you drink alcohol, or if you take other medicines to lower blood sugar.

Lactic Acidosis: In rare cases, METFORMIN can cause a serious side effect called lactic acidosis. This is caused by a buildup of lactic acid in your blood. This build-up can cause serious damage. Lactic acidosis caused by METFORMIN is rare and has occurred mostly in people whose kidneys were not working normally. Although rare, if lactic acidosis does occur, it can be fatal in up to half the people who develop it.

It is also important for your liver to be working normally when you take METFORMIN. Your liver helps remove lactic acid from your blood.

Make sure you tell your doctor before you use METFORMIN if you have kidney or liver problems.

You should also stop using METFORMIN and call your doctor right away if you have signs of lactic acidosis. Lactic acidosis is a medical emergency that must be treated in a hospital.

If your medical condition suddenly changes, stop taking METFORMIN and call your doctor right away. This may be a sign of lactic acidosis or another serious side effect.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		
Symptom/effect		Stop taking drug and call your doctor or pharmacist
Uncommon	Feeling very weak, tired or uncomfortable	✓
	Unusual muscle pain	✓
	Trouble breathing	✓
	Unusual or unexpected stomach discomfort	✓
	Feeling cold	✓
	Feeling dizzy or lightheaded	✓
	Suddenly developing a slow or irregular heartbeat	✓
Rare	Lactic Acidosis (a build up of lactic acid in the blood) that can cause death or cardiovascular mortality Symptoms include: • Feeling very weak, tired, or uncomfortable • Unusual muscle pain • Trouble breathing • Unusual or unexpected stomach discomfort • Stomach pain with nausea and vomiting, or diarrhea • Feeling cold • Feeling dizzy or lightheaded • Suddenly developing a slow or irregular heartbeat	✓

This is not a complete list of side effects. For any unexpected effects while taking METFORMIN, contact your healthcare professional. If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

HOW TO STORE IT

Store at room temperature (15° to 30°C) in well closed containers. Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

Keep all medicines out of reach and sight of children.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada,
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document, plus the full Product Monograph prepared for health professionals, can be obtained by contacting the sponsor, Sanis Health Inc., at:
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