Diabetmin Film-coated Tablet

Metformin hydrochloride (250mg, 500mg, 850mg, 1000mg)

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What Diabetmin Film-coated Tablet is used for

Used to treat type 2 diabetes or noninsulin dependent diabetes mellitus (NIDDM) in adults whose high blood sugar levels cannot be lowered through exercising or monitoring food intake.

How Diabetmin Film-coated Tablet works

This medicine belongs to a group called biguanides that lowers the high blood sugar levels in the body.
It works by:

- reducing the amount of blood sugar produced in the liver • improving your body's sensitivity towards insulin and the way the body uses insulin.
- slowing down the rate of glucose being absorbed in the intestines.

Before you use Diabetmin Film-coated Tablet

- *When you must not use it*

Do not take this medicine if:

- you are allergic to meformin, any other biguanide, or its excipients
- you have diabetic coma (when your blood sugar is abnormally high and body is severely dehydrated)
- you have severe burns and infections
- you have severely reduced kidney function
- you have liver problems
- you have undergone/are undergoing major surgery
- you have severe trauma
- you 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).
- you have severe breathing difficulties
- you have heart or blood vessel problems eg. heart failure, heart attack, sudden/rapid development of blood failing to circulate in the body
- you are breastfeeding or plan to breastfeed
- you are pregnant or plan to become pregnant.

- *Before you start to use it*

Risk of lactic acidosis

Diabetmin Film-coated 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 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 Diabetmin Film-coated 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 Diabetmin Film-coated 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.

During treatment with Diabetmin Film-coated 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.

Tell your doctor if:

- you have allergies to any other medicines, foods, dyes or preservatives
- you drink alcohol
- you have heart failure
- you have kidney problems
- you are breastfeeding
- you are pregnant, think you are pregnant, or plan to get pregnant.

- *Taking other medicines*

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.
Some medicines interfere with metformin hydrochloride.

They include:

- acute or chronic ingestion of alcohol
- cimetidine or other cationic medications excreted by renal tubular transport
- furosemide
- hyperglycemia-causing and hypoglycemia-causing medications

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Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Diabetmin Film-coated Tablet

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults

- **Diabetmin Film-coated Tablet 250 mg Tablet**: take 2 tablets, 2 to 3 times a day
- **Diabetmin Film-coated Tablet 500 mg Tablet**: take 1 tablet, 2 to 3 times a day
- **Diabetmin Film-coated Tablet 850 mg Tablet**: take 1 tablet 2 times a day
- **Diabetmin Film-coated Tablet 1000 mg** Tablet: take 1 tablet once a day.

Diabetmin Film-coated Tablet is not recommended for children.

Dosages for elderly will be adjusted based on their kidney function and the possibility of decreased kidney function.

Swallow the tablet(s) with a full glass of water.

- *When to use it*

Use:
- **Diabetmin Film-coated Tablet 250 mg Tablet** with food
- **Diabetmin Film-coated Tablet 500 mg Tablet** with or without food
- **Diabetmin Film-coated Tablet 850 mg Tablet** with or without food
- **Diabetmin Film-coated Tablet 1000 mg Tablet** with or without food.

- *How long to use it*

You are advised to take it as long as your doctor tells you to.

- *If you forget to use it*

Do not take double dose to make up for a forgotten dose.

If you forget to take your dose, take it as soon as you remember. Skip the missed dose if it is almost time for your next 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.

You may experience the following if you take more than you should:

- low blood sugar
- lactic acidosis (symptoms include feeling sleepy, very tired, feeling sick, vomiting, trouble breathing and have unusual muscle pain, stomach pain or diarrhoea).

While you are using Diabetmin Film-coated Tablet

- *Things you must do*

Recognise the signs and symptoms of low blood sugar (hypoglycaemia) and high blood sugar (hyperglycaemia).
Initial signs and symptoms of hypoglycaemia:
- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

These may progress to:
- loss of coordination
- slurred speech
- confusion
- fits or loss of consciousness.

Signs and symptoms of hyperglycaemia:
- frequent urination
- increased thirst
- feeling hungry all the time.

Tell your doctor if:
- you become ill
- you become dehydrated
- you are injured
- you have fever or serious infection such as influenza, respiratory tract infection or urinary tract infection you are having a major surgery

- *Things you must not do*

Do not:
- give this medicine to anyone else, even if their symptoms seem similar to yours
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist
- stop taking the medicine or change the dosage on your own before asking your doctor
- take your medicine without food.

- *Things to be careful of*

Be careful not to let your blood sugar levels drop too low when doing activities that need you to be alert like driving and using machines. Drinking alcohol will make it worse. Watch your intake.

Side effects

All medicines can cause unwanted side effects. These effects can be serious but most of the time, they are mild and temporary.

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine.

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Metformin hydrochloride (250mg, 500mg, 850mg, 1000mg)

Very common side effects:
- gastrointestinal adverse effects including anorexia, diarrhea, dyspepsia, flatulence, nausea, vomiting
- headache
- metallic taste
- weight loss
- anemia
- megaloblastic
- hypoglycemia
- lactic acidosis

Common side effects (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.

Other unwanted side effects not listed may occur. Tell your doctor immediately.

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

Storage and Disposal of Diabetmin Film-coated Tablet

- *Storage*

Keep out of reach of children. Protect from light and moisture.

Store:
- **Diabetmin Film-coated Tablet 250 mg Tablet** below 30°C
- **Diabetmin Film-coated Tablet 500 mg Tablet** below 30°C
- **Diabetmin Film-coated Tablet 850 mg Tablet** below 30°C
- **Diabetmin Film-coated Tablet 1000 mg Tablet** 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?*

Diabetmin Film-coated Tablet 250 mg Tablet: Round, white film-coated tablet, bevel-edged and shallow convex faces and scored on one side.

Diabetmin Film-coated Tablet 500 mg Tablet: Round, white film-coated tablet, bevel-edged and shallow convex faces with deep score line on one side.

Diabetmin Film-coated Tablet 850 mg Tablet: Round, white film-coated tablet with deep convex faces and 'hovid' embossed on one face.

Diabetmin Film-coated Tablet 1000 mg Tablet: Oblong, white film-coated tablet, deep convex faces, deep scored and "HD" embossed on one face and scored on the other face.

- *Ingredients*

-Active ingredients

Each
- **Diabetmin Film-coated Tablet 250 mg Tablet** contains 250 mg Metformin Hydrochloride
- **Diabetmin Film-coated Tablet 500 mg Tablet** contains 500 mg Metformin Hydrochloride
- **Diabetmin Film-coated Tablet 850 mg Tablet** contains 850 mg Metformin Hydrochloride.
- **Diabetmin Film-coated Tablet 1000 mg Tablet** contains 1000 mg Metformin Hydrochloride.

-Inactive ingredients

Diabetmin Film-coated Tablet 250 mg Tablet:
Polyvinylpyrrolidone
Microcrystalline Cellulose
Pregelatinised Starch
Sodium Starch Glycolate
Magnesium Stearate
Hydroxypropyl Methylcellulose
Isopropyl Alcohol (IPA)
Polyethylene Glycol
Purified Water

Diabetmin Film-coated Tablet 500 mg Tablet:
Microcrystalline Cellulose
Hydroxypropyl Methylcellulose
Polyvinylpyrrolidone
Pregelatinised Cornstarch
Magnesium Stearate
Sodium Starch Glycolate
Isopropyl Alcohol
Polyethylene Glycol

Diabetmin Film-coated Tablet 850 mg Tablet:
Magnesium Stearate
Sodium Starch Glycolate
Microcrystalline Cellulose
Polyethylene Glycol
Hydroxypropyl Methylcellulose
Kollidone K-30
Isopropyl Alcohol
Pregelatinised Starch

Diabetmin Film-coated Tablet 1000 mg Tablet:
Polyvinylpyrrolidone
Microcrystalline Cellulose
Pregelatinised Starch
Microcrystalline Cellulose
Sodium Starch Glycolate
Magnesium Stearate
Hydroxypropyl Methylcellulose
Polyethylene Glycol
Purified Water

Diabetmin Film-coated Tablet

Metformin hydrochloride (250mg, 500mg, 850mg, 1000mg)

- MAL Number:

Diabetmin Film-coated Tablet 250 mg Tablet: MAL11125006AZ

Diabetmin Film-coated Tablet 500 mg Tablet: MAL19860193AZ

Diabetmin Film-coated Tablet 850 mg Tablet: MAL05051079AZ

Diabetmin Film-coated Tablet 1000 mg Tablet: MAL13115199AZ

Product Registration Holder

HOVID Bhd.
121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar), 30010
Ipoh, Perak, Malaysia.

Manufacturer

HOVID Bhd.
Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Perak,
Malaysia.

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