

DIAMIDE FILM-COATED TABLET

Glibenclamide/Metformin (5/500 mg, 2.5/500 mg)

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What Diamide tablet is used for

This anti-diabetic medication is a combination of two drugs (glibenclamide and metformin). It is used along with a diet and exercise program to control high blood sugar in patients with type 2 diabetes (non-insulin-dependent diabetes).

How Diamide tablet works

Diamide tablet combines two glucose-lowering drugs, glibenclamide and metformin.

These two drugs work together to improve the different metabolic defects found in type 2 diabetes. Glibenclamide lowers blood sugar primarily by causing more of the body's own insulin to be released, and metformin lowers blood sugar, in part, by helping your body use your own insulin more effectively. Together, they are efficient in helping you to achieve better glucose control.

Before you use Diamide tablet

- When you must not use it

You should not take Diamide tablet if:

- You have kidney or liver problems
- You have congestive heart failure which is treated with medications, eg, digoxin or furosemide

- You drink alcohol excessively (all the time or short-term "binge" drinking)
- You are seriously dehydrated (have lost a large amount of body fluids)
- You are going to have surgery
- You develop a serious condition, such as a heart attack, severe infection, or stroke

- Before you start to use it

Before taking Diamide tablet, tell your doctor your medical history such as heart disease, liver disease, or a history of heart attack or stroke, alcohol use, obstructive lung disease, severe asthma, anemia, vitamin B12 deficiency, electrolyte imbalance, ovulation problems, adrenal / pituitary insufficiency, thyroid disease, syndrome of inappropriate antidiuretic hormone-SIADH and autonomic neuropathy. Tell your doctor or pharmacist if you are allergic to glibenclamide or metformin; or if you have any other allergies.

- Taking other medicines

Remind your doctor that you are taking Diamide tablet when any new drug is prescribed or a change is made in how you take a drug already prescribed. Diamide tablet may interfere with the way some drugs work and some drugs may interfere with the action of Diamide tablet.

The following medicines can increase the blood sugar lowering effect of Diamide. This can lead to a risk of hypoglycaemia (low blood sugar):

- Medicinal products to treat pain and inflammation (phenylbutazone, azopropazone and salicylates)
- Medicinal products to treat urinary infections (such as some long acting sulfonamides)
- Medicinal products to treat bacterial and fungal infections (fluconazole, miconazole)
- Medicinal products to inhibit blood

clotting (coumarin derivatives such as warfarin)

- Medicinal products to treat Depression (fluoxetine, MAO-inhibitors)

- Medicinal products lowering high blood pressure (ACE inhibitors)

How to use Diamide tablet

- How much to use

The dosage is based on your medical condition and response to therapy. Your doctor may direct you to take a low dose at first, gradually increasing the dose to lower the chance of side effects such as upset stomach and low blood sugar. Your doctor will adjust your dose based on your blood sugar levels to find the best dose for you. Follow your doctors and pharmacists directions carefully. The usual maximum dose for adults is 2000 milligrams of metformin and 20 milligrams of glibenclamide each day.

- When to use it

Take this medication by mouth, usually one tablet twice a day with meals or as directed by your doctor. Drink plenty of fluids while taking this medication unless otherwise directed by your doctor.

- How long to use it

It is important to use this medicine regularly to get the most benefit.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

- If you use too much (overdose)

If overdose is suspected, contact emergency room immediately. Overdose can cause lactic acidosis and low blood sugar.

While you are using Diamide tablet

- Things you must do

- Take this medication exactly as it was prescribed for you. Take Diamide tablet with meals.
- Diamide tablet is only part of a complete program of treatment that also includes diet, exercise, and weight control.
- It is important that you do not miss any scheduled visits to your doctor.
- Your medication needs may change if you become sick or injured, if you have a serious infection, or if you have any type of surgery.
- Take care not to let your blood sugar get too low, causing hypoglycemia.
- Always keep a source of sugar available in case you have symptoms of low blood sugar.

- Things you must not do

- Do not take the medication in larger or smaller amounts, or take it for longer than recommended by your doctor.
- Avoid drinking alcohol while taking Diamide tablet. Alcohol lowers blood sugar and may increase the risk of lactic acidosis while you are taking this medicine.

- Things to be careful of

- Before having surgery, tell your doctor that you are taking this medication. You will need to temporarily stop this medication before the time of your surgery/procedure.
- You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely.
- Limit alcohol while taking this medication because it can increase the risk of developing low blood sugar and lactic acidosis.
- It may be harder to control your blood sugar when your body is stressed (e.g., due to fever, infection, injury, or surgery).
- Elderly people may be at greater risk for side effects such as lactic

acidosis or low blood sugar while using this drug.

- This drug could have undesirable effects on a nursing infant. Therefore, breast-feeding is not recommended while using this drug.
- Diamide tablet is not recommended for children.

Side effects

- The most common side effects of Diamide tablet are normally minor ones such as diarrhea, nausea, and upset stomach.
- Less frequently, symptoms of hypoglycemia (low blood sugar), such as lightheadedness, dizziness, shakiness, or hunger may occur.
- Cross sensitivity to sulphonamides or their derivatives may occur.
- Transient visual disturbances may occur at the start of the treatment.
- Reversible leucopenia (decrease of white blood cells) and thrombocytopenia (decrease of platelets in blood) have been reported but are rare.
- Agranulocytosis (concentration of granulocytes (major class of white blood cells) drops below normal value), pancytopenia (reduction in the number of red and white blood cells) and haemolytic anaemia (fast breakdown of red blood cells) have been reported very rarely.
- Treatment with sulphonylureas has been associated with occasional disturbances of liver function and cholestatic jaundice.
- Diamide tablet rarely causes serious side effects. The most serious side effect that Diamide tablet can cause is called lactic acidosis.

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 by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Diamide tablet

- Storage

Store below 30°C. Protect from light and moisture.

- Disposal

Properly discard this product when it is expired or no longer needed.

Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

Product description

- What it looks like

Diamide 5 mg/ 500 mg

Oblong, yellow film-coated tablet, shallow convex faces.

Diamide 2.5 mg /500 mg

White, oblong, transparent film-coated tablet, shallow convex faces, “HD” embossed and scored at the same face

- Ingredients

- Active Ingredients

Diamide 5 mg/ 500 mg

Glibenclamide 5 mg
Metformin Hydrochloride 500 mg

Diamide 2.5 mg/ 500 mg

Glibenclamide 2.5 mg
Metformin Hydrochloride 500 mg

- Inactive ingredients

Diamide 5 mg/ 500 mg

Propylene Glycol
Iron Oxide Yellow
Hydroxypropyl Methylcellulose
Titanium Dioxide
Polyvinylpyrrolidone
Microcrystalline Cellulose
Magnesium Stearate.
Sodium Starch Glycolate

Pregelatinised Starch

Talc

Isopropyl Alcohol

Diamide 2.5 mg/ 500 mg

Propylene Glycol

Hydroxypropyl Methylcellulose

Polyvinylpyrrolidone

Microcrystalline Cellulose

Magnesium Stearate.

Sodium Starch Glycolate

Pregelatinised Starch

Talc

Isopropyl Alcohol

- ***MAL number (s):***

Diamide 5 mg/ 500 mg

MAL09011430A

Diamide 2.5 mg/ 500 mg

MAL10120037A

Manufacturer

HOVID Berhad

Lot 56442, 7¹/₂ Miles,

Jalan Ipoh / Chemor,

31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.

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Date of revision

06/12/2013