

METFORMIN TABLET

Metformin hydrochloride (500 mg).

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1. What METFORMIN is used for

Metformin belongs to a group of medicines called biguanides (a type of oral hypoglycaemic). Metformin is used for the sort of diabetes called Type 2 diabetes or non-insulin-dependent diabetes mellitus.

This medicine is given when diet and exercise alone has not been able to control your blood sugar levels.

Metformin can be given on its own. However, sometimes it is given with other medicines for diabetes or with insulin.

2. How METFORMIN works

In type 2 diabetes, there is too much sugar (glucose) in your blood. This is because your body does not make enough insulin or because it makes insulin that does not work properly.

Insulin is a hormone that allows your body tissue to take glucose from the blood and use it for energy or for storage for future use.

Metformin works by improving the sensitivity of your body to insulin. It helps your body to use glucose in the normal way again

3. Before you use METFORMIN

• When you must not take it

Do not take Metformin if:

- you are allergic (hypersensitive) to metformin or any of the other ingredients in this tablet (see section on Product description (ingredients)). An allergic reaction can include a rash, itching or shortness of breath.
- you have recently had a heart attack or any other heart problems
- you have severe circulation problems or difficulty in breathing
- you have liver or kidney problems

- you have had serious problems with your diabetes in the past called diabetic ketoacidosis. When you have this you lose weight quickly, feel sick (nausea) or are sick (vomiting). See also the section on 'side effects'.
- you have recently had a severe infection, injury or trauma (shock)
- you are dehydrated
- you are a heavy drinker of alcohol
- you are pregnant, planning to get pregnant or are breast-feeding (see Pregnancy and Breast-feeding).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking metformin.

• Before you start to take it

Take special care and check with your doctor or pharmacist before taking metformin if:

- You are elderly
- You are on a very low calorie diet (less than 1000 calories a day) or are fasting. This could increase the chances of you getting a very rare, but serious side effect called lactic acidosis (See also the section on 'side effects')

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking metformin. Operations and tests while taking Metformin

- The amount of sugar in your blood or urine should be checked regularly. Your doctor will also check your kidneys are working properly.
- If you are going to have an X-ray, tell your doctor you are taking metformin.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking metformin before the operation.

• Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription, including herbal medicines. This is because metformin can affect the way some other medicines work. Also, some medicines can affect the way metformin works.

In particular, tell your doctor or pharmacist if you are taking the following medicine:

- Anticoagulants - an interaction between Metformin and anticoagulants is a possibility and dosage of the latter may need adjustment.

If the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking metformin.

Taking metformin with food and drink

- You need to eat carbohydrates regularly throughout the day. If your doctor has given you advice on your diet, you need to continue to follow this.

- Do not drink large amounts of alcohol or take medicines containing alcohol while taking metformin

Pregnancy and breast-feeding

Do not take this medicine and talk to your doctor if you are pregnant, planning to get pregnant or are breast-feeding

Driving and using machines

- Metformin on its own does not usually affect your ability to drive.
- However, if you also take other medicines which lower blood sugar you may feel faint, dizzy, weak or shaky. If this happens, do not drive or use any tools or machines.

4. How to take METFORMIN

Always take metformin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablets whole with a glass of water.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

• How much to take it

Adults

- The usual starting dose is one tablet 2 or 3 times a day. Your doctor will tell you when to take this
- Your doctor may slowly increase your dose until the right dose for you is reached. This will help lower the chances of getting side effects such as feeling sick (nausea) or being sick (vomiting).
- The maximum daily dose is six 500mg tablets.

Elderly

- Your doctor may give you a much lower starting dose as there is a risk of kidney problems.

• When to take it

- Take metformin with meals. This lowers the chance of getting an upset stomach.
- Try to take your medicine at the same time each day so that it becomes part of your daily routine.

• How long to take it

Keep taking this medicine until your doctor tells you to stop. Do not stop taking metformin just because you feel better. If you stop your illness may get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

• If you forget to take a dose,

- take it as soon as you remember, with your next meal. However, if it is time for your next dose, do not take the missed dose.

Take only a single dose as usual.

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

• If you take too much (overdose),

Tell your doctor or go to the nearest hospital casualty department straight away. Remember to take the pack and any remaining tablets with you. This is so the doctor knows what you have taken.

The following effects may happen if you take too much metformin: feeling very sick or being very sick, very fast breathing which you cannot stop, stomach pains or feeling cold. You may have something called lactic acidosis.

5. While you are using METFORMIN

• Things you must do

- Have a regular monitoring of renal function
- Have an annual estimation of Vitamin B12 levels
- Have a regular blood glucose level monitoring.

• Things you must not do

- Not to engage in excessive exercises or in activities that may cause dehydration.

• Things to be careful of

- This medication may cause changes in your blood sugar. You should know the symptoms of low and high blood sugar and what to do if you have these symptoms.
- You may experience hypoglycemia (low blood sugar) while you are taking this medication. Your doctor will tell you what you should do if you develop hypoglycemia. He or she may tell you to check your blood sugar, eat or drink a food or beverage that contains sugar, such as hard candy or fruit juice, or get medical care.
- Follow these directions carefully if you have any of the following symptoms of hypoglycemia: Shakiness, dizziness or lightheadedness, sweating, nervousness or irritability, sudden changes in behavior or mood, headache, numbness or tingling around the mouth, weakness, pale skin, hunger, clumsy or jerky movements
- If hypoglycemia is not treated, severe symptoms may develop. Be sure that your family, friends, and other people who spend time with you know that if you have any of the following symptoms, they should get medical treatment for you immediately: Confusion, seizures, loss of consciousness

6. Side Effects

Like all medicines metformin can cause side effects, although not everybody gets them.

Stop taking metformin and see a doctor or go to a hospital straight away if you get any of the following very rare side effects:

- unexpected weight loss
- feeling very sick (nausea) or being very sick (vomiting)
- very fast breathing which you cannot stop

- stomach pains or feeling cold

This may mean you have something called “diabetic ketoacidosis” or “lactic acidosis”. These can be signs of serious problems with your diabetes. If this happens, see a doctor as you will need treatment straight away.

Other side effects:

- Stomach problems such as feeling sick (nausea), being sick (vomiting), diarrhoea, stomach pain and loss of appetite. These side effects are most likely to happen at the start of treatment.

- They usually last for a short time. It helps to take the dose with or after a meal.

- taste of metal in your mouth

- low levels of vitamin B12. Over time this may lead to anaemia, a sore mouth or tongue or possibly numbness or tingling in the limbs.

If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

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)

7. Storage and Disposal of METFORMIN

Storage

- Keep your medicine in a safe place out of the reach and sight of children.
- Do not store above 25°C. Store in the original package.

Disposal

- Do not take this medicine after the expiry date which is stated on the packagings.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product description

• What it looks like

Metformin Tablet 500mg is white, flat, round, scored tablets with the marking 'M' on the surface.

Metformin Tablet 500mg is available in blister pack of 10 tablets (in boxes of 10x10's and 100x10's) and plastic container of 1000 tablets.

(Not all pack sizes may be marketed.)

- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

• Ingredients

Each tablet contains 500mg of metformin hydrochloride as the active ingredient. Other ingredients are starch, lactose, PVP K90, isopropyl alcohol (IPA) & magnesium stearate

- MAL No.: MAL19961876A

9. Manufacturer and product registration holder:

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2497, Mk. 1, Lorong Perusahaan Baru
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MALAYSIA

10. Date of Revision:

1 April 2014