

FORMET TABLET

Consumer Medication Information Leaflet (RiMUP)

Metformin hydrochloride 250mg/500mg/850mg

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What Formet Tablet is used for

The name of this medicine is Formet Tablet. The active ingredient is metformin. It belongs to a group of medicines called biguanides (a type of oral hypoglycaemic).

Metformin is used for Type 2 diabetes or non-insulin-dependent diabetes mellitus.

How Formet Tablet 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.

Before you use Formet Tablet

- *When you must not take it*
Do not take Formet Tablet if -you are allergic (hypersensitive) to metformin or any of the other ingredients in this product. 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).

-you have recently had a severe infection, injury or trauma (shock)

-you are dehydrated

-you are going to have an X-ray where you will be injected with a dye

-you are a heavy drinker of alcohol

-you are pregnant, planning to get pregnant or are 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.

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

-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.

• *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 any of the following medicines:

- Medicines for high blood pressure (hypertension) such as water tablets (diuretics), ACE inhibitors (such as enalapril)
- Medicines for asthma such as salbutamol or formoterol (beta-2-agonists)

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

How to take Formet Tablet

- *How much to take*

Adults

The usual starting dose is one 500mg or 850mg tablet 2 or 3 times a day. Your doctor will tell you when to take this

After 10 to 15 days, 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 or three 850mg tablets.

Elderly

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

Teenagers and children aged 10 years or older

The usual starting dose is one 500mg or 850mg tablet once a day. Your doctor will tell you when to take this

After 10 to 15 days, your doctor may slowly increase your dose until the right dose is reached. This will help lower the chances of getting side effects such as feeling sick (nausea) or being sick (vomiting).

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The maximum daily dose is four 500mg tablets or two 850mg tablets.

Taking metformin with insulin

If your doctor wants you to take metformin with insulin the usual starting dose of metformin is one tablet 2 or 3 times a day. The insulin dose will change depending on your blood sugar level.

• *When to take it*

Take metformin with or after food. This lowers the chance of getting an upset stomach. Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.

• *How long to take it*

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

• *If you forget to take it*

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.

Keep taking this medicine until your doctor tells you to stop. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

• *If you take too much (overdose)*

If you accidentally take too many tablets, 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. The doctor may use a method called 'haemodialysis' to remove the extra lactate and metformin from your body.

While you are using Formet Tablet

• *Things you must do*

Try to take your medicine at the same time each day so that it becomes part of your daily routine.

Keep taking metformin until your doctor tells you to stop.

• *Things you must not do*

Do not stop taking metformin just because you feel better. If you stop your illness may get worse.

• *Things to be careful of* Operations and tests while taking metformin

• The amount of sugar in your blood or urine should be checked regularly. Your doctor will also check if your kidneys are working properly. This should be done at least once a year (more often if you are elderly or have kidney problems).

• If you are going to have an X-ray, tell your doctor you are taking metformin. If this involves having a dye injected, you must stop 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. Your doctor may stop you taking metformin for a couple of days before and after the operation.

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.

Side Effects

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

- 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
- skin rash (including redness, itching, hives).
- 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.

• liver problems, abnormal liver function tests and hepatitis (inflammation of the liver) that may result in jaundice. If you notice yellowing of the eyes/skin contact your doctor immediately.

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).

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Storage and Disposal of Formet Tablet

- *Storage*

Store below 30°C and protect from light.

- *Disposal*

Do not use after the expiry date stated on the label.

Take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

- *What it looks like*

850mg: White, capsule shaped tablets with breakline on one side and plain on the other side.

500mg: White colored, round, 12.1 mm diameter, biconvex tablets plain on both sides.

250mg: White colored, round, 9.6 mm diameter, biconvex tablets plain on both sides.

- *Ingredients*

Active Ingredient

850mg: Each film coated tablet contains: Metformin Hydrochloride BP 850 mg.

500mg: Each film coated tablet contains: Metformin Hydrochloride BP 500 mg.

250mg: Each film coated tablet contains: Metformin Hydrochloride BP 250 mg.

Inactive ingredients

Povidone (K-30),
Microcrystalline Cellulose,
Croscarmellose Sodium,
Magnesium Stearate, Colloidal
Anhydrous Silica, Purified
Water, Hypermellose,
Propylene Glycol, Titanium
Dioxide, Purified Talc,
Isopropyl Alcohol,
Dichloromethane

- *MAL No.*

Formet Tablet 850mg:

MAL 10100159A

Formet Tablet 500mg:

MAL10100161A

Formet Tablet 250mg:

MAL10100164A

Manufacturer

Strides Arcolab Ltd.

Oral Dosage Forms Division
Site no. 36/7,
Suragajakkanahalli, Indlavadi
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562106, INDIA

Product Registration Holder

Actavis Sdn Bhd

**(formerly known as Ascent
Pharmahealth Malaysia Sdn
Bhd)**

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Date of Revision

16-10-2013