

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about FORMET.

It does not contain all of the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FORMET against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor, pharmacist or diabetes educator.**

**Keep this leaflet with your medicine.**

You may need to read it again.

### What FORMET is used for

FORMET is used to control blood glucose in patients with diabetes mellitus.

There are two types of diabetes mellitus:

- type 1, also called insulin dependent diabetes
- type 2, also called non-insulin dependent diabetes mellitus or maturity onset diabetes.

People with type 2 diabetes are unable to make enough insulin or their body does not respond properly to the insulin it does make. This causes a build up of glucose in the blood, which can lead to serious medical problems.

FORMET is used in the treatment of type 2 diabetes mellitus. It is especially useful in those who are overweight, when diet and exercise are not enough to control your blood glucose levels. FORMET can be used alone, or in combination with other medicines for treating diabetes.

It can also be used in patients with type 1 diabetes mellitus where insulin alone is not enough to control blood glucose levels.

FORMET is not recommended for use in children, except for those with insulin resistant diabetes who are being treated in hospital.

FORMET is available only with a doctor's prescription.

#### How it works

FORMET belongs to a group of medicines called biguanides. FORMET lowers blood glucose by helping your body to make better use of the insulin produced by your pancreas.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose).

Hypoglycaemia (low blood glucose) can occur suddenly. Symptoms may include:

- weakness, trembling or shaking
- sweating
- light-headedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these symptoms may progress to:

- loss of co-ordination

- slurred speech
- confusion
- fits or loss of consciousness.

Hyperglycaemia (high blood glucose) usually occurs more slowly than hypoglycaemia. Symptoms of hyperglycaemia may include:

- lethargy or tiredness
- headache
- thirst
- passing large amounts of urine
- blurred vision.

Long-term hyperglycaemia can lead to serious problems with your heart, eyes, circulation and/or kidneys.

### Before you take it

#### When you must not take it

**Do not take FORMET if you are allergic to:**

- medicines containing metformin or any other biguanide
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take FORMET if you have any of the following medical conditions:**

- type 1 diabetes mellitus that is well controlled by insulin alone
- type 2 diabetes that is already controlled by diet alone
- diabetic ketoacidosis
- kidney disease
- severe liver disease
- certain heart or blood vessel problems, including a recent heart attack or severe heart failure
- excessive alcohol intake, binge drinking, alcohol dependence
- dehydration, severe blood loss, shock
- severe infection
- severe breathing difficulties
- gangrene
- blood clots in the lungs
- inflammation of the pancreas.

**If you are not sure whether you should start taking FORMET, ask your doctor.**

**Do not take FORMET if you are pregnant or plan to become pregnant.**

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace FORMET with insulin while you are pregnant.

**Do not take FORMET if the expiry date (Exp.) printed on the pack has passed.**

**Do not take FORMET if the packaging shows signs of tampering or the tablets do not look quite right.**

#### Before you start to take it

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have any medical conditions, especially the following:**

- heart failure
- kidney problems.

Your doctor may want to take special care if you have any of these conditions.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

It is not known whether FORMET passes into breast milk. FORMET is usually not recommended while you are breastfeeding. Your doctor will discuss the risks and benefits of taking FORMET when breastfeeding.

**Tell your doctor if you drink alcohol in any amount.**

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with FORMET may also lead to serious side effects. Discuss this with your doctor.

**If you have not told your doctor about any of the above, tell them before you start taking FORMET.**

#### Taking other medicines

**Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by FORMET or may affect how well it works. These include:

- other medicines used to treat diabetes
- medicines used to treat high blood pressure and some heart conditions
- medicines used to prevent blood clots
- diuretics, also called fluid tablets
- thyroid preparations
- cimetidine, a medicine used to treat reflux and ulcers
- corticosteroids such as prednisone, cortisone.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking FORMET.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

### How to take it

#### How much to take

The dose varies from patient to patient. Your doctor will decide the right dose for you.

The usual starting dose for adults is 500 mg one to two times a day. Your doctor may increase or decrease the dose, depending on your blood glucose levels. The maximum recommended dose is 1 g three times a day.

The elderly and people with kidney problems may need smaller doses.

FORMET can be taken by children with diabetes who cannot be controlled with insulin and are being treated in hospital. Your child's doctor will decide the dose.

#### How to take FORMET

**Swallow the tablets with a glass of water.**

**Take FORMET during or immediately after food.**

This will lessen the chance of a stomach upset.

### How long to take it for

Keep taking FORMET for as long as your doctor recommends.

FORMET will help control diabetes but will not cure it. Most people will need to take FORMET for long periods of time.

### If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember (with food), and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

### If you take too much FORMET (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much FORMET. Do this even if there are no signs of discomfort or poisoning.

If you take too much FORMET, you may feel sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early symptoms of a serious condition called lactic acidosis (high lactic acid in the blood).

You may also experience symptoms of hypoglycaemia (low blood glucose). This usually only happens if you take too much FORMET together with other medicines for diabetes or with alcohol.

If you do experience any signs of hypoglycaemia, raise your blood glucose quickly by eating jelly beans, sugar or honey, drinking non-diet soft drink or taking glucose tablets.

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### While you are taking it

#### Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking FORMET.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FORMET.

If you become pregnant while taking FORMET, tell your doctor.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia, and know how to treat them.

#### Hypoglycaemia

FORMET does not normally cause hypoglycaemia unless you are also taking other medicines for diabetes such as insulin or sulfonylureas.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately. You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

#### Hyperglycaemia

If you experience any of the symptoms of hyperglycaemia, contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less FORMET than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

#### Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery)
- are having X-ray procedures that require injection of contrast agents.

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may replace FORMET with insulin.

#### Visit your doctor regularly for check ups.

Your doctor may want to check your kidneys, liver, heart and blood while you are taking FORMET.

#### Make sure you check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

When you start treatment with FORMET, it can take up to two weeks for your blood glucose levels to be properly controlled.

Carefully follow your doctor's and dietician's advice on diet, drinking alcohol and exercise.

#### Things you must not do

Do not skip meals while taking FORMET.

Do not stop taking FORMET or change the dose without checking with your doctor.

Do not give FORMET to anyone else, even if they have the same condition as you.

#### Things to be careful of

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, FORMET by itself is unlikely to affect how you drive or operate machinery.

If you become sick with a cold, fever or flu, it is very important to continue eating your normal meals.

Your diabetes educator or dietician can give you a list of foods to eat on sick days.

When you are travelling, it is a good idea to:

- wear some form of identification (eg bracelet) showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, such as sugar sachets or jelly beans
- carry emergency food rations in case of a delay, such as dried fruit, biscuits or muesli bars
- bring enough FORMET tablets with you, so you don't miss any doses.

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### Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FORMET.

FORMET helps most people with diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects. Report any side effects to your doctor promptly.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset such as feeling sick (nausea), vomiting
- diarrhoea
- skin rash.

These are generally mild side effects which usually occur during the first few weeks. Taking FORMET with meals can help reduce nausea and diarrhoea. Skin rash is rare and should go away in a few days.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following symptoms of lactic acidosis (high lactic acid in the blood):

- nausea, vomiting, stomach pain
- trouble breathing
- feeling weak, tired or generally unwell
- unusual muscle pain
- sleepiness
- dizziness or light-headedness
- shivering, feeling extremely cold
- slow heart beat.

Lactic acidosis with FORMET is a very rare, but serious side effect that requires urgent medical attention or hospitalisation. If lactic acidosis does occur, it can be fatal.

The risk of lactic acidosis is higher in some patients including

- elderly
- those taking doses greater than 2 g per day
- those drinking excessive amounts of alcohol
- those whose kidneys are not working properly
- those whose diabetes is poorly controlled
- those with certain heart conditions.

**Other side effects not listed above may also occur in some people. Tell your doctor if you notice anything that is making you feel unwell.**

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#### After using it

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##### *Storage*

**Keep FORMET where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store FORMET or any other medicine in the bathroom or near a sink.**

**Do not leave FORMET in the car or on window sills.**

Heat and dampness can destroy some medicines.

##### *Disposal*

**If your doctor tells you to stop taking FORMET, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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#### Product description

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##### *What it looks like*

FORMET comes in 2 strengths of tablets:

- 500 mg tablet - white to off-white round, biconvex, film-coated tablets debossed with "500" on one side and plain on the other. Each pack contains 100 tablets.
- 850 mg tablet - white to off-white round, biconvex, film-coated tablets debossed with "850" on one side and plain on the other. Each pack contains 60 tablets.

##### *Ingredients*

The active ingredient in FORMET is metformin hydrochloride:

- each 500 mg tablet contains 500 mg of metformin hydrochloride
- each 850 mg tablet contains 850 mg of metformin hydrochloride

The 500mg and 850mg tablets also contain:

- Sodium starch glycollate
- Starch - maize
- Magnesium stearate
- Colloidal anhydrous silica
- Hypromellose
- Macrogol 6000
- Talc - purified
- Propylene glycol

The tablets do not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

##### *Supplier*

##### **Arrow Pharma Pty Ltd**

15-17 Chapel Street  
Cremorne VIC 3121  
Australia

##### **Australian registration numbers:**

FORMET 500 - AUST R 193136  
FORMET 850 - AUST R 193137

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