

Consumer Medicine Information

ARROW - METFORMIN

Metformin 250 mg, 500 mg, 850 mg and 1000 mg Tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - METFORMIN.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - METFORMIN 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 ARROW - METFORMIN is used for

ARROW - METFORMIN Tablets are used to control blood glucose in patients with diabetes mellitus.

There are two types of diabetes mellitus:

- type 1, also called insulin dependent diabetes mellitus
- 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.

ARROW - METFORMIN is used when diet and exercise are not enough to control your blood glucose levels. ARROW - METFORMIN can be used alone, or in combination with other medicines for treating diabetes.

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

ARROW - METFORMIN is not recommended for use in children except for those with insulin resistant diabetes who are being treated in hospital.

Your doctor may, however, prescribe ARROW - METFORMIN for another reason. Ask your doctor if you have any questions about why ARROW - METFORMIN has been prescribed for you.

There is no evidence that ARROW - METFORMIN is addictive.

ARROW - METFORMIN is available only with a doctor's prescription.

How ARROW - METFORMIN works

ARROW - METFORMIN belongs to a group of medicines called biguanides. ARROW - METFORMIN lowers blood glucose by helping your body 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. Signs 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 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. Signs of hyperglycaemia may include:

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

Before you take ARROW - METFORMIN

When you must not take it

Do not take ARROW - METFORMIN if you are allergic to medicines containing metformin or other biguanides, or any of the ingredients listed at the end of this leaflet.

Some of the 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
- lumpy skin rash ("hives"), hayfever or fainting.

Do not take ARROW - METFORMIN if you have any of the following medical conditions:

- type 1 diabetes mellitus that is well controlled by insulin alone
- type 2 diabetes mellitus that is already well controlled by diet alone
- diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- severe kidney disease or kidney failure
- severe liver disease
- certain heart or blood vessels problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
- gangrene
- blood clots in the lungs (symptoms like coughing, shortness of breath, chest pain and a fast heart rate)
- inflammation of the pancreas (symptoms like severe upper stomach pain, often with nausea and vomiting)
- severe infection
- dehydration, severe blood loss, shock
- excessive alcohol intake, binge drinking, alcohol dependence
- severe breathing difficulties.

Do not take ARROW - METFORMIN if you plan to have any X-ray procedures requiring an injection of iodinated contrast (dye).

Using this type of dye while you are taking ARROW - METFORMIN may cause kidney problems and increase the risk of a serious condition called lactic acidosis. Your doctor will tell you when to temporarily stop taking the tablets before the X-ray and when it safe to restart them.

If you are not sure whether you should start taking ARROW - METFORMIN, ask your doctor.

Do not take ARROW - METFORMIN if you are pregnant or plan to become pregnant.

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

Do not take ARROW - METFORMIN if you are breastfeeding or wish to breastfeed.

It is not known whether ARROW - METFORMIN may pass into the breast milk. ARROW - METFORMIN is usually not recommended while you are breastfeeding. Your doctor will discuss the risks and benefits of taking ARROW - METFORMIN when breastfeeding.

Do not take ARROW - METFORMIN if the expiry date (Exp.) printed on the pack has passed.

Do not take ARROW - METFORMIN 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, or have had, any medical conditions, especially the following:

- heart failure
- kidney problems
- surgery recently
- infection.

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

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breastfeeding or intend to breastfeed.

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 ARROW - METFORMIN 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 ARROW - METFORMIN.

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 ARROW - METFORMIN, 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 medicines
- cimetidine, a medicine commonly used to treat reflux and ulcers
- corticosteroids such as prednisone, cortisone.

Your doctor 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 ARROW - METFORMIN.

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

How to take ARROW - METFORMIN

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 three times a day. Your doctor may increase or decrease the dose, depending on your blood glucose levels. The maximum recommended dose is 1 gram three times a day. Elderly may need smaller doses.

ARROW - METFORMIN can be taken by children with diabetes that cannot be controlled with insulin and who is being treated in hospital. Your child's doctor will decide the dose.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take ARROW - METFORMIN

Swallow the tablets with a glass of water.

When to take ARROW - METFORMIN

Take ARROW - METFORMIN during or immediately after food.

This will lessen the chance of a stomach upset.

Take the tablet at about the same time of each day.

Taking your tablet at the same time each day will have the best effect on your infection. It will also help you to remember when to take it.

How long to take ARROW - METFORMIN

Keep taking ARROW -METFORMIN for as long as your doctor recommends. ARROW - METFORMIN will help control diabetes but will not cure it. Most people will need to take ARROW - METFORMIN for long periods of time.

If you forget to take ARROW - METFORMIN

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 ARROW - METFORMIN (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - METFORMIN Tablets.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ARROW - METFORMIN, you may feel sleepy, very tired, sick, vomit; have difficulty breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs 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 ARROW - METFORMIN 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.

While you are taking ARROW - METFORMIN

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - METFORMIN.

If you become pregnant while taking ARROW - METFORMIN, tell your doctor.

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

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.

ARROW - METFORMIN does not normally cause hypoglycaemia unless you are taking other medicines for diabetes such as insulin or sulfonylureas.

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

The risk of hyperglycaemia is increased in the following situations:

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

Tell your doctor if any of the following happen:

- you become ill
- you become dehydrated
- you are injured
- you have a fever
- you have a serious infection
- you are having surgery
- you 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 ARROW - METFORMIN with insulin.

Visit your doctor regularly for check ups.

Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B₁₂ level while you are taking ARROW - METFORMIN.

Make sure you check your blood glucose levels regularly.

This is 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 ARROW - METFORMIN, 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, exercise and limiting alcohol intake.

Things you must not do

Do not skip meals while taking ARROW - METFORMIN.

Do not stop taking ARROW - METFORMIN or change the dose without checking with your doctor.

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

Do not use ARROW - METFORMIN to treat any other conditions unless your doctor tells you to.

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 level may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, ARROW - METFORMIN 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 (e.g. bracelet) showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- carry emergency food rations in case of a delayed meal, for example, dried fruit, biscuits or muesli bars

- take enough ARROW - METFORMIN with you, so you don't miss any doses.

Side effects

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

ARROW - METFORMIN 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 increased chance of getting side effects. Report any side effects to your doctor promptly.

You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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
- metallic taste, loss of appetite.

These are generally mild side effects which usually occur during the first few weeks. Taking ARROW - METFORMIN with meals can help reduce nausea and diarrhoea. Skin rash has been rarely reported.

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

- 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 heartbeats.

Lactic acidosis with ARROW - METFORMIN is a very rare but serious effect, which requires urgent medical attention in hospital. The risk of lactic acidosis is higher in some patients, including the elderly, those taking doses greater than 2

grams per day, those with certain heart conditions, those drinking excessive amounts of alcohol and people with kidney problems.

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

After taking ARROW - METFORMIN

Storage

Keep ARROW - METFORMIN 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 ARROW - METFORMIN or other medicines in the bathroom or near a sink.

Do not leave ARROW - METFORMIN in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

ARROW - METFORMIN comes in 4 strengths of tablets:

- 250 mg tablet - round, white tablet, marked with 'MO' on one side and '>' on the other side.

Each pack contains 100 tablets.

- 500 mg tablet - oblong, white tablet, marked 'M | O' on one side and '>' on the other.
- Each pack contains 100 and 500 tablets.
- 850 mg tablet - round, white tablet, marked 'MO' on one side and '>' on the other.
- Each pack contains 60 tablets.

- 1000 mg tablet - oblong, white tablet, marked 'M | O' on one side and '> |>', on the other. Each pack contains 90 tablets.

Ingredients

The active ingredient in ARROW - METFORMIN is Metformin hydrochloride:

- each ARROW - METFORMIN 250 tablet contains 250 mg of metformin hydrochloride
- each ARROW - METFORMIN 500 tablet contains 500 mg of metformin hydrochloride
- each ARROW - METFORMIN 850 tablet contains 850 mg of metformin hydrochloride
- each ARROW - METFORMIN 1000 tablet contains 1000 mg of metformin hydrochloride.

The tablets also contain

- povidone
- magnesium stearate
- Opadry Clear OY-29020

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

Supplier

ARROW - METFORMIN is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited
Mount Eden Central Business Park
33a Normanby Road, Mt Eden
Auckland, New Zealand.

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