

## Chemmart Metformin

contains the active ingredient metformin hydrochloride

### Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

#### What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

#### What this medicine is used for

Metformin used to treat type 2 diabetes (also called non-insulin dependent diabetes mellitus or maturity onset diabetes) in adults and children over 10 years of age.

Metformin belongs to a group of medicines called biguanides.

It lowers high 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).

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 with your heart, eyes, circulation or kidneys.

It is especially useful in those who are overweight, when diet and exercise are not enough to lower high blood glucose levels (hyperglycaemia).

For adult patients, metformin can be used alone, or in combination with other oral diabetic medicines or in combination with insulin in insulin requiring type 2 diabetes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

#### Use in children

This medicine should not be used in children under 10 years of age.

#### Before you take this medicine

##### When you must not take it

Do not take this medicine if you have an allergy to:

metformin or any other biguanide

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

rash, itching or hives on the skin

Do not take this medicine if you have any of the following medical conditions:

type 1 diabetes that is well controlled by insulin alone

type 2 diabetes that is already well controlled by diet alone

any type of metabolic acidosis such as lactic acidosis, 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 liver disease

excessive alcohol intake, binge drinking or alcohol dependence

severe kidney disease or kidney failure

a severe infection

certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)

dehydration, severe blood loss or shock

severe breathing difficulties

blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)

gangrene

inflammation of the pancreas (pancreatitis) - symptoms include severe upper stomach pain, often with nausea and vomiting

Do not take this medicine if you need to have major surgery or an examination such as an X-ray or scan requiring an injection of iodinated contrast (dye).

You must stop taking metformin for a certain time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Do not take this medicine if you are pregnant or plan to become pregnant.

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

Do not take this medicine if you are breastfeeding.

Metformin may pass into human breast milk.

Your doctor will discuss the options available to you.

The expiry date (EXP) printed on the pack has passed.

The packaging is torn, shows signs of tampering or it does not look quite right.

##### Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

kidney problems

- heart failure

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes.

Drinking excessive amounts of alcohol while you are being treated with metformin may also lead to serious side effects. Your doctor may suggest you

stop drinking or reduce the amount of alcohol you drink.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine whilst pregnant or breastfeeding until you and your doctor have discussed the risks and benefits involved.

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

#### Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with metformin. These include:

other medicines used to treat diabetes such as insulin, glitinides (repaglinide) and sulfonylureas (e.g. gliclazide or glibenclamide)

iodinated contrast agents (dyes)

- medicines that contain alcohol, such as cough and cold syrups
- tetracosactrin, used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, used to treat endometriosis
- medicines used to treat high blood pressure and some heart conditions, such as beta-blockers (metoprolol), calcium channel blockers (nifedipine, amlodipine) and ACE inhibitors (captopril, enalapril, fosinopril, lisinopril, perindopril, ramipril, quinapril andtrandolapril).
- medicines used to prevent blood clots such as warfarin
- diuretics, also called fluid or water tablets, such as amiloride, bumetanide, frusemide, hydrochlorothiazide and spironolactone
- thyroid hormones, such as thyroxine
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam
- cimetidine, a medicine commonly used to treat reflux and ulcers
- corticosteroids such as prednisolone, prednisone and cortisone
- some medicines used to treat asthma such as salbutamol or terbutaline
- medicines that are substrates/ inhibitors of organic cation transporters – OCT 1 such as verapamil; OCT 2 such as dolutegravir, crizotinib, olaparib, daclatasvir or vandetanib
- medicines that are inducers of OCT 1 such as rifampicin
- medicines that may increase the risk of lactic acidosis when concomitantly used with metformin such as topiramate and other carbonic anhydrase inhibitors (zonisamide, acetazolamide or dichlorphenamide)

These medicines may be affected by metformin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### *How much to take*

Your doctor will tell you how much of this medicine you should take. This depends on your condition and whether you are taking any other medicines.

#### **Adults:**

The usual starting dose for adults is 500mg 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 1000mg three times a day.

People over 65 years of age or those with kidney problems may need smaller doses.

#### **Children & Adolescents:**

The usual starting dose for children from 10 years of age and adolescents is one tablet of 500mg or 850mg once daily. Your doctor may increase or decrease the dose, depending on your blood glucose levels.

The maximum recommended dose is 2000mg daily taken as two or three divided doses.

### *How to take it*

Swallow the tablets with a glass of water.

### *When to take it*

Take your medicine during or immediately after a meal, at about the same time each day.

This will reduce the chance of a stomach upset.

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

### *How long to take it for*

Continue taking your medicine for as long as your doctor tells you.

Metformin will help control your diabetes but will not cure it. Most people will need to take metformin on a long-term basis.

### *If you forget to take it*

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting low blood sugar levels (hypoglycaemia).

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

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

You may need urgent medical attention.

If you take too much metformin you may feel sleepy, very tired, sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs of a serious condition called lactic acidosis (build-up of lactic acid in the blood).

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

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## While you are taking this medicine

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### *Things you must do*

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**

Metformin does not normally cause hypoglycaemia, although you may experience it if you also take other medicines for diabetes such as sulfonylureas or repaglinide or if you also use insulin.

Hypoglycaemia can occur suddenly. Initial 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

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 these extra carbohydrates will prevent a second drop in your blood glucose level.

### **HYPERGLYCAEMIA**

Hyperglycaemia is often asymptomatic (doesn't cause any immediate symptoms) in many people. However, some people will develop symptoms. Those people who develop symptoms may experience the following:

- high levels of sugar in the urine
- frequent urination
- increased thirst

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

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less metformin than prescribed

- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

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

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 metformin, it can take up to two weeks for your blood glucose levels to be properly controlled.

Carefully follow the advice of your doctor and dietician on diet, drinking alcohol and exercise.

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 such as influenza, respiratory tract infection or urinary tract infection
- you are having surgery (including dental surgery) or are going into hospital
- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye)

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 metformin with insulin.

### *Things you must not do*

Do not skip meals while taking this medicine.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

### *Things to be careful of*

If you need 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, 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 taking metformin even if you feel unable to eat your normal meal.

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

If 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 delay, for example, dried fruit, biscuits or muesli bars
- bring your medicine with you, so you don't miss any doses

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## Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine.

Metformin helps most people with diabetes, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- stomach upset such as feeling sick (nausea)
- vomiting
- taste disturbance
- loss of appetite
- diarrhoea
- skin reactions such as redness of the skin, itching or an itchy rash (urticaria).

These are generally mild side effects. Stomach upset and diarrhoea are common but usually short-lived. Taking your medicine with meals can help reduce nausea and diarrhoea.

Tell your doctor immediately or go to Accident or Emergency at the nearest hospital if you notice any of the following symptoms:

- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

Symptoms of lactic acidosis (build-up of 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 heartbeat

LACTIC ACIDOSIS IS A VERY RARE BUT SERIOUS SIDE EFFECT REQUIRING URGENT MEDICAL ATTENTION OR HOSPITALISATION. ALTHOUGH RARE, IF IT DOES OCCUR, LACTIC ACIDOSIS CAN BE FATAL. THE RISK OF LACTIC ACIDOSIS IS HIGHER IN THE ELDERLY, OR PEOPLE WITH POORLY CONTROLLED DIABETES, PROLONGED FASTING, CERTAIN HEART CONDITIONS, SEVERE LIVER OR KIDNEY PROBLEMS OR PEOPLE WHO DRINK ALCOHOL.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Some side effects (e.g. reduced vitamin B12 levels) can only be found when your doctor does tests from time to time to check your progress.

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## Storage and disposal

### Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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.

### Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

### What Chemmart Metformin looks like

500 mg tablets:

White coloured, film-coated biconvex capsule shaped tablet with central break-line on one side and '500' embossed on the other side. AUST R 174817.

Available in blister packs of 100 tablets.

850 mg tablets:

White coloured, film-coated, round biconvex tablets plain on one side and '850' embossed on the other side. AUST R 174818.

Available in blister packs of 60 tablets.

1000 mg tablets:

White, film-coated, capsule-shaped, biconvex tablet, plain on one side and a break-line on the other. AUST R 176510.

Available in blister packs of 10, 30, 60 and 90 tablets.

\* Not all strengths and/or pack sizes may be available.

### Ingredients

Each tablet contains 250 mg 500 mg, 850 mg or 1000 mg of metformin hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- hypromellose
- macrogol 6000
- magnesium stearate
- povidone
- propylene glycol
- colloidal anhydrous silica
- sodium starch glycollate
- maize starch
- purified talc
- titanium dioxide.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

### Sponsor

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