

Metex XR

metformin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about METEX XR.

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 METEX XR against the benefits they expect it will have for you.

Talk to your doctor, pharmacist or diabetes educator if you have any concerns about taking this medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What METEX XR is used for

The medicine is used to control blood glucose in patients with Type 2 diabetes mellitus, especially in those who are overweight. It is used when diet and exercise are not enough to control your blood glucose levels.

It can be used alone, or in combination with other medicines for treating diabetes.

Type 2 diabetes mellitus is also called non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

Insulin is a hormone that enables body tissues to take up glucose from the blood and use it for energy or fat storage for future use.

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 (hyperglycaemia), which can lead to serious medical problems.

Long term hyperglycaemia can lead to heart disease, blindness, kidney damage, poor blood circulation and gangrene.

Signs of hyperglycaemia include:

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

METEX XR is available only with a doctor's prescription.

There is no evidence that the medicine is addictive.

How METEX XR works

METEX XR belongs to a group of medicines called biguanides. It lowers high blood glucose levels by:

- improving your body's sensitivity to insulin and restoring the way it normally uses glucose
- reducing the amount of glucose your liver makes
- delaying the amount of glucose your intestine absorbs.

Ask your doctor if you have any questions about why METEX XR has been prescribed for you.

Before you take it

When you must not take it

Do not take METEX XR 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 METEX XR 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
- certain heart or blood circulation problems, including a recent heart attack or heart failure
- gangrene
- blood clots in the lungs, severe breathing difficulties
- inflammation of the pancreas.

Ask your doctor if you are not sure whether you should start taking METEX XR.

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

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

Do not take it if you are breastfeeding.

Your doctor will discuss the options available to you.

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

Do not take it 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.

Before starting METEX XR your doctor will ask you to have a blood test to check your kidney function.

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 the medicine may also lead to serious side effects.

Your doctor may suggest that you stop drinking or reduce the amount of alcohol you drink.

Tell your doctor before you start taking METEX XR if you have not told them about any of the above.

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 METEX XR 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 such as warfarin
- diuretics, also called fluid tablets
- thyroid preparations such as thyroxine
- corticosteroids such as prednisone, cortisone
- medicines that contain alcohol, such as cough and cold syrups
- medicines used to treat asthma such as salbutamol and terbutaline
- NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen and piroxicam
- medicines used to treat ulcers and reflux, such as cimetidine.

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 METEX XR.

Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines.

How to take it

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

They may differ from the information contained in this leaflet.

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 tablet) with the evening meal. Your doctor may

increase the dose, depending on your blood glucose levels.

The maximum recommended dose is 2 g (4 tablets) once a day.

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

How to take it

Swallow the tablets with a glass of water.

Do not break, crush or chew the tablets.

If you break, chew or crush the tablets, they will not work as well.

Take METEX XR with your evening meal.

This will lessen the chance of a stomach upset. Taking it at the same time each day will also have the best effect.

How long to take it for

Keep taking it for as long as your doctor recommends.

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

When you first start treatment with METEX XR, it may take some weeks before your blood glucose levels are properly controlled.

If you forget to take it

Take the next dose at the usual time.

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

Ask your doctor or pharmacist if you are not sure what to do.

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 you or anyone else may have taken too much METEX XR. Do this

even if there are no signs of discomfort or poisoning.

If you take too much medicine, 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 level 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 METEX XR together with other medicines for diabetes or with alcohol.

If you 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 it

Things you must do

Tell your doctor or pharmacist that you are taking METEX XR before starting any new medicine.

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

Tell your doctor if you become pregnant while taking METEX XR.

If you are about to undergo surgery or an operation, tell your doctor or surgeon that you are taking METEX XR.

Your doctor will tell you when to temporarily stop METEX XR and when to restart them.

Tell your doctor if you plan to have any X-ray procedures that require an injection of iodinated contrast (dye).

Using this type of contrast while you are taking the medicine can cause serious kidney problems and increase the risk of lactic acidosis.

Things to be aware of

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

Hypoglycaemia

METEX XR does not normally cause hypoglycaemia although you may experience it if you are also taking other medicines for diabetes such as insulin or sulfonylureas.

Hypoglycaemia 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.

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.

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

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

Hyperglycaemia

Contact your doctor immediately if you experience any of the symptoms of hyperglycaemia (high blood sugar).

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less METEX XR 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
- become pregnant
- have a serious infection
- having surgery (including dental surgery)
- having X-ray procedures that require injection of iodinated contrast agents (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 METEX XR 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 METEX XR.

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.

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 METEX XR.

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

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

Things to be careful of

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

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, the medicine 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.

Side effects

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

The medicine 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.

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
- stomach pain
- skin rash, itching, hives
- taste disturbance, loss of appetite.

These are generally mild side effects which usually occur during the first few weeks. Taking the medicine 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 IS A VERY RARE, BUT SERIOUS SIDE EFFECT OF METEX XR 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:

- the elderly
- those drinking excessive amounts of alcohol
- those whose kidneys or liver are not working properly

- those whose diabetes is poorly controlled
- those with certain heart conditions
- those with prolonged fasting.

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

It is very important that you speak to your doctor immediately if a side effect is severe, occurred suddenly or gets rapidly worse.

Other side effects not listed above may also occur in some people.

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

You may not experience any of them.

After taking it

Storage

Keep the 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.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

Heat and dampness can destroy some medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over if your doctor tells you to stop taking METEX XR, or your tablets have passed their expiry date.

Product description

What it looks like

METEX XR is a white capsule shaped tablet, marked XR5 on one side and '>' on the other.

Available in blister packs of 120 tablets.

Ingredients

The active ingredient in METEX XR is metformin hydrochloride. Each tablet contains 500 mg of metformin hydrochloride.

The tablets also contain:

- carmellose sodium
- hypromellose
- colloidal anhydrous silica
- microcrystalline cellulose
- magnesium stearate.

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

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian Registration Number
AUST R 143464

Date of preparation:
February 2016.