DIAFORMIN® ALPHAPHARM XR

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DIAFORMIN ALPHAPHARM XR?

DIAFORMIN ALPHAPHARM XR contains the active ingredient metformin hydrochloride. DIAFORMIN ALPHAPHARM XR are used to control blood glucose (sugar) in people with Type 2 diabetes mellitus.
For more information, see Section 1. Why am I using DIAFORMIN ALPHAPHARM XR? in the full CMI.

2. What should I know before I use DIAFORMIN ALPHAPHARM XR?

Do not use if you have ever had an allergic reaction to DIAFORMIN ALPHAPHARM XR or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**
For more information, see Section 2. What should I know before I use DIAFORMIN ALPHAPHARM XR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DIAFORMIN ALPHAPHARM XR and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use DIAFORMIN ALPHAPHARM XR?

The usual starting dose is 500 mg once daily with the evening meal. Your doctor may increase the dose slowly, depending on your blood glucose levels.
More instructions can be found in Section 4. How do I use DIAFORMIN ALPHAPHARM XR? in the full CMI.

5. What should I know while using DIAFORMIN ALPHAPHARM XR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using DIAFORMIN ALPHAPHARM XR. • Make sure that you, your friends, family and work colleagues can recognize the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.
Things you should not do	• Do not skip meals while taking DIAFORMIN ALPHAPHARM XR. • Do not stop taking your medicine or change the dose without checking with your doctor.
Driving or using machines	• DIAFORMIN ALPHAPHARM XR by itself is unlikely to affect how you drive or operate machinery. • Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery.
Drinking alcohol	• Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with DIAFORMIN ALPHAPHARM XR may also lead to serious side effects.
Looking after your medicine	• Keep the pack in a cool, dry place (below 25 °C) in its original packaging. • Do not store DIAFORMIN ALPHAPHARM XR in the bathroom, near a sink, on a window sill or in the car.

For more information, see Section 5. What should I know while using DIAFORMIN ALPHAPHARM XR? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea, vomiting, diarrhoea, stomach pain, taste disturbance, loss of appetite, redness of the skin or itching. **Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following symptoms**: trouble breathing, feeling weak, tired or generally unwell, unusual muscle pain, sleepiness, dizziness, shivering, feeling extremely cold or slow heart beat. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

DIAFORMIN® ALPHAPHARM XR

Active ingredient(s): *metformin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DIAFORMIN ALPHAPHARM XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DIAFORMIN ALPHAPHARM XR.**

Where to find information in this leaflet:

1. Why am I using DIAFORMIN ALPHAPHARM XR?
2. What should I know before I use DIAFORMIN ALPHAPHARM XR?
3. What if I am taking other medicines?
4. How do I use DIAFORMIN ALPHAPHARM XR?
5. What should I know while using DIAFORMIN ALPHAPHARM XR?
6. Are there any side effects?
7. Product details

1. Why am I using DIAFORMIN ALPHAPHARM XR?

DIAFORMIN ALPHAPHARM XR contains the active ingredient metformin hydrochloride. DIAFORMIN ALPHAPHARM 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

DIAFORMIN ALPHAPHARM XR is used to control blood glucose (sugar) in people with Type 2 diabetes mellitus, especially in those who are overweight. It is used when diet and exercise are not enough to control high levels of blood glucose.

DIAFORMIN ALPHAPHARM XR can be used alone, or in combination with other medicines for treating diabetes.

TYPE 2 DIABETES MELLITUS

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 to 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 buildup of glucose in the blood, 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 may include:

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

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

DIAFORMIN ALPHAPHARM XR are not recommended in children as its safety and effectiveness have not been established in this age group.

DIAFORMIN ALPHAPHARM XR are available only with a doctor's prescription.

There is no evidence that DIAFORMIN ALPHAPHARM XR is addictive.

After the active ingredient metformin is absorbed into your body, you may see the empty tablet shell in your faeces (bowel motions). This is normal and does not affect the way DIAFORMIN ALPHAPHARM XR works.

2. What should I know before I use DIAFORMIN ALPHAPHARM XR?

Warnings

Do not use DIAFORMIN ALPHAPHARM XR if:

- you are allergic to any medicine containing metformin or any other biguanide, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - skin rash, itching or hives
  - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
  - wheezing or shortness of breath.

  Always check the ingredients to make sure you can use this medicine.
- you have any of the following conditions:
  - type 1 diabetes mellitus that is well controlled by insulin alone
  - type 2 diabetes that is already well controlled by diet alone
  - serious complications with your diabetes or any type of metabolic acidosis such as lactic acidosis, diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies accumulate in the blood - you may notice this as an unusual fruity odour on your breath)
  - kidney failure or severe kidney disease
  - dehydration (for instance due to persistent or severe vomiting or diarrhoea)
  - shock from severe injury or blood loss
  - severe liver disease
  - acute alcohol intoxication, chronic alcohol dependence

- certain heart or blood circulation problems, including a recent heart attack or heart failure (when the heart fails to pump blood effectively)
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate), severe breathing difficulties
- inflammation of the pancreas (symptoms include severe upper stomach pain, often with nausea and vomiting) if associated with severe infection or hypoxia (lack of oxygen)
- a severe infection or gangrene
- hypothyroidism (a condition where the thyroid gland does not produce enough thyroid hormone)

You must stop taking DIAFORMIN ALPHAPHARM XR for a certain period of 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 after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines or any foods, preservatives or dyes.
- have or have had any of the following medical conditions:
    - kidney problems
    - liver problems
    - heart or blood vessel problems including heart failure
    - a known or suspected mitochondrial disease e.g. Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) or Maternal Inherited Diabetes and Deafness (MIDD)

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

- drink alcohol

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with DIAFORMIN ALPHAPHARM XR may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

If you have not told your doctor about any of the above, tell him/her before you start taking DIAFORMIN ALPHAPHARM XR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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 DIAFORMIN ALPHAPHARM XR with insulin while you are pregnant.

Do not take DIAFORMIN ALPHAPHARM XR if you are breastfeeding.

Your doctor will discuss the options available to you.

3. What if I am taking other medicines?

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

Some medicines and DIAFORMIN ALPHAPHARM XR may interact with each other. These include:

- other medicines used to treat diabetes
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisone or cortisone
- tetracosactrin, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, a medicine used to treat endometriosis
- medicines used to treat high blood pressure and some heart conditions, such as beta-blockers, calcium channel blockers or ACE inhibitors
- some medicines used to treat asthma such as salbutamol or terbutaline
- diuretics, also called fluid tablets
- 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, used to treat ulcers and reflux
- medicines used to prevent blood clots such as warfarin
- thyroid hormones, such as levothyroxine
- 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 hydrochloride such as topiramate and other carbonic anhydrase inhibitors

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DIAFORMIN ALPHAPHARM XR.

4. How do I use DIAFORMIN ALPHAPHARM XR?

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

They may differ from the information contained in this leaflet.

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

How much to take

- The dose varies from person to person. Your doctor will decide the right dose for you.
- The usual starting dose is 500 mg once daily with the evening meal. Your doctor may increase the dose slowly, depending on your blood glucose levels.
- The maximum recommended dose is 2 grams once per day.
- The elderly and people with kidney problems may need smaller doses.

How to take it

- **Swallow the tablets whole with a glass of water.**
- **Do not break, crush or chew the tablets.**
- If you break, crush or chew DIAFORMIN ALPHAPHARM XR they will not work as well. DIAFORMIN ALPHAPHARM XR are extended release tablets. This means they have a special coating which allows the active ingredient, metformin, to be released slowly over time.

When to take DIAFORMIN ALPHAPHARM XR

- **Take your medicine everyday with the evening meal.**

Taking DIAFORMIN ALPHAPHARM XR during or with your evening meal will reduce the chance of a stomach upset.

Taking it 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

- **Keep taking DIAFORMIN ALPHAPHARM XR for as long as your doctor recommends.**
- DIAFORMIN ALPHAPHARM XR will help control diabetes but will not cure it. Most people will need to take DIAFORMIN ALPHAPHARM XR for long periods of time.
- When you start treatment with DIAFORMIN ALPHAPHARM XR, it can take up to some weeks for your blood glucose levels to be properly controlled.

If you forget to take DIAFORMIN ALPHAPHARM XR

DIAFORMIN ALPHAPHARM XR should be taken regularly at the same time each day.

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 use too much DIAFORMIN ALPHAPHARM XR

If you think that you have used too much DIAFORMIN ALPHAPHARM XR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much DIAFORMIN ALPHAPHARM XR, 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 DIAFORMIN ALPHAPHARM XR 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 a non-diet soft drink or taking glucose tablets.

5. What should I know while using DIAFORMIN ALPHAPHARM XR?

Things you should do

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

Tell all the other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor.

Tell your doctor if you plan to have:

- surgery with general anaesthesia
- any x-ray procedures requiring an injection of an iodinated contrast agent (dye).

Your doctor will advise you when to stop taking DIAFORMIN ALPHAPHARM XR before you have these procedures and when to start again.

HYPOGLYCAEMIA

DIAFORMIN ALPHAPHARM XR does not normally cause hypoglycaemia (low blood sugar), although you may experience it while taking other medicines for diabetes such as insulin, sulfonylureas or glinide.

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

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

HYPERGLYCAEMIA

If you experience any of the signs of hyperglycaemia (high blood sugar), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less DIAFORMIN ALPHAPHARM XR 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 (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- you are injured
- you have a fever
- you have a serious infection such an influenza, respiratory tract infection or urinary tract infection
- you are having major surgery
- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye).
- you become pregnant.

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 DIAFORMIN ALPHAPHARM XR with insulin.

Visit your doctor regularly for check-ups.

Your doctor may want to check your kidneys, liver, heart and blood levels while you are taking DIAFORMIN ALPHAPHARM 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 the advice of your doctor and dietician on diet, drinking alcohol and exercise.

Things you should not do

Do not take DIAFORMIN ALPHAPHARM XR 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 skip meals while taking DIAFORMIN ALPHAPHARM XR.

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

Driving or using machines

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, DIAFORMIN ALPHAPHARM XR by itself is unlikely to affect how you drive or operate machinery.

Drinking alcohol

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 DIAFORMIN ALPHAPHARM XR may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

Looking after your medicine

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store DIAFORMIN ALPHAPHARM XR 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 it 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal

6. Are there any side effects?

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

DIAFORMIN ALPHAPHARM XR helps most people with diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• stomach upset such as feeling sick (nausea), vomiting • diarrhoea • stomach pain • taste disturbance • loss of appetite • skin reactions such as redness of the skin, itching or an itchy rash (urticaria).	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

These are generally mild side effects which disappear after the first few weeks. Taking DIAFORMIN ALPHAPHARM XR with meals can help reduce nausea and diarrhoea.

Serious side effects

Serious side effects	What to do
• nausea, vomiting, stomach pain • trouble breathing • feeling weak, tired or generally unwell • fever • yellowing of the skin and eyes (jaundice) • dark coloured urine • unusual muscle pain • sleepiness • dizziness or lightheadedness • shivering, feeling extremely cold • slow heart beat • reduction of TSH level in patients treated or untreated with hypothyroidism	**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 (build-up of lactic acid in the blood)**

Lactic acidosis is a very rare but serious side effect requiring urgent medical attention or hospitalisation. Although rare, if lactic acidosis does occur, it can be fatal. The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems.

Tell your doctor or pharmacist if you notice anything else that may be 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 worse rapidly.

Other side effects not listed here may occur in some people.

Some side effects (e.g. reduced vitamin B_{12} level) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DIAFORMIN ALPHAPHARM XR contains

Active ingredient (main ingredient)	Each extended release tablet contains either 500 mg or 1000 mg of metformin hydrochloride.
Other ingredients (inactive ingredients)	• colloidal anhydrous silica • povidone • hypromellose • magnesium stearate
Potential allergens	

The tablets are gluten free.

Do not take this medicine if you are allergic to any of these ingredients.

What DIAFORMIN ALPHAPHARM XR looks like

DIAFORMIN ALPHAPHARM XR metformin 500 mg modified release tablets are white capsule shaped uncoated tablets, debossed with "XR 500" on one side and plain on the other side. It is available in blister packs of 30, 60, 90, 100, and 120 tablets. AUST R 232658.

DIAFORMIN ALPHAPHARM XR metformin 1000 mg tablets are white capsule shaped uncoated tablets, debossed with "XR 1000" on one side and plain on the

other side. It is available in blister packs of 30, 60, 90, 100, and 120 tablets.
AUST R 232652.

Not all pack sizes are marketed in Australia.

Who distributes DIAFORMIN ALPHAPHARM XR

Strides Pharma Science Pty Ltd 5/148 Spit Road,

Mosman NSW 2088

Website: www.strides.com

Email: drugsafety@strides.com

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