DIAFORMIN® VIATRIS XR TABLETS

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 being treated with DIAFORMIN VIATRIS XR?

DIAFORMIN VIATRIS XR contains the active ingredients metformin (as hydrochloride). DIAFORMIN VIATRIS XR is used to lower blood sugar levels in adults with type 2 diabetes mellitus.

For more information, see Section 1. Why am I using DIAFORMIN VIATRIS XR? in the full CMI.

2. What should I know before treatment with DIAFORMIN VIATRIS XR?

Do not use if you have ever had an allergic reaction to DIAFORMIN VIATRIS 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 VIATRIS XR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DIAFORMIN VIATRIS 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 is DIAFORMIN VIATRIS XR given?

Take your DIAFORMIN VIATRIS XR tablets once a day with a meal

More instructions can be found in Section 4. How do I use DIAFORMIN VIATRIS XR? in the full CMI.

5. What should I know during treatment with DIAFORMIN VIATRIS XR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are

	taking DIAFORMIN VIATRIS XR. • Call your doctor straight away if you if you become pregnant while taking DIAFORMIN VIATRIS XR.
Things you should not do	• Do not stop taking this medicine or change the dose without checking with your doctor. • Do not skip meals while taking DIAFORMIN VIATRIS XR.
Drinking alcohol	• Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with DIAFORMIN VIATRIS XR may also lead to serious side effects.
Looking after your medicine	• Keep your tablets in the pack until it is time to take them. • Store DIAFORMIN VIATRIS XR where the temperature stays below 25°C

For more information, see Section 5. What should I know while during treatment with DIAFORMIN VIATRIS XR? in the full CMI.

6. Are there any side effects?

Common side effects include: nausea, vomiting, diarrhoea, stomach pain, taste disturbance and loss of appetite.

Serious side effects that need to be noted are: lactic acidosis; trouble breathing; feeling weak, tired or generally unwell; unusual muscle pain; sleepiness; dizziness or lightheadedness; shivering, feeling extremely cold; slow heartbeat.

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® VIATRIS XR

Active ingredient(s): *metformin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DIAFORMIN VIATRIS 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 VIATRIS XR.**

Where to find information in this leaflet:

1. Why am I being treated with DIAFORMIN VIATRIS XR?

2. What should I know before treatment with DIAFORMIN VIATRIS XR?

3. What if I am taking other medicines?

4. How is DIAFORMIN VIATRIS XR given?

5. What should I know during treatment with DIAFORMIN VIATRIS XR?

6. Are there any side effects?

7. Product details

1. Why am I being treated with DIAFORMIN VIATRIS XR?

DIAFORMIN VIATRIS XR contains active ingredient: metformin. Metformin which belongs to a class of medicines called biguanides.

DIAFORMIN VIATRIS XR 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 DIAFORMIN VIATRIS XR has been prescribed for you.

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

DIAFORMIN VIATRIS XR is available only with a doctor's prescription. There is no evidence that DIAFORMIN VIATRIS XR is addictive.

This medicine has been prescribed for you personally and you should not pass it onto others even if their symptoms are the same as yours.

2. What should I know before treatment with DIAFORMIN VIATRIS XR?

Warnings

Do not take DIAFORMIN VIATRIS XR if:

- you are allergic to medicines containing metformin (such as Diaformin, Glucophage) or any other biguanide
- any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

- 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.

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

You must stop taking DIAFORMIN VIATRIS 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.

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?

Before you start to take DIAFORMIN VIATRIS XR

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

Kidney function tests

Before starting DIAFORMIN VIATRIS XR your doctor will ask you to have a blood test to check your kidney function. Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- heart or blood vessel problems including heart failure.

Pregnancy and breastfeeding

DIAFORMIN VIATRIS XR is not recommended for use during pregnancy. Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not take DIAFORMIN VIATRIS XR while breastfeeding or if planning to breastfeed.

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

Children

Children and adolescents below 18 years should not use this medicine. DIAFORMIN VIATRIS XR is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. DIAFORMIN VIATRIS XR has not been studied in children younger than 10 years of age

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

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 VIATRIS XR may interfere with each other.

These include:

- medicines used to treat diabetes such as insulin, glitinides (Novonorm), and sulfonylureas (e.g. Amaryl, Daonil, Diamicron, Glimel, Glyade, Melizide, Minidiab)
- iodinated contrast agents (dyes)
- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisone (Panafacort, Sone) and cortisone (Cortate)

- 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, metoprolol (e.g. Betaloc, Minax), calcium channel blockers such as nifedipine (e.g. Adalat, Adefin), ACE inhibitors such as captopril (e.g. Capoten, Acenorm), enalapril (e.g. Alphapril, Amprace, Renitec) fosinopril (Monopril), lisinopril (e.g. Lisodur, Prinivil, Zestril), perindopril (Coversyl), quinapril (Accupril, Asig).
- Some medicines used to treat asthma such as salbutamol (Ventolin) or terbutaline (Bricanyl). diuretics, also called fluid tablets, such as amiloride (Midamor, Kaluril), bumetanide (Burinex), frusemide (Lasix, Uremide, Urex), hydrochlorothiazide (Dithiazide), spironolactone (Aldactone, Spiractin).
- 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, including arthritis such as aspirin (e.g. Disprin, Solprin), diclofenac (e.g. Voltaren, Fenac), ibuprofen (e.g. Actiprofen, Brufen, Rafen), meloxicam (Mobic), naproxen (e.g. Naprogesic, Naprosyn, Inza) and piroxicam (e.g. Feldene, Mobilis)
- medicines used to treat ulcers and reflux, such as cimetidine (e.g. Tagamet, Magicul)
- medicines used to prevent blood clots such as warfarin (e.g. Coumadin, Marevan)

- thyroid hormones, such as thyroxine (e.g. Oroxine, Eutroxsig)
- 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 VIATRIS XR 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 DIAFORMIN VIATRIS XR.

4. How is DIAFORMIN VIATRIS XR given?

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 1 tablet (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.
- Follow the instructions provided and use DIAFORMIN VIATRIS XR until your doctor tells you to stop.

How to take DIAFORMIN VIATRIS XR

- Swallow the tablets whole with a glass of water.
- Do not break, crush or chew the tablets.
- If you break, crush or chew DIAFORMIN VIATRIS XR, they will not work as well. DIAFORMIN VIATRIS 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 VIATRIS XR

Take your medicine everyday with the evening meal.

- Taking DIAFORMIN VIATRIS 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 DIAFORMIN VIATRIS XR

- Keep taking DIAFORMIN VIATRIS XR for as long as your doctor recommends.

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

If you forget to take DIAFORMIN VIATRIS XR

If you missed your dose at the usual time, take it as soon as you remember, and then go back to taking your next dose when you are meant to.

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 DIAFORMIN VIATRIS XR

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 VIATRIS XR, you may feel 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 VIATRIS 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.

If you take too much DIAFORMIN VIATRIS XR, you may feel sick, vomit, have trouble breathing and have stomach pain or diarrhoea. These may be the early signs of a serious condition called lactic acidosis.

If you experience any of these symptoms, immediately get medical help

5. What should I know during treatment with DIAFORMIN VIATRIS 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 VIATRIS 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.

Call your doctor straight away if you:

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

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

HYPOGLYCAEMIA

DIAFORMIN VIATRIS 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 VIATRIS 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 VIATRIS 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 VIATRIS 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 use DIAFORMIN VIATRIS 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 VIATRIS XR.**
- **Do not stop taking your medicine or change the dose 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.

Be careful before you drive or use any machines or tools until you know how DIAFORMIN VIATRIS XR affects you.

There is no information to suggest that DIAFORMIN VIATRIS XR affects your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Things to be aware of

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

Looking after your medicine

- Store DIAFORMIN VIATRIS XR in a cool dry place away where the temperature stays below 25oC.
- Keep your tablets in the pack until it is time to take them.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date

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 VIATRIS XR.

DIAFORMIN VIATRIS XR 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.

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.

Less serious side effects

Less serious side effects	What to do
• drowsiness on the day following use	**Speak to your doctor if you/ your child have any of these less serious**

Less serious side effects	What to do
• dizziness • incoordination • dry mouth, nose and/or throat • headache • muscle weakness • thicker nasal discharge	**side effects and they worry you.**

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

Tell your doctor as soon as possible if you notice any of the following: Symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, yellowing of the skin and eyes (jaundice) and dark coloured urine.

Serious side effects

Serious side effects	What to do
• Symptoms of LACTIC ACIDOSIS (build up of lactic acid in the blood): o nausea, vomiting, stomach pain o trouble breathing o feeling weak, tired or generally unwell	**Call your/your child's doctor immediately, or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
o unusual muscle pain o sleepiness o dizziness or lightheadedness o shivering, feeling extremely cold o slow heartbeat	

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 SEVERE KIDNEY OR LIVER PROBLEMS.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Some side effects (e.g. reduced vitamin B12 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/your child 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 VIATRIS XR contains

Active ingredient	Metformin hydrochloride
Other ingredients	Microcrystalline cellulose Magnesium stearate Povidone Hypromellose

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

What DIAFORMIN VIATRIS XR looks like

DIAFORMIN VIATRIS XR 500 extended release tablets: White to off-white coloured, capsule shaped biconvex debossed with ‘500’ on one side and plain on other side.

DIAFORMIN VIATRIS XR 1000 extended release tablets: White to off-white coloured, oval shaped biconvex tablets debossed with '1000 on one side and plain on other side.

Australian Registration Numbers are as follows:

Aust R 423411

Aust R 423390

Who distributes DIAFORMIN VIATRIS XR

Sponsor

Medreich Australia Pty Ltd

Unit 8, Homebush Business Village

11-21 Underwood Road,

Homebush, NSW 2140

Distributor

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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