

ARX-VILDAGLIPTIN/METFORMIN

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 ARX-VILDAGLIPTIN/METFORMIN?

ARX-VILDAGLIPTIN/METFORMIN contains the active ingredients Vildagliptin and Metformin Hydrochloride. ARX-VILDAGLIPTIN/METFORMIN is used to treat type 2 diabetes mellitus in people who are already taking vildagliptin and metformin tablets separately, or whose diabetes cannot be controlled by metformin alone.

For more information, see Section [1. Why am I using ARX-VILDAGLIPTIN/METFORMIN?](#) in the full CMI.

2. What should I know before I use ARX-VILDAGLIPTIN/METFORMIN?

Do not use if you have ever had an allergic reaction to Vildagliptin or Metformin 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 ARX-VILDAGLIPTIN/METFORMIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-VILDAGLIPTIN/METFORMIN 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 ARX-VILDAGLIPTIN/METFORMIN?

- Swallow ARX-VILDAGLIPTIN/METFORMIN tablets whole with a glass of water
- Take your medicine at about the same time each day either with or just after food.

More instructions can be found in Section [4. How do I use ARX-VILDAGLIPTIN/METFORMIN?](#) in the full CMI.

5. What should I know while using ARX-VILDAGLIPTIN/METFORMIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, diabetes educator, or pharmacist you visit that you are using ARX-VILDAGLIPTIN/METFORMIN.• ARX-VILDAGLIPTIN/METFORMIN should not be taken if you are pregnant. Insulin is more suitable for controlling blood glucose during pregnancy.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give this medicine to anyone else, even if their condition seems similar to yours.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how ARX-VILDAGLIPTIN/METFORMIN affects you.
Drinking alcohol	Tell your doctor if you drink alcohol. Alcohol may increase the risk of your blood glucose becoming too low.
Looking after your medicine	Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it: <ul style="list-style-type: none">• in the bathroom or near a sink, or• in the car or on windowsills.

For more information, see Section [5. What should I know while using ARX-VILDAGLIPTIN/METFORMIN?](#) in the full CMI.

6. Are there any side effects?

The common side effects include skin reddening or itching, peeling of skin or blister, skin lesions, joint pain, swelling of the hands, ankles, or feet, low blood glucose, diarrhea, abdominal pain, a burning sensation in the chest rising to the throat (heartburn), metallic taste, loss of appetite, constipation, wind (flatulence), and weight increase.

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.

ARX-VILDAGLIPTIN/METFORMIN

Active ingredient(s): *Vildagliptin/Metformin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-VILDAGLIPTIN/METFORMIN. **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 ARX-VILDAGLIPTIN/METFORMIN.**

Where to find information in this leaflet:

- [1. Why am I using ARX-VILDAGLIPTIN/METFORMIN?](#)
- [2. What should I know before I use ARX-VILDAGLIPTIN/METFORMIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-VILDAGLIPTIN/METFORMIN?](#)
- [5. What should I know while using ARX-VILDAGLIPTIN/METFORMIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARX-VILDAGLIPTIN/METFORMIN?

ARX-VILDAGLIPTIN/METFORMIN contains two active ingredients vildagliptin and metformin hydrochloride. Vildagliptin belongs to class of medicine called 'sGLT2 inhibitors', and metformin belongs to 'biguanide class'.

ARX-VILDAGLIPTIN/METFORMIN is used to treat type 2 diabetes mellitus in people who are already taking vildagliptin and metformin tablets separately, or whose diabetes cannot be controlled by metformin alone.

ARX-VILDAGLIPTIN/METFORMIN is also used with a sulfonylurea by patients whose blood sugar levels are not adequately controlled when taking only metformin and a sulfonylurea.

ARX-VILDAGLIPTIN/METFORMIN is also added to insulin in patients when a stable dose of insulin and metformin do not provide adequate blood sugar control.

It is prescribed by your doctor together with diet and exercise.

Type 2 diabetes mellitus used to be known as 'non-insulin-dependent diabetes mellitus (NIDDM)' or 'maturity onset diabetes'.

Type 2 diabetes develops if the body does not produce enough insulin, or where the insulin that your body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance which helps to lower the level of sugar in your blood, especially after meals. Glucagon is another substance which triggers the production of sugar

by the liver, causing the blood sugar to rise. The pancreas makes both of these substances.

ARX-VILDAGLIPTIN/METFORMIN helps to control the blood sugar level. It works by making the pancreas produce insulin and less glucagon (effect of vildagliptin) and also by helping the body to make better use of the insulin it produces (effect of metformin).

Your doctor will prescribe ARX-VILDAGLIPTIN/METFORMIN either alone or in combination with another antidiabetic medicine to replace the antidiabetic medicine(s) you are already taking, where that medicine(s) alone is not enough to control your blood sugar level.

It is important that you continue to follow the diet and/or exercise recommended for you whilst you are on treatment with ARX-VILDAGLIPTIN/METFORMIN.

ARX-VILDAGLIPTIN/METFORMIN is not a substitute for insulin. It is not used to treat type 1 diabetes (where your body does not produce insulin at all), or diabetic ketoacidosis.

2. What should I know before I use ARX-VILDAGLIPTIN/METFORMIN?

Warnings

Do not use ARX-VILDAGLIPTIN/METFORMIN if:

- you are allergic to vildagliptin or metformin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have an allergy to any other similar medicines (such as medicines of the same class or with a similar structure, if listed in the PI).

Check with your doctor if you have:

- Severely reduced kidney function where your doctor has considered use of ARX-VILDAGLIPTIN/METFORMIN to be unsuitable.
- Taken this medicine before and your doctor told you to stop taking it because of liver problems.
- Had a recent heart attack or heart failure.
- Serious circulation problems, including shock and breathing problems.
- Serious complications of diabetes for example diabetic ketoacidosis (a complication of diabetes involving rapid weight loss, nausea or vomiting) or diabetic coma.
- **Type 1 diabetes** (a condition where your body does not produce any insulin at all. ARX-VILDAGLIPTIN/METFORMIN is not suitable for insulin).
- **Diabetic ketoacidosis** (a complication in patients with diabetic mellitus who have little to no insulin. ARX-

VILDAGLIPTIN/METFORMIN is not a substitute for insulin)

- Hypothyroidism (a condition where the thyroid gland does not produce enough thyroid hormone)
- Genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome or Maternal inherited diabetes and deafness (MIDD).

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 it

Discard any other medicines containing metformin that your doctor might have prescribed to you in the past and that you may still have in your possession.

ARX-VILDAGLIPTIN/METFORMIN contains metformin. If you have more than one metformin-containing medicine in your possession you may accidentally take too much (overdose). Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.

ACCIDENTAL METFORMIN OVERDOSING IS A SIGNIFICANT SAFETY RISK.

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing metformin.

Metformin is sold under many different brand names in Australia. Your doctor or pharmacist will know which other medicines also contain metformin.

Pregnancy and breastfeeding

Call your doctor straight away if you become pregnant while taking this medicine.

ARX-VILDAGLIPTIN/METFORMIN should not be taken if you are pregnant. Insulin is more suitable for controlling blood glucose during pregnancy.

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

It is not known if the active ingredient of ARX-VILDAGLIPTIN/METFORMIN passes into breast milk and could affect your baby.

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.

You may need to different amounts of your medicine or to take different medicines while you are taking ARX-VILDAGLIPTIN/METFORMIN.

This is particularly important with the following medicines:

- Certain medicines used to treat infections (e.g., vancomycin, trimethoprim)
- Certain medicines used to treat inflammations (e.g., corticosteroids)

- Certain medicines used to treat high blood pressure (e.g., amiloride, triamterene, nifedipine, enalapril, losartan, diuretics)
- Certain medicines used to treat irregular heartbeat (e.g., digoxin, quinidine)
- Certain medicines used to treat pain (e.g., morphine, diclofenac)
- Certain medicines used to treat stomach disorders (e.g., cimetidine, ranitidine)
- Certain medicines used to treat psychiatric disorders (e.g., phenothiazine)
- Certain medicines used to treat thyroid disorders (e.g., levothyroxine)
- Oral contraceptives and certain medicines used to reduce symptoms in women experiencing menopause or osteoporosis (e.g., oestrogen)
- If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking ARX-VILDAGLIPTIN/METFORMIN before or at the time of injection. This medicine may affect your kidney function so you will need to stop taking it before or at the time of the procedure and for a few days after.

Your doctor will decide when you must stop and when to start your treatment with ARX-VILDAGLIPTIN/METFORMIN.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

4. How do I use ARX-VILDAGLIPTIN/METFORMIN?

How much to take

- The usual dose of ARX-VILDAGLIPTIN/METFORMIN is one tablet twice a day. Your doctor will tell you exactly how many tablets to take. Do not exceed two tablets a day.
- Your doctor will monitor your blood glucose levels and may increase or decrease the dose of ARX-VILDAGLIPTIN/METFORMIN to maintain good control of your diabetes.
- If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking any anti-diabetic medicine known as sulfonylureas your doctor may prescribe a lower dose.

When to take ARX-VILDAGLIPTIN/METFORMIN

- ARX-VILDAGLIPTIN/METFORMIN should be taken at the same time each day will have best effect. It will also help you remember when to take it.

How to take ARX-VILDAGLIPTIN/METFORMIN

Swallow ARX-VILDAGLIPTIN/METFORMIN tablets whole with a glass of water.

Take this medicine either with or just after food.

This will reduce the chance of you getting an upset stomach.

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

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Do not stop taking ARX-VILDAGLIPTIN/METFORMIN unless your doctor tells you to.

If you forget to take ARX-VILDAGLIPTIN/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 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 you missed.

This may increase the chance of you getting an unwanted side effect.

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

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

If you use too much ARX-VILDAGLIPTIN/METFORMIN

If you think that you have used too much ARX-VILDAGLIPTIN/METFORMIN, 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.

Keep the telephone numbers for these places handy.

You may need urgent medical attention.

Symptoms of an overdose include:

- swelling in hands or feet
- tingling or numbness in hands or feet
- muscle pain
- fever

Symptoms of an overdose can also include the symptoms of lactic acidosis:

- feeling cold (especially in your arms and legs)
- feeling very weak, tired
- feeling light-headed, dizzy
- severe nausea or vomiting
- feeling uncomfortable
- muscle pain
- drowsiness
- abdominal pain
- unexplained weight loss
- irregular heartbeat
- rapid or difficult breathing

5. What should I know while using ARX-VILDAGLIPTIN/METFORMIN?

Things you should do

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

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

Your doctor will do regular checks to help prevent you from having side effects from the medicine or developing a serious complication of diabetes.

These will include test for:

- Blood and urine

These should be regularly tested for sugar.

- Kidney function

This should be checked at the start of treatment and at least once a year whilst you are on treatment.

This should be checked more often if you are elderly.

- Liver function

This should be checked at the start of treatment and every 03 months during your first year of treatment, and regularly thereafter.

- General blood tests

This should be done at least once a year.

- Vitamin B12 levels

This will be checked at least every 2 to 3 years.

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.

Tell your doctor if you become ill or experience extra stress, injury, fever, infection or need surgery.

Your blood glucose may become difficult to control at these times.

Make sure you keep enough medicine to last over weekends and holidays.

It is important to keep your blood glucose controlled at all times to prevent serious complications of diabetes from happening.

Remind your doctor and pharmacist that you are taking ARX-VILDAGLIPTIN/METFORMIN if you are about to be started on any new medicine.

Tell your doctor, dentist or pharmacist who treats you that you are taking ARX-VILDAGLIPTIN/METFORMIN.

Things you should not do

Do not stop using this medicine suddenly.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful when doing any of the following things, which increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-VILDAGLIPTIN/METFORMIN affects you.

If your blood glucose levels become too low, you may feel dizzy, lightheaded, weak, or tired and your reaction time may be slower than usual. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the risk of your blood glucose becoming too low.

Looking after your medicine

- **Keep your medicine in the original container until it is time to take it.**
- **Store it in a cool dry place where the temperature stays below 30°C.**
- **Protect from moisture.**

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 windowsills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters 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.

Do not use this medicine after the expiry date.

<ul style="list-style-type: none"> • Joint pain • Swelling of the hands, ankles, or feet • Low blood glucose • Diarrhoea • Abdominal pain • A burning sensation in the chest rising to the throat (heartburn) • Metallic taste • Loss of appetite • Constipation • Wind (flatulence) • Weight increase 	<p>pharmacist, or diabetes educator if you have any of these less serious side effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Swelling of the face, lips, mouth, tongue, or throat may cause difficulty in swallowing or breathing or sudden onset of a rash or hives. <p>These are the symptoms of allergic reactions.</p> <ul style="list-style-type: none"> • Yellow skin and eyes, nausea, loss of appetite, dark urine (possible symptoms of liver problem) <p>These are symptoms of liver problems.</p> <ul style="list-style-type: none"> • Nausea, excessive sweating, weakness, dizziness, trembling, headache, chills <p>These are signs of a low blood sugar level which could be due to lack of food, too much exercise without enough food or too much alcohol.</p> <ul style="list-style-type: none"> • Severe upper stomach pain <p>This is a possible sign of an inflamed pancreas.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

6. Are there any side effects?

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.

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
<ul style="list-style-type: none"> • Skin reddening or itching • Peeling of skin or blisters • Skin lesions 	<p>Speak to your doctor,</p>

Very Serious side effects

Very Serious side effects	What to do
<p>Stop taking ARX-VILDAGLIPTIN/METFORMIN if you get any of the symptoms of lactic acidosis and go to Accident and Emergency immediately.</p> <p>Metformin has caused lactic acidosis in rare cases. This is a medical emergency that can cause death. It is caused by build-up of lactic acid in your blood. The symptoms of lactic acidosis are:</p> <ul style="list-style-type: none"> • Feeling cold (especially in your arms and legs) • Feeling very weak, tired • Feeling light-headed, dizzy • Severe nausea or vomiting • Feeling uncomfortable • Muscle pain • Drowsiness • Abdominal pain • Unexplained weight loss • Irregular heartbeat • Rapid or difficult breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

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. It is not addictive.

There is not enough information to recommend this medicine for use in children under 18 years of age.

What ARX-VILDAGLIPTIN/METFORMIN contains

Active ingredient (main ingredient)	Vildagliptin Metformin hydrochloride
Other ingredients (inactive ingredients)	Microcrystalline cellulose Copovidone Crospovidone

	Hyprolose Magnesium stearate Hypromellose Titanium dioxide Macrogol 8000 Purified talc Iron oxide yellow Iron oxide red (for 50/500 mg only)
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ARX-VILDAGLIPTIN/METFORMIN does not contain lactose, gluten, tartrazine or any other azo dyes.

What ARX-VILDAGLIPTIN/METFORMIN looks like

ARX-VILDAGLIPTIN/METFORMIN 50/500 is a light yellow, ovaloid, film-coated tablet with bevelled edge, plain surface on both sides.

ARX-VILDAGLIPTIN/METFORMIN 50/850 is a yellow, ovaloid, film-coated tablet with bevelled edge, plain surface on both sides.

ARX-VILDAGLIPTIN/METFORMIN 50/1000 is a dark yellow, ovaloid, film-coated tablet with bevelled edge, plain surface on both sides.

ARX-VILDAGLIPTIN/METFORMIN is available in blister packs containing 60 tablets.

Who distributes ARX-VILDAGLIPTIN/METFORMIN

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

Australian Registration Numbers:

ARX-VILDAGLIPTIN/METFORMIN 50/500 tablets – AUST R 432003

ARX-VILDAGLIPTIN/METFORMIN 50/850 tablets – AUST R 432004

ARX-VILDAGLIPTIN/METFORMIN 50/1000 tablets – AUST R 432002

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