VELMETIA®

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 VELMETIA?

VELMETIA contains the active ingredients sitagliptin (as phosphate monohydrate) and metformin (as hydrochloride). VELMETIA is used to lower blood sugar levels in adults with diabetes mellitus.

For more information, see Section 1. Why am I taking VELMETIA? in the full CMI.

2. What should I know before I take VELMETIA?

Do not take if you have ever had an allergic reaction to VELMETIA 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 take VELMETIA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VELMETIA 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 take VELMETIA?

- Your doctor will tell you how many VELMETIA tablets to take and how often to take them.
- Take VELMETIA with meals to lower your chance of an upset stomach.

More instructions can be found in Section 4. How do I take VELMETIA? in the full CMI.

5. What should I know while taking VELMETIA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using VELMETIA. • Call your doctor straight away if you if you become pregnant while taking VELMETIA.
Things you should not do	• Do not stop taking this medicine suddenly. • Do not give VELMETIA to anyone else, even if they have the same condition as you.
Driving or using machines	• There is no information to suggest that VELMETIA affects your ability to drive a car or operate machinery.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your tablets in the blister pack until it is time to take them. • Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while taking VELMETIA? in the full CMI.

6. Are there any side effects?

Serious side effects in particular that need to be noted are:

- Allergic reactions including rash, hives, swelling of the face, lips, tongue, and throat with difficulty in breathing or swallowing.
- Severe and persistent stomach pain, often with nausea and vomiting.
- Blisters or the breakdown of your skin (erosion).
- Low blood sugar when used in combination with a sulfonylurea medicine or with insulin.
- Kidney problems (sometimes requiring dialysis).
- Thyroid problems in patients with low thyroid function including fatigue, feeling cold, dry skin, poor memory and concentration, weight gain

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.

VELMETIA

Active ingredient(s): *Sitagliptin (as phosphate monohydrate)/Metformin (as hydrochloride)*

Consumer Medicine Information (CMI)

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

Keep this leaflet with the medicine.

You may need to read it again.

Where to find information in this leaflet:

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

1. Why am I taking VELMETIA?

VELMETIA contains two active ingredients: sitagliptin and metformin. Sitagliptin is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and metformin which belongs to a class of medicines called biguanides. Sitagliptin and metformin work together to control blood sugar levels in adults with type 2 diabetes mellitus.

VELMETIA is used to lower blood sugar levels in adults with type 2 diabetes mellitus. VELMETIA can be taken alone or in combination with certain other medicines that lower blood sugar along with a recommended diet and exercise program.

2. What should I know before I take VELMETIA?

Warnings

Do not take VELMETIA if:

- you are allergic to sitagliptin or metformin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have or have had type 1 diabetes mellitus or
- have or have had increased ketones in the blood or urine (diabetic ketoacidosis).
- are known to suffer from a genetically inherited disease affecting mitochondria (the energy producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic Acidosis and Stroke-like episodes) or Maternal Inherited Diabetes and Deafness (MIDD).
- have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g., pain or numbness), migraine and deafness.
- have or have had severe kidney problems
- have any liver or heart problems including congestive heart failure, or any past or present medical problems.
- drink excessive alcohol (all the time or short term "binge" drinking).
- are going to get or receive an injection of dye or contrast agent for an X-ray procedure, or if you plan to have surgery. Talk to your doctor about when to stop VELMETIA and when to start again.
- have hypothyroidism (low levels of thyroid hormones).
- take any medicines for any other condition

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

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

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

Children

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

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.

VELMETIA may affect how well other drugs work and some drugs can affect how well VELMETIA works.

Medicines that may cause low blood sugar when used in combination with VELMETIA include:

- Sulfonylureas
- Insulin

A reduction in the amount of the sulfonylurea or insulin may be required.

Other medicines that tend to produce high blood sugar (hyperglycaemia) and may lead to a loss of blood sugar control. Some examples include:

- Thyroid products

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

4. How do I take VELMETIA?

How much to take

- Your doctor will tell you how many VELMETIA tablets to take and how often to take them.
- Take VELMETIA with meals to lower your chance of an upset stomach.

When to take VELMETIA

- Take your VELMETIA at about the same time each day.

If you forget to take VELMETIA

VELMETIA should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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

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

If you take too much VELMETIA

If you think that you have taken too much VELMETIA, 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.

5. What should I know while taking VELMETIA?

Things you should do

Call your doctor straight away if you:

- Become pregnant while taking VELMETIA, or

Tell your doctor if you:

- Become ill
- Become dehydrated
- Are injured
- Have a fever
- Have a serious infection
- Plan to have surgery

Your blood glucose may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis. During these times, your doctor may temporarily replace VELMETIA with insulin.

Low blood sugar or high blood sugar

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

Low blood sugar

Signs of low blood sugar 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 quickly, these symptoms may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness

At the first signs of low blood sugar, you need to raise your blood glucose quickly. You can do this by taking one of the following:

- 5 -7 jelly beans
- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2-3 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.

High blood sugar

If you notice any signs of high blood sugar, contact your doctor immediately.

The risk of high blood sugar is increased with:

- uncontrolled diabetes
- illness, infection or stress
- taking less VELMETIA than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Your blood glucose sugar may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis. During these times, your doctor may temporarily replace VELMETIA with insulin.

Stop taking VELMETIA if you have symptoms of lactic acidosis, such as feeling very weak and tired, unusual (not normal) muscle pain, trouble breathing, stomach pain with nausea and vomiting, or diarrhoea, feeling cold, especially in your arms and legs, feeling dizzy or lightheaded, a slow or irregular heart beat or your medical condition suddenly changes.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor's recommended diet, exercise and weight loss program while taking VELMETIA.

Make sure you check your blood glucose sugar levels regularly.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

See you doctor once a year for a check on your body's level of vitamin B12.

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

Remind any doctor, dentist or pharmacist you visit that you are taking VELMETIA.

Things you should not do

- Do not stop taking this medicine or change your dose without checking with your doctor.
- Do not skip meals while taking VELMETIA.
- Do not give VELMETIA to anyone else, even if they have the same condition as you.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

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?

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
• Signs of an infection of the breathing passages, including runny nose, sore throat, cough • Nausea, vomiting, stomach discomfort, diarrhoea or constipation • Headache • Muscle aches or joint, arm, leg or back pain • Itching or blisters	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Allergic reactions including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. • Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition. • Kidney problems (sometimes requiring dialysis) • Itching, blisters or the breakdown of your skin (erosion). • Low blood sugar when VELMETIA is used in combination with a sulfonylurea medicine or with insulin. • Thyroid problems in patients with low thyroid function including fatigue, feeling cold, dry skin, poor memory and concentration, weight gain	**Stop taking VELMETIA. 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.**

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.

What VELMETIA contains

Active ingredients (main ingredients)	Sitagliptin 50 mg and metformin 500, 850, or 1000 mg per tablet
Other ingredients (inactive ingredients)	Microcrystalline cellulose Povidone Sodium lauryl sulfate Sodium stearylfumarate Polyvinyl alcohol Macrogol 3350 Purified talc Titanium dioxide Iron oxide red Iron oxide black

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

What VELMETIA looks like

VELMETIA 50/500 is a light pink, film coated tablet with "575" on one side and plain on the other (AUST R 220155).

VELMETIA 50/850 is a pink, film coated tablet with "515" on one side and plain on the other (AUST R 220156).

VELMETIA 50/1000 is a red, film coated tablet with "577" on one side and plain on the other (AUST R 220157).

Who distributes VELMETIA

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

MACQUARIE PARK NSW 2113

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