

# JANUVIA®

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## 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.

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### 1. Why am I taking JANUVIA?

JANUVIA contains the active ingredient sitagliptin (as phosphate monohydrate). JANUVIA is used to lower blood sugar levels in adults with type 2 diabetes mellitus.

For more information, see Section [1. Why am I taking JANUVIA?](#) in the full CMI.

### 2. What should I know before I take JANUVIA?

Do not use if you have ever had an allergic reaction to JANUVIA 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 JANUVIA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with JANUVIA 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 JANUVIA?

- Take JANUVIA once a day by mouth, with or without food

More instructions can be found in Section [4. How do I take JANUVIA?](#) in the full CMI.

### 5. What should I know while taking JANUVIA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking JANUVIA.</li><li>• Call your doctor straight away if you become pregnant while taking JANUVIA.</li></ul>
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<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop taking this medicine suddenly.</li> <li>• Do not give JANUVIA to anyone else, even if they have the same condition as you.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Keep your tablets in the blister pack until it is time to take them.</li> <li>• Store JANUVIA in a cool dry place below 25°C, away from moisture, heat or sunlight.</li> </ul>

For more information, see Section [5. What should I know while taking JANUVIA?](#) 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.
- Low blood sugar when used in combination with a sulfonylurea medicine or with insulin.
- Blisters or the breakdown of your skin (erosion).
- Kidney problems.

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.

# JANUVIA

**Active ingredient:** *Sitagliptin (as phosphate monohydrate)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking JANUVIA. **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 JANUVIA.**

**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 JANUVIA?](#)
- [2. What should I know before I take JANUVIA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take JANUVIA?](#)
- [5. What should I know while take JANUVIA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking JANUVIA?

**JANUVIA contains the active ingredient sitagliptin.** JANUVIA is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4

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inhibitors) that lowers blood sugar levels in adults with type 2 diabetes mellitus.

**JANUVIA is used to lower blood sugar levels in adults with type 2 diabetes mellitus. Januvia can be used 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 JANUVIA?**

### **Warnings**

#### **Do not take JANUVIA if:**

- you are allergic to sitagliptin, 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.
- have or have had increased ketones in the blood or urine (diabetic ketoacidosis).
- have or have had any kidney problems or any past or present medical problems.
- 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. JANUVIA is not recommended for use during pregnancy.

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

## **Children**

Children and adolescents below 18 years should not use this medicine. JANUVIA is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. JANUVIA 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.

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

- Sulfonylureas

- Insulin

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

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

## **4. How do I take JANUVIA?**

### **How much to take**

- Take JANUVIA once a day by mouth, with or without food
- If you have kidney problems, your doctor may prescribe lower doses, and monitor your kidney function.
- Your doctor may prescribe JANUVIA on its own, or with certain other medicines that lower blood sugar.

### **When to take JANUVIA**

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

### **If you forget to take JANUVIA**

JANUVIA 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 JANUVIA**

If you think that you have taken too much JANUVIA, 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 JANUVIA?**

### **Things you should do**

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 JANUVIA.

### **Call your doctor straight away:**

- If you become pregnant while taking JANUVIA.

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

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

## **Things you should not do**

- Do not stop taking this medicine suddenly. Continue to take JANUVIA as long as your doctor prescribes it so it can continue to help control your blood sugar.
- Do not give JANUVIA to anyone else, even if they have the same condition as you.

## **Driving or using machines**

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

## **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 below 25°C, 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

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• Signs of an infection of the breathing passages including runny nose, sore throat, cough, soreness in the back of the nose and throat and discomfort when swallowing, headache, flu-like symptoms</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Stomach discomfort and vomiting, diarrhoea or constipation.</li> <li>● Muscle aches or pain in the joints, back, arm, or leg</li> <li>● Itching, or blisters or the breakdown of your skin (erosion).</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Allergic reactions including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.</li> <li>● Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be a serious, potentially life-</li> </ul>	<p><b>Stop taking JANUVIA. 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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>threatening medical condition.</p> <ul style="list-style-type: none"> <li>● Low blood sugar when JANUVIA is used in combination with a sulfonylurea medicine or with insulin.</li> <li>● Severe blistering or the breakdown of your skin (erosion).</li> <li>● Kidney problems (sometimes requiring dialysis)</li> </ul>	

**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](http://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 JANUVIA contains

<b>Active ingredient (main ingredient)</b>	Sitagliptin 25, 50 or 100 mg per tablet
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose Calcium hydrogen phosphate Croscarmellose sodium Magnesium stearate Sodium stearyl fumarate Propyl gallate* Polyvinyl alcohol Macrogol 3350 Purified talc Titanium dioxide Iron oxide red Iron oxide yellow

\*AUST Rs 408437, 408436, 408435 only

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

## **What JANUVIA looks like**

JANUVIA 25 mg is a pink, round, film coated tablet with "221" on one side and plain on the other (AUST Rs 133188, 408437).

JANUVIA 50 mg is a light beige, round, film coated tablet with "112" on one side and plain on the other AUST Rs 133187, 408436).

JANUVIA 100 mg is a beige, round, film coated tablet with "277" on one side and plain on the other (AUST Rs 133182, 408435).

## **Who distributes JANUVIA**

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

MACQUARIE PARK NSW 2113

[www.msinfo.com.au/januviacmi](http://www.msinfo.com.au/januviacmi)

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