

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 Galvus?

Galvus contains the active ingredient Vildagliptin. Galvus is used to treat diabetes mellitus type 2 in people 18 years of age and above.

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

2. What should I know before I use Galvus?

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

3. What if I am taking other medicines?

Some medicines may interfere with Galvus 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 Galvus?

- Take 50 mg or 100 mg of Galvus daily.
- If the dose is 50 mg, take once daily (1 tablet daily) in the morning. If the dose is 100 mg take it twice daily (50 mg tablet in morning and evening)
- Swallow the Galvus tablet whole orally with or without a meal.

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

5. What should I know while using Galvus?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using Galvus. • Check your blood sugar level and update your doctor accordingly. • Keep all your doctor's appointments so that your progress can be checked. • If you become pregnant while taking Galvus, tell your doctor immediately. |
| Things you should not do | <ul style="list-style-type: none"> • Do not stop using this medicine suddenly. |
| Driving or using machines | <ul style="list-style-type: none"> • Galvus may cause dizziness, light-headedness, tiredness in some people. • Be careful before you drive or use any machines or tools until you know how Galvus affects you. |
| Drinking alcohol | <ul style="list-style-type: none"> • Be careful while drinking alcohol as it has a risk of lowering your blood sugar levels. |
| Looking after your medicine | <ul style="list-style-type: none"> • Keep your capsules in the pack until it is time to take them. • Store below 30°C |

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

6. Are there any side effects?

Common side effects include swelling of hands, ankles and feet, dizziness, light headedness, headache, weakness, feeling sick.

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.

Galvus

Active ingredient(s): *vildagliptin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Galvus. **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 Galvus.**

Where to find information in this leaflet:

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

1. Why am I using Galvus?

Galvus contains the active ingredient vildagliptin. Galvus is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that help to lower your blood sugar levels.

Galvus is used to treat diabetes mellitus type 2 in people 18 years of age and above. It is used to lower the blood sugar levels. It is either used alone or in combination with another medication. Type 2 diabetes develops when the body does not produce the required quantity of insulin or when the body does not use the insulin effectively. Insulin is a substance that helps to lower the blood sugar levels especially after the intake of meals.

2. What should I know before I use Galvus?

Warnings

Do not use Galvus if:

- you are allergic to vildagliptin, or any of the ingredients listed at the end of this leaflet.
- you have type 1 diabetes or if you have high levels of ketones in your blood.

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

Check with your doctor if you have:

- Heart issues
- Problems with your pancreas
- Problems with your liver and kidney
- Pain and discomfort in joints
- Any skin issues such as boils, blisters, redness

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.

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

You should avoid taking Galvus if you are breast feeding. It is unknown if the active ingredient in Galvus is excreted in breast milk.

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 take other medicines along with Galvus. Consult your doctor for more information.

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

4. How do I use Galvus?

How much to take

- The dose may differ from the information contained in this leaflet. Please contact your doctor or pharmacist if you have any difficulties in understanding the dose.
- Take 50 mg or 100 mg of Galvus daily.
- If the dose is 50 mg, take once daily (1 tablet daily) in the morning. If the dose is 100 mg take it twice daily (50 mg tablet in morning and evening)
- Do not take two tablets together at a time.
- Follow the instructions provided and use Galvus until your doctor tells you to stop.

How to take Galvus

- Swallow the Galvus tablet whole orally with or without a meal.

If you forget to use Galvus

Galvus should be used 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.

•Ask your doctor or pharmacist if you are unsure what to do.

If you use too much Galvus

If you think that you have used too much Galvus, you may need urgent medical attention.

Symptoms of overdose:

- Swelling of hands or feet
- Muscle pain
- Numbness in hands or feet
- Fever

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 using Galvus?

Things you should do

- If you become pregnant while taking Galvus, tell your doctor immediately
- Keep all your doctor's appointments so that your progress can be checked.
- Check your blood glucose levels regularly and let your doctor know about it.

Call your doctor straight away if you:

- Feel ill or experience extra stress, injury, fever, infection or need surgery.
- Remind any doctor, dentist or pharmacist you visit that you are using Galvus.

Things you should not do

- Do not stop using this medicine suddenly.
- Avoid driving vehicles or using machines if you feel dizzy, tired.

Additional Tests

- Your doctor may do regular blood checks to prevent you from having any side effects from the medicine or developing serious complications of diabetes.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Galvus affects you.

Galvus may cause dizziness, light-headedness, tiredness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol as it may increase the risk of having low blood sugar level in your blood.

Looking after your medicine

- Store below 30°C

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

Follow the instructions in 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 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.

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 |
|--|---|
| General issues such as: <ul style="list-style-type: none">• Swelling on hands, ankles and feet.• Dizziness or light headedness• Headache• Unintentional shaking movements in one or more parts of the body• Weight gain• Lack of energy• Chills• Excessive sweating of palms, soles of feet or underarms not related to heat or exercise. Tummy problems such as: <ul style="list-style-type: none">• Constipation• Feeling sick• Diarrhea• Burning sensation in the chest rising up to the throat | Speak to your doctor if you have any of these less serious side effects and they worry you. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider. |

Serious side effects

| Serious side effects | What to do |
|--|---|
| Skin problems: <ul style="list-style-type: none">• Swelling on hands, ankles, feet, lips, face.• Pinkish itchy swellings on the skin, itchy rash | Call your doctor straight away or go straight to the Emergency |

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> Fluid filled boils on skin, blisters. <p>Tummy problems:</p> <ul style="list-style-type: none"> Yellowing of the skin and eyes, dark coloured urine, feeling sick, vomiting, loss of appetite, fever (Hepatitis disease). Severe upper stomach pain or pain in middle or right side of your stomach with vomiting and feeling sick (Cholecystitis disease) Pain in tummy, indigestion and pain after eating, fast and shallow breathing, fever, vomiting (Pancreatitis disease) General issues: Low level of blood sugar in your blood having symptoms such as weakness, paleness, tiredness, blurred vision, having fast heartbeat. Joint pain and swelling of joints. | <p>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.

What Galvus contains

| | |
|---|--|
| Active ingredient (main ingredient) | vildagliptin |
| Other ingredients (inactive ingredients) | lactose anhydrous, magnesium stearate cellulose – microcrystalline sodium starch glycollate |
| Potential allergens | lactose |

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

What Galvus looks like

Galvus tablets are white to light yellowish in colour, round flat-faced with bevelled edges, unscored tablet. One side is debossed with "NVR" and the other side with "FB"

(50 mg tablet - AUST R 159561).

GALVUS is available in blisters packs containing 14, 60 or 112 tablets.

Who distributes Galvus

Galvus is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Web site: www.novartis.com.au

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