

Vildagliptin (Galvus) for type 2 diabetes

This *Medicine Update* is for people who are taking, or thinking about taking, vildagliptin.

Summary

Vildagliptin (brand name Galvus) is a new medicine. It is a tablet that can be used by people with type 2 diabetes whose blood glucose cannot be controlled effectively with certain other medicines.

If you are prescribed vildagliptin, you will take it in addition to your existing diabetes medicine. Vildagliptin, taken with your other medicine, can help better control blood glucose. Controlling blood glucose is important if you are to avoid the long-term complications of diabetes.

Vildagliptin has been through the required clinical trials and is effective in helping to lower blood glucose. But because it is a new medicine, it is not yet known if it reduces the long-term complications of diabetes.

www.nps.org.au/medicineupdate

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Asking the right questions about new medicines

What is Medicine Update?

Medicine Update provides independent information about new medicines and new listings on the PBS. It tells you about the possible benefits and harms of new medicines, who can and can't use them, and some of the other treatment options available.

How to use Medicine Update

Medicine Update is a tool to help you understand your treatment choices and to discuss them with your doctor. *Medicine Update* doesn't describe all possible side effects, precautions, or interactions with other medicines – so you should always read the consumer medicine information (CMI) leaflet (see back page).

Who is it for?

Medicine Update is for anyone who is starting this medicine or thinking of starting it, and their carers.

Where does Medicine Update come from?

Medicine Update is written by NPS in consultation with consumers and health professionals. NPS is an independent, non-profit, government-funded organisation.

NPS takes reasonable care to ensure this information is accurate and up-to-date at the time of creation. It is for your information only and is not medical advice. NPS does not warrant its completeness and excludes liability where permitted by law. We recommend you seek advice from a health professional about your medical condition.

1. What vildagliptin is

The active ingredient of this medicine is **vildagliptin** (pronounced VIL-da-GLIP-tin). It is also known by the brand name **Galvus**.

Vildagliptin is a medicine for type 2 diabetes.

The active ingredient is the chemical in the medicine that makes the medicine work.

Many medicines are known by their brand names as well as by the name of the active ingredient. Some medicines are available under several different brand names.

2. What vildagliptin is for

Vildagliptin treats type 2 diabetes.

People with type 2 diabetes have too much glucose (sugar) in their blood because their body does not produce enough insulin, or their insulin has become less effective (called insulin resistance).

Having high blood glucose levels increases your risk of developing the long-term complications of diabetes.

These complications are serious. People with diabetes may develop heart disease, kidney disease, eye disease, pain or loss of feeling and poor circulation in the feet, and problems with sexual function.

Vildagliptin treats type 2 diabetes by controlling blood glucose levels.

3. Who can take vildagliptin

Vildagliptin is available on the Pharmaceutical Benefits Scheme (PBS) for people with type 2 diabetes, but there are some restrictions on its use. In general terms, you can get vildagliptin through the PBS if:

- you are already taking metformin (e.g. Diabex, Diaformin) or a sulfonylurea (e.g. Amaryl, Daonil, Diamicron, Minidiab), and
- your HbA_{1c} (a measurement that reflects your average blood glucose levels over the last 10-12 weeks) is over 7%, and
- you cannot use a combination of metformin and a sulfonylurea, or the combination causes you intolerable side effects.

Please note — vildagliptin is not taken on its own. You will need to continue taking your metformin or sulfonylurea when you start vildagliptin.

Speak to your doctor if you have liver or kidney problems. Vildagliptin is not suitable for people with liver problems. Your doctor will have to take into account any kidney problems you have before prescribing vildagliptin.

Talk with your doctor about all the treatment options for type 2 diabetes.

4. How to take vildagliptin

Your doctor will tell you to take either one or two tablets each day. If you take one tablet, you should take it in the morning. If you take two tablets, take one tablet in the morning and the other tablet in the evening.

You can take vildagliptin tablets with or without food. Swallow the tablets whole with a glass of water.

It's important that you take the right number of vildagliptin tablets each day. Ask your doctor if you are not sure whether you should be taking one or two tablets.

5. What does vildagliptin do?

Vildagliptin reduces glucose levels in the blood. It does this by:

- increasing the amount of insulin in the blood
- reducing the amount of glucose produced by the liver.

It is not yet known if vildagliptin reduces the long-term complications of diabetes (see section 9).

6. Important side effects to consider

The most common side effects of vildagliptin are headache and cold-like symptoms.

Some rare but serious side effects can occur with vildagliptin, such as:

- allergic reactions
- pancreatitis (inflammation of the pancreas that can result in severe, long-lasting abdominal pain).

Allergic reactions are rare, but you should seek medical attention if you have any swelling of the face, mouth, tongue or throat.

Pancreatitis has developed in a few people after starting vildagliptin. But it's not known for sure if vildagliptin caused the pancreatitis.

Vildagliptin has been tested in clinical trials, but it is a new medicine, so the full range of side effects is not yet known. You should be aware of this and talk to your doctor if you have any concerns.

For a list of possible side effects, see the consumer medicine information leaflet for vildagliptin.

Ask your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

You can also discuss side effects with a pharmacist, by calling the Adverse Medicine Events (AME) Line on 1300 134 237 (Mon-Fri, 9am-5pm).

A clinical trial is a research study conducted with patients, which compares one treatment with one or more other treatments, or with no other treatment, to assess its effectiveness and safety.

7. What else you should know about vildagliptin

Some other medicines can interact with vildagliptin.

You should tell your doctor about all the medicines you take, including any you get from a pharmacy, supermarket or health food store.

Vildagliptin tablets contain lactose — you should talk to your doctor if you are lactose intolerant.

8. Other medicines available for type 2 diabetes

The medicines you take for your diabetes may change over time. For example, you might only need a single tablet — like metformin or a sulfonylurea — to control your blood glucose initially. But diabetes tends to get worse as you get older, and at some point your doctor may recommend that you take more than one type of tablet, or that you take insulin, or a combination of tablets and insulin. Each medicine will work in a different way to control your blood glucose level.

The other types of medicines you might take are:

- metformin
- sulfonylureas
- glitazones
- exenatide
- insulin
- acarbose and repaglinide.

Sitagliptin (Januvia) is another medicine you may be asked to consider. It belongs to the same group of medicines as vildagliptin. You can read more about sitagliptin at www.nps.org.au/consumers/publications/medicine_update/issues/sitagliptin

Metformin

Metformin (e.g. Diabex, Diaformin) is the first tablet most people take for type 2 diabetes. It makes your own insulin more effective and reduces the amount of glucose produced by your liver.

Metformin may cause nausea, loss of appetite and diarrhoea.

Sulfonylureas

Sulfonylureas are often added to metformin. They may also be used as the first tablet by people who cannot take metformin. Sulfonylureas increase your body's production of insulin.

The sulfonylureas include glibenclamide (e.g. Daonil), gliclazide (e.g. Diamicon), glimepiride (e.g. Amaryl, Dimirel) and glipizide (e.g. Minidiab).

Many people taking sulfonylureas gain weight and may have hypoglycaemic episodes (when blood glucose drops below normal levels). Allergic reactions may occur.

Most people start taking medicines when lifestyle changes, diet and exercise are not sufficient to manage their diabetes.

Your medicine options will depend on your blood glucose control, your response (including side effects), your age and health, and other medicines that you are taking.

8. Other medicines available for type 2 diabetes ... *continued*

Glitazones

Pioglitazone (Actos) and rosiglitazone (Avandia) are relatively new medicines for type 2 diabetes. Like vildagliptin, pioglitazone and rosiglitazone can be taken with metformin or a sulfonylurea. Glitazones make your own insulin more effective.

Glitazones can cause fluid retention and weight gain, and increase the risk of some bone fractures in women.

Glitazones are not suitable for people with heart failure. Rosiglitazone should not be used by people with heart disease.

Exenatide

Exenatide (Byetta) is a new injectable medicine, but it is not insulin. It is used in addition to tablets to help reduce blood glucose levels.

Some people feel nauseous when they start using exenatide. People using exenatide can have hypoglycaemic episodes, particularly if they are taking a sulfonylurea at the same time.

Insulin

If you can no longer make enough of your own insulin, tablets such as metformin and sulfonylureas will not work properly. At this point your doctor might suggest that you start using insulin to control your blood glucose level.

Insulin can be used on its own or with some other medicines for type 2 diabetes. Vildagliptin is not usually used with insulin.

Insulin is injected – usually once, twice or three times a day. While many people worry about injecting insulin, most find the injections are not painful.

The main side effects of insulin are weight gain and hypoglycaemia. Allergic reactions are possible and some people get skin reactions at the site of injections.

For more information on starting insulin, see the leaflet at www.nps.org.au/diabetes/starting_insulin.

Acarbose and repaglinide

Acarbose (Glucobay) and repaglinide (Novonorm) are used by a small number of people for whom other medicines are unsuitable.

9. How to decide between vildagliptin and other medicines

There are two main reasons to treat your diabetes:

- to keep your blood glucose levels down
- to reduce your risk of developing the complications of diabetes.

Like all medicines used for type 2 diabetes, vildagliptin reduces the level of glucose in the blood.

But it is not known if it can reduce your risk of developing the complications of diabetes. This will only become clear when vildagliptin has been used by more people for longer periods of time.

Insulin, metformin and sulfonylureas have been shown to reduce the complications of diabetes. This is a very important benefit of these medicines.

Weight gain and hypoglycaemia

Most medicines for type 2 diabetes — except metformin — can sometimes cause hypoglycaemia. Hypoglycaemia is more likely with insulin than with tablets, and is more likely with sulfonylureas than with other tablets.

Vildagliptin does not appear to increase the risk of hypoglycaemia when taken with metformin. Nor does it cause weight gain. However, hypoglycaemia and weight gain may still occur if vildagliptin is used with a sulfonylurea.

A medicine that suits one person may not suit another. You may wish to avoid certain side effects or, if the medicine is working well, you may be willing to put up with the possible side effects.

10. What does vildagliptin cost?

Cost to the Government

The full cost of vildagliptin is as follows:

- \$97.24 for 50 mg vildagliptin tablets (pack size 60 tablets)

Each prescription lasts 30 days or 60 days, and you can get up to 5 repeats.

Cost to the individual

If you get vildagliptin through the Pharmaceutical Benefits Scheme (PBS), the Australian Government pays most of the cost and you will pay only a part, called the co-payment.

At the time of publication, the co-payment for people who are entitled to get vildagliptin through the PBS was:

- \$33.30 for people without a concession card
- \$5.40 for concession card holders.

If you are not eligible to get vildagliptin through the PBS, you will need to pay the full price for a prescription.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian Government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

For more information see www.pbs.gov.au.

11. Other ways to help type 2 diabetes



A healthy, balanced diet is important for all people with diabetes. A dietitian, diabetes educator or doctor can help you with this.

Physical activity

Regular physical activity is important for managing diabetes. Many people find that their diabetes is easier to manage with regular physical activity (e.g. 30 minutes of physical activity on five or more days per week). Resistance training (e.g. using light weights) is recommended, as is aerobic exercise (e.g. walking or cycling). A diabetes educator, exercise physiologist or doctor can help you with this.

Diet

If you have just been diagnosed with type 2 diabetes, your doctor will usually recommend that you eat a healthy, balanced diet and exercise regularly for three months to see if this controls your diabetes without the need for medication (unless the symptoms of diabetes are severe).

Even when using medicines, you should continue to follow a healthy, balanced diet and carry out regular exercise. This can help you to maintain a healthy weight. It may also improve your blood glucose control, reduce your need for medicines and help to prevent some of the long-term complications of diabetes.

Testing your glucose

Testing your own blood glucose levels regularly can help you to manage your diabetes. Speak to your diabetes educator or doctor.

Smoking

If you smoke, you should make every effort to quit. The combination of smoking and diabetes greatly increases the risk of heart disease and other complications of diabetes. Quitting smoking will also have a positive impact on your health and substantially reduce your risk of other illnesses. For more information, contact the Quitline on 13 QUIT (13 7848) or get an online quitting coach from www.quitcoach.org.au.

Alcohol

If you drink alcohol, then a low-to-moderate intake is best. You should discuss this with your health professional. Alcohol can interact with some diabetes medicines, and make hypoglycaemia more likely.

Blood pressure

If you have diabetes and high blood pressure, it's important that you work with your doctor to keep your blood pressure under control. Studies have shown that good blood pressure control can prevent some of the long-term complications of diabetes.

**For more information, contact
Diabetes Australia on 1300 136 588
or at www.diabetesaustralia.com.au**

Where to find out more information

Read the consumer medicine information (CMI) leaflet

The CMI for Galvus will tell you:

- who should not use the medicine
- which medicines should not be used at the same time (medicine interactions)
- how to take the medicine
- most of the possible side effects
- the ingredients.

You can get the CMI leaflet for Galvus from:

- your doctor or pharmacist
- CMI search on the NPS website
- Novartis, the makers of Galvus (vildagliptin), on 1800 671 203.

Information over the phone

NPS works with *healthdirect Australia* to provide consumers with information on medicines.

To get information about vildagliptin call **1300 MEDICINE** (1300 633 424) from anywhere in Australia for the cost of a local call (excluding mobiles). Service is available Monday to Friday 9am–5pm EST except NSW public holidays.

To report a side effect with vildagliptin

Call the **Adverse Medicine Events (AME) Line** on 1300 134 237 (Monday to Friday, 9am–5pm EST).

The AME Line lets you report and discuss side effects that might be related to your medicine. The side effects of your medicine — but not your personal details — are reported to the Australian medicines regulatory agency (the Therapeutic Goods Administration or TGA for short). The information helps to improve the safe use of medicines.

For more information about the AME Line visit www.nps.org.au/ame_line.

More about taking medicines

For more information on how new medicines are tested and approved in Australia see the NPS factsheet *New medicines: are they always better?* at www.nps.org.au/consumers/publications/factsheets

More information on understanding side effects is available from www.asmi.com.au

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ABN 61 082 034 393 | Level 7/418A Elizabeth Street Surry Hills NSW 2010 | PO Box 1147 Strawberry Hills NSW 2012
Phone: 02 8217 8700 | Fax: 02 9211 7578 | email: info@nps.org.au | web: www.nps.org.au