

medicineupdate

Asking the right questions about new medicines

Sitagliptin (Januvia) for type 2 diabetes

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get to know your medicines

to find out more about this medicine

- call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon–Fri 9am–6pm EST — cost of a local call, mobile calls more)
- read the Consumer Medicine Information (CMI) leaflet for this medicine (available from your doctor or pharmacist, from the consumer section at www.nps.org.au, or from the manufacturer).



National Prescribing Service Limited

NPS is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.

Summary

Sitagliptin is a new tablet that reduces the amount of glucose in the blood in people with type 2 diabetes. It is used in addition to other oral medicines, not on its own. It has been through the required tests and clinical trials but, like all new medicines, the long-term benefits and side effects of sitagliptin are not fully known.

When you are considering a new medicine, it is important to weigh up the expected benefits and the possible risks of the new medicine, compared with other available medicines or treatments.

Remember that risks and benefits differ between medicines and from person to person.

Your doctor can help you compare different medicines and treatments to decide what is best for your particular situation.

1. What this medicine is

The active ingredient is **sitagliptin**, which is pronounced SIT-a-GLIP-tin.

The brand name is **Januvia**, which is pronounced Ja-NOO-vee-a.

It is a tablet which is used once a day.

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

2. What this medicine treats

Sitagliptin treats type 2 diabetes. In this condition, insulin becomes less effective than it should be, so people have too much glucose in their blood.

The long-term complications of diabetes are serious, particularly when blood glucose is poorly controlled. People with diabetes may develop heart disease, kidney disease, eye disease, pain and loss of feeling in the arms and legs, and problems with the circulation and with sexual function.

3. How this medicine works

Sitagliptin is thought to work by changing the levels of hormones in the intestines, which increases the amount of insulin in the blood. In this way, it helps the body's naturally occurring insulin to control glucose.

It is not yet known whether or not it reduces the long-term complications of diabetes (see section 6).

4. Who can use this medicine

Sitagliptin can be used by people with type 2 diabetes who are already taking a certain medicine (metformin or a sulfonylurea), but this medicine is not controlling blood glucose well enough on its own. See section 11 for more details.

Do not use sitagliptin if you do not have type 2 diabetes.
Do not use sitagliptin if you use insulin.

5. Other medicines available for this condition

There are a number of other medicines used to treat type 2 diabetes. They all work in different ways to increase the amount of insulin in the body or improve the way the body uses insulin. They are used alone and also in various combinations for different people. Sitagliptin can be combined with one other oral medicine when other combinations can't be used or cause side effects. Individual medicines and combinations of medicines often become less effective over time.

The different types of medicines available can be grouped as:

- metformin
- sulfonylureas
- glitazones
- insulin
- others.

Metformin

Metformin (e.g. Diabex, Diaformin) has been used for many decades. Metformin works by increasing the sensitivity of the cells to the body's naturally occurring insulin. That is, it makes the body's own insulin more effective.

Metformin is the main medicine used for type 2 diabetes and is the first medicine that people take unless it is not recommended for them.

Sulfonylureas

Sulfonylureas have been used for many decades. They increase the production of the body's naturally occurring insulin.

A number of sulfonylureas are available. They include glibenclamide (e.g. Daonil), gliclazide (e.g. Diamicon), glimepiride (e.g. Amaryl) and glipizide (e.g. Minidiab).

Sulfonylureas will often be the first medicine that people use if they cannot use metformin.

Glitazones

These medicines are newer and have been available in Australia for only 4–5 years. They are thought to work by increasing the sensitivity of the cells to the body's naturally occurring insulin. That is, they make the body's own insulin more effective.

The glitazones include pioglitazone (Actos) and rosiglitazone (Avandia). They are generally used by people in combination with metformin, a sulfonylurea, or both. Pioglitazone may also be used with insulin.

Glitazones are an alternative to sitagliptin for people when they can't take other combinations of oral medicines.

Sitagliptin may be combined with a glitazone, but this is not covered by the Pharmaceutical Benefits Scheme (PBS).

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It is reasonably common for people with type 2 diabetes to start taking metformin, then to add a sulfonylurea after a period of time. Some people cannot use these medicines together, because one is not suitable for them or causes side effects. If that happens, there is a choice of whether to go on to insulin or to add another oral medicine. Sitagliptin may be considered at this stage.

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

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5. Other medicines available for this condition

Insulin

Insulin has been used for many decades. It increases the ability of cells to take up glucose from the blood. Insulin is injected usually once or twice a day. People tend to use insulin when oral medicines such as metformin and sulfonylureas no longer control blood glucose. So insulin is an alternative to sitagliptin. Insulin can be used on its own or with some oral medicines.

Others

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

A new medicine, which is not currently available through the PBS, is exenatide (Byetta). It is injected twice a day before meals. Its side effects include nausea, vomiting and diarrhoea.

6. How well it works compared with other medicines

There are two main reasons to treat your diabetes:

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

Sitagliptin has been shown to reduce the level of HbA_{1c}, which is a protein found in the blood. The level of HbA_{1c} reflects how much glucose has been in the blood for the previous month or so. The HbA_{1c} level changes slowly over a period of weeks, rather than rapidly like blood glucose levels.

Because sitagliptin reduces the level of HbA_{1c}, like all medicines used for type 2 diabetes, it reduces the amount of glucose in the blood.

No clinical trials have assessed the effect of sitagliptin on diabetes complications in the long term (i.e. after 2 years). Therefore, it is not known whether or not sitagliptin will reduce the complications of diabetes, and the number of people dying from diabetes and its complications.

Insulin and metformin have been shown to reduce the complications of diabetes. Metformin has been shown to reduce the number of people dying from diabetes and its complications. Glibenclamide (a sulfonylurea) has also been shown to reduce some of the complications of diabetes. Other medicines used to treat diabetes have so far not shown these very important long-term benefits.

Sitagliptin works to reduce blood glucose levels, as do all medicines for diabetes.

It is not known whether or not sitagliptin reduces the complications of diabetes.

7. Important side effects to consider

In clinical trials, some people complained of a cold, a sore throat, a sore nose and a headache. Some people had no side effects.

Serious allergic reactions have occurred in a small number of people taking sitagliptin.

Sitagliptin is a new medicine and is different from other medicines for diabetes. The full range of side effects with sitagliptin is not known. It takes time for doctors and pharmacists to have seen enough people using the medicine to establish what are the important side effects and what are not, and how commonly or not they occur.

If you choose to use sitagliptin, you should tell your doctor about any new symptoms or changes that you notice.

For a list of possible side effects, see the Consumer Medicine Information leaflet for Januvia.

Talk to 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.

More information on understanding side effects is available from the Australian Self-Medication Industry at www.asmi.com.au/QUM.htm#sideeffects.

8. How these side effects compare with other medicines

Most medicines for type 2 diabetes, except metformin, have an increased risk of hypoglycaemia, or low blood sugar levels. This risk is higher for people taking insulin than for those taking tablets. Among people taking tablets, the risk is higher with sulfonylureas.

It appears from the clinical trials that sitagliptin, when used alone or with metformin, does not increase the risk of hypoglycaemia. Nor does it cause weight gain. Hypoglycaemia and weight gain may still occur if sitagliptin is used with a sulfonylurea.

In general, it is hard to know how the side effects of sitagliptin compare with other medicines for diabetes. Sitagliptin is a new medicine and few clinical trials have made direct comparisons between it and other medicines.

Here are the main side effects of other medicines used to treat diabetes.

Metformin

Metformin may cause nausea, loss of appetite and diarrhoea. It may also cause problems with absorption of vitamin B12, which is needed to make blood.

Sulfonylureas

Many people taking sulfonylureas gain weight and may have episodes of hypoglycaemia. Allergic reactions may occur.

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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.

For more information see section 13 — How new medicines are tested and approved for use in Australia.

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8. How these side effects compare with other medicines

Glitazones

Many people taking glitazones retain fluid and gain weight. Do not use glitazones if you have heart failure.

People using rosiglitazone may have an increased risk of having a heart attack. Do not use rosiglitazone if you have heart disease.

Glitazones increase the risk of fractured bones in women. You should discuss with your doctor whether or not you should use glitazones if you have osteoporosis.

Less serious, but more common, side effects of glitazones include dizziness, joint pains and headaches.

Insulin

Many people taking insulin gain weight and have episodes of hypoglycaemia. Allergic reactions are possible and some people get skin reactions at the site of injections.

Others

Acarbose may cause excessive wind, diarrhoea and abdominal pain.

Repaglinide may cause abdominal pain, nausea, vomiting and diarrhoea.

9. How to reduce your risk of side effects

Follow a healthy eating plan and exercise regularly — that may reduce the need for medication.

If you have kidney disease, you should discuss this with your doctor as you may need to take a lower dose.

10. What else you should know about this medicine

Consumer Medicine Information leaflets are available for most prescription medicines. They will tell you:

- who should and who should not use the medicine
- which medicines should not be used while taking sitagliptin
- how to use the medicine
- the most likely side effects
- the ingredients.

You can get the Consumer Medicine Information leaflet for Januvia from:

- your doctor or pharmacist
- www.nps.org.au/consumers
- Merck, Sharp & Dohme, the makers of Januvia, on 1800 645 712 or www.msd-australia.com.au.

11.

Who can be prescribed this medicine on the Pharmaceutical Benefits Scheme (PBS)

People can be prescribed sitagliptin through the PBS if:

- they have type 2 diabetes
- their HbA_{1c} is greater than 7% (see section 6 for more information)
- they are already taking metformin or a sulfonylurea
- the combination of metformin and a sulfonylurea cannot be used or causes intolerable side effects.

People *cannot* be prescribed sitagliptin through the PBS if it is to be used:

- in combination with two other medicines for type 2 diabetes
- in combination with a glitazone, or
- as the only medicine to treat diabetes.

If they are already taking two medicines for type 2 diabetes, they can be prescribed sitagliptin through the PBS only if one of the other medicines is stopped.

At the time of publication, the cost of a normal prescription through the PBS was:

- \$31.30 for people without a concession card
- \$5.00 for concession card holders.

The full cost of each sitagliptin prescription is \$90.76. But if you are prescribed sitagliptin through the PBS, you pay only the cost of a normal prescription, and the Australian Government pays the rest.

Each prescription lasts 28 days, and you can get up to 5 repeats.

Most medicines prescribed by your doctor are covered by the Pharmaceutical Benefits Scheme. 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 Pharmaceutical Benefits Scheme, or is not available on the Pharmaceutical Benefits Scheme for your specific condition.

12.

Other ways to help this condition

A healthy eating plan is important for all people with diabetes. A dietitian, diabetes educator or doctor can help with this.

Regular exercise is also important for managing diabetes. Many people find that their diabetes is easier to manage with regular exercise. A diabetes educator or doctor can help with this.

People with newly diagnosed type 2 diabetes should follow a healthy eating plan and carry out regular exercise for 3 months, to see if this controls their diabetes without the need for medication (unless the symptoms of diabetes are severe).

Even when using medicines, people with type 2 diabetes should continue to follow a healthy eating plan and carry out regular exercise. It will help keep diabetes under control, may reduce the need for medicines and can help prevent some of the long-term complications of diabetes.

People with diabetes who smoke should make every effort to quit. Quitting smoking will substantially reduce the risk of heart disease and other illnesses in these people. For more information, contact the Quitline on 13 7848 (13 QUIT) or get an online quitting coach from www.quitcoach.org.au.

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

13.

How new medicines are tested and approved for use in Australia

Prescription medicines go through many tests and clinical trials before they can be prescribed in Australia. All medicines go through four types of tests to assess their effectiveness, side effects and safety:

- **laboratory tests** (not involving people)
- **phase 1** clinical trials, typically with 20–80 healthy volunteers, to test the safety and dosage in people with normal physical health
- **phase 2** clinical trials, typically with 100–500 volunteers with the condition, to test the effectiveness and safety
- **phase 3** clinical trials, typically with 1000–3000 volunteers with the condition, to confirm the medicine's effectiveness and find out more about its side effects.

Sometimes, less common side effects do not become obvious until large numbers of people have used the medicine.

The Therapeutic Goods Administration (Australia's regulatory agency for medicines) checks clinical trial results before it approves the registration of the medicine for use in Australia.

Medicines are made available on the Pharmaceutical Benefits Scheme if they are shown to be as good as or better than other available medicines for the same condition.

Why *Medicine Update*?

Medicine Update lets you know about new medicines and new PBS listings. When medicines are new, less is known about their expected benefits and possible harms than for older medicines. It's important to understand what evidence is available about both benefits and harms. *Medicine Update* provides balanced information to help you decide if a medicine is right for you.

Who wrote *Medicine Update*?

National Prescribing Service Limited (NPS), an independent, non-profit, government-funded organisation, wrote this information in consultation with consumers and health professionals.

Who is it for?

Medicine Update is written for people who are thinking about a new medicine, or have had a medicine suggested or prescribed for them and want to find out more.

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Visit the NPS website to find out about our free activities and resources for consumers www.nps.org.au/consumers



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