PACKAGE LEAFLET

Package leaflet: Information for the patient

Vildakombi 50 mg/850 mg film-coated tablets
Vildakombi 50 mg/1000 mg film-coated tablets
vildagliptin/metformin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vildakombi is and what it is used for

The active substances of Vildakombi, vildagliptin and metformin, belong to a group of medicines called “oral antidiabetics”.

Vildakombi is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as non-insulin-dependent diabetes mellitus. Vildakombi is used when diabetes cannot be controlled by diet and exercise alone and/or with other medicines used to treat diabetes (insulin or sulphonylureas).

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How Vildakombi works
Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

2. What you need to know before you take Vildakombi

Do not take Vildakombi
- if you are allergic to vildagliptin, metformin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to any of these, talk to your doctor before taking Vildakombi.
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic

acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called ketone bodies accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing which could be a sign of heart problems.
- if you have severely reduced kidney function.
- if you have a severe infection or are seriously dehydrated (have lost a lot of water from your body).
- if you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye). Please also see information about this in section "Warnings and precautions".
- if you have liver problems.
- if you drink alcohol excessively (whether every day or only from time to time).
- if you are breast-feeding (see also "Pregnancy and breast-feeding").

Warnings and precautions

<u>Risk of lactic acidosis</u>
Vildakombi may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).
If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Vildakombi for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Vildakombi and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.
Symptoms of lactic acidosis include:
- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat.

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:
- You 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).
- You 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.

Vildakombi is not a substitute for insulin. Therefore, you should not receive Vildakombi for the treatment of type 1 diabetes.

Talk to your doctor, pharmacist or nurse before taking Vildakombi if you have or have had a disease of the pancreas.

Talk to your doctor, pharmacist or nurse before taking Vildakombi if you are taking an anti-diabetic medicine known as a sulphonylurea. Your doctor may want to reduce your dose of the sulphonylurea when you take it together with Vildakombi in order to avoid low blood glucose (hypoglycaemia).

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Vildakombi. Should these occur, you should promptly consult your doctor.

If you need to have major surgery you must stop taking Vildakombi during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Vildakombi.

A test to determine your liver function will be performed before the start of Vildakombi treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

During treatment with Vildakombi, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or have worsening renal function.

Your doctor will test your blood and urine for sugar regularly.

Children and adolescents
The use of Vildakombi in children and adolescents up to 18 years of age is not recommended.

Other medicines and Vildakombi
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Vildakombi before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Vildakombi.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Vildakombi. It is especially important to mention the following:
- glucocorticoids generally used to treat inflammation
- beta-2 agonists generally used to treat respiratory disorders
- other medicines used to treat diabetes
- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- certain medicines affecting the thyroid
- certain medicines affecting the nervous system
- certain medicines used to treat angina (e.g. ranolazine)
- certain medicines used to treat HIV infection (e.g. dolutegravir)
- certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
- certain medicines used to treat heartburn and peptic ulcers (e.g cimetidine).

Vildakombi with alcohol
Avoid excessive alcohol intake while taking Vildakombi since this may increase the risk of lactic acidosis (please see section “Warnings and precautions”).

Pregnancy and breast-feeding
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risk of taking Vildakombi during pregnancy.
- Do not use Vildakombi if you are pregnant or breast-feeding (see also "Do not take Vildakombi").

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you feel dizzy while taking Vildakombi, do not drive or use any tools or machines.

Vildakombi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Vildakombi

The amount of Vildakombi that people have to take varies depending on their condition. Your doctor will tell you exactly the dose of Vildakombi to take.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one film-coated tablet of either 50 mg/850 mg or 50 mg/1000 mg taken twice a day.

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Your doctor may prescribe this medicine alone or with certain other medicines that lower the level of sugar in your blood.

When and how to take Vildakombi
- Swallow the tablets whole with a glass of water.
- Take one tablet in the morning and the other in the evening with or just after food. Taking the tablet just after food will lower the risk of an upset stomach.

Continue to follow any advice about diet that your doctor has given you. In particular, if you are following a diabetic weight control diet, continue with this while you are taking Vildakombi.

If you take more Vildakombi than you should
If you take too many Vildakombi tablets, or if someone else takes your tablets, **talk to a doctor or pharmacist immediately**. Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Vildakombi
If you forget to take a tablet, take it with your next meal unless you are due to take one then anyway. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Vildakombi
Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking Vildakombi unless your doctor tells you to. If you have any questions about how long to take this medicine, talk to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should **stop taking Vildakombi and see your doctor immediately** if you experience the following side effects:

- **Lactic acidosis** (very rare: may affect up to 1 in 10 000 people): Vildakombi may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens you must **stop taking Vildakombi and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.
- Angioedema (rare: may affect up to 1 in 1 000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives, which may indicate a reaction called "angioedema".
- Liver disease (hepatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
- Inflammation of the pancreas (pancreatitis) (uncommon: may affect up to 1 in 100 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects
Some patients have experienced the following side effects while taking Vildakombi:

- Common (may affect up to 1 in 10 people): sore throat, runny nose, fever, itchy rash, excessive sweating, joint pain, dizziness, headache, trembling that cannot be controlled, constipation, nausea (feeling sick), vomiting, diarrhoea, flatulence, heartburn, pain in and around the stomach (abdominal pain).
- Uncommon (may affect up to 1 in 100 people): tiredness, weakness, metallic taste, low blood glucose, loss of appetite, swollen hands, ankles or feet (oedema), chills, inflammation of the pancreas, muscle pain.
- Very rare (may affect up to 1 in 10 000 people): signs of a high level of lactic acid in the blood (known as lactic acidosis) such as drowsiness or dizziness, severe nausea or vomiting, abdominal pain, irregular heart beat or deep, rapid breathing; redness of the skin, itching; decreased vitamin B12 levels (paleness, tiredness, mental symptoms such as confusion or memory disturbances).

Since this product has been marketed, the following side effects have also been reported:

- Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vildakombi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister after EXP. The

expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vildakombi contains
- The active substances are vildagliptin and metformin hydrochloride.
  Vildakombi 50 mg/850 mg film-coated tablets: Each film-coated tablet contains 50 mg vildagliptin and 850 mg metformin hydrochloride.
  Vildakombi 50 mg/1000 mg film-coated tablets: Each film-coated tablet contains 50 mg vildagliptin and 1000 mg metformin hydrochloride.
- The other ingredients (excipients) are hydroxypropylcellulose (E463), mannitol (E421), sodium stearyl fumarate (E470a) and magnesium stearate (E470b) in the tablet core and hypromellose (E464), titanium dioxide (E171), talc (E553b), propylene glycol (E1520) and yellow iron oxide (E172) in film coating. See section 2 "Vildakombi contains sodium".

What Vildakombi looks like and contents of the pack
Vildakombi 50 mg/850 mg: brownish yellow, oval, biconvex, film-coated tablets (tablets) with mark V1 on one side of the tablet. Tablet dimensions: approximately 20 mm x 11 mm.
Vildakombi 50 mg/1000 mg: brown-yellow, oval, biconvex, film-coated tablets (tablets) with mark V2 on one side of the tablet. Tablet dimensions: approximately 21 mm x 11 mm.

Vildakombi is available in packs containing 10, 30, 60, 120 and 180 film-coated tablets and in multi-packs containing 120 (2 x 60) and 180 (3 x 60) film-coated tablets in blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the European Economic Area under the following names:
[To be completed nationally]

This leaflet was last revised in 2025-03-26.

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}