

PACKAGE LEAFLET

Package leaflet: Information for the patient

Janeo 50 mg, filmomhulde tabletten
Janeo 100 mg, filmomhulde tabletten
Sitagliptin

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 Janeo is and what it is used for
2. What you need to know before you take Janeo
3. How to take Janeo
4. Possible side effects
5. How to store Janeo
6. Contents of the pack and other information

1. What Janeo is and what it is used for

Janeo contains the active substance sitagliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take Janeo

Do not take Janeo

- if you are allergic to sitagliptin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Janeo (see section 4).

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Janeo.

Tell your doctor if you have or have had:

- a disease of the pancreas (such as pancreatitis)
- gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis (see section 4).
- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- any past or present kidney problems
- an allergic reaction to sitagliptin (see section 4)

This medicine is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

Children and adolescents

Children and adolescents below 18 years should not use this medicine. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Other medicines and Janeo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking digoxin (a medicine used to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if taking with Janeo.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take this medicine during pregnancy.

It is not known if this medicine passes into breast milk. You should not take this medicine if you are breast-feeding or plan to breast-feed.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

Janeo 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 Janeo

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

The usual recommended dose is:

- one 100 mg film-coated tablet
- once a day
- by mouth

If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg).

The mentioned dose of 25 mg is not available for Janeo; however, products are available with a dosage of 25 mg.

You can take this medicine with or without food and drink.

Your doctor may prescribe this medicine alone or with certain other medicines that lower blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise recommended by your doctor while taking Janeo.

If you take more Janeo than you should

If you take more than the prescribed dosage of this medicine, contact your doctor immediately.

If you forget to take Janeo

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of this medicine.

If you stop taking Janeo

Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first.

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

4. Possible side effects

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

STOP taking Janeo and contact a doctor immediately if you notice any of the following serious side effects:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).

If you have a serious allergic reaction (frequency **not known**), including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced the following side effects after adding sitagliptin to metformin:

Common (may affect up to 1 in 10 people):

- low blood sugar,
- nausea,
- flatulence,
- vomiting.

Uncommon (may affect up to 1 in 100 people):

- stomach ache,
- diarrhea,
- constipation,
- drowsiness.

Some patients have experienced different types of stomach discomfort when starting the combination of sitagliptin and metformin together (frequency is **common**).

Some patients have experienced the following side effects while taking sitagliptin in combination with a sulphonylurea and metformin:

Very common (may affect more than 1 in 10 people):

- low blood sugar.

Common:

- constipation.

Some patients have experienced the following side effects while taking sitagliptin and pioglitazone:

Common:

- flatulence,
- swelling of the hands or legs.

Some patients have experienced the following side effects while taking sitagliptin in combination with pioglitazone and metformin:

Common:

- swelling of the hands or legs.

Some patients have experienced the following side effects while taking sitagliptin in combination with insulin (with or without metformin):

Common:

- flu.

Uncommon:

- dry mouth.

Some patients have experienced the following side effects while taking sitagliptin alone in clinical studies or during post-approval use alone and/or with other diabetes medicines:

Common:

- low blood sugar,
- headache,
- upper respiratory infection,
- stuffy or runny nose and sore throat,
- osteoarthritis,
- arm or leg pain.

Uncommon:

- dizziness,
- constipation,
- itching.

Rare:

- reduced number of platelets

Frequency not known:

- kidney problems (sometimes requiring dialysis),
- vomiting,
- joint pain,
- muscle pain,
- back pain,
- interstitial lung disease,
- bullous pemphigoid (a type of skin blister).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Nederlands Bijwerkingen Centrum Lareb Website: www.lareb.nl

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Janeo

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 blister or bottle label and the carton after 'EXP'. The expiry date refers to the last day of that month.

Shelf life after first opening of the HDPE container: 1 month.

This medicine does not require any special storage conditions.

Do not throw away 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 Janeo contains

The active substance is sitagliptin.

Each film-coated tablet contains 50 mg sitagliptin (as hydrochloride).

Each film-coated tablet contains 100 mg sitagliptin (as hydrochloride).

The other ingredients are:

- Tablet core: cellulose, microcrystalline (E460), calcium hydrogen phosphate anhydrous (E341), croscarmellose sodium (E468), magnesium stearate (E470b), sodium stearyl fumarate.
- Film-coating Opadry II Pink 85F540099 (100 mg) and Opadry II Pink 85F540265 (50 mg) contain: polyvinyl alcohol-part hydrolysed (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), red iron oxide (E172), yellow iron oxide (E172).

What Janeo looks like and contents of the pack

Janeo 50 mg film-coated tablets

Round, pink film-coated tablets approx. 7.9 mm in diameter and 3.6 mm thick, debossed with “S16” on one side and “H” on the other side.

Janeo 100 mg film-coated tablets

Round, pink film-coated tablets, approx. 9.9 mm in diameter and 4.7 mm thick, debossed with “S15” on one side and “H” on the other side.

PVC/PE/PVDC-Aluminum Blister. Packs of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets and 50 x 1 film-coated tablets in perforated unit dose blisters.

HDPE container with polypropylene cap. Pack of 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

DEMO S.A. Pharmaceutical Industry
21st Km National Road Athens–Lamia, Krioneri,
Attiki 145 68, Griekenland

Manufacturer

DEMO S.A. Pharmaceutical Industry
21st Km National Road Athens–Lamia, Krioneri,
Attiki 145 68, Griekenland

Pharmadox Healthcare Limited,
KW20A Kordin Industrial Park,
Paola, PLA 3000, Malta.

This medicine is authorised in the Member States of the European Economic Area

under the following names:

Nederland: Janeo 50 mg, filmomhulde tabletten

Janeo 100 mg, filmomhulde tabletten

Griekenland: JANE0 50mg Επικαλυμμένα με λεπτό υμένιο δισκία

JANE0 100mg Επικαλυμμένα με λεπτό υμένιο δισκία

Deze bijsluiter is voor het laatst goedgekeurd in december 2021.