

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

This medicine can be sold under doctor's prescription only

JANUET[®]
50 mg/500 mg
Tablets

Each tablet contains:
Sitagliptin (as monohydrate phosphate) 50 mg
Metformin Hydrochloride 500 mg

JANUET[®]
50 mg/850 mg
Tablets

Each tablet contains:
Sitagliptin (as monohydrate phosphate) 50 mg
Metformin Hydrochloride 850 mg

JANUET[®]
50 mg/1000 mg
Tablets

Each tablet contains:
Sitagliptin (as monohydrate phosphate) 50 mg
Metformin Hydrochloride 1000 mg

For a list of inactive ingredients please refer to section 6.

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **JANUET**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.
- This medicine is not intended for administration to children under 18 years of age.

1. WHAT JANUET IS AND WHAT IT IS USED FOR?

1.1 What is JANUET?

THERAPEUTIC GROUP: Sitagliptin: DPP-4 enzyme inhibitor. Metformin: biguanide.

1.2 What is JANUET used for?

JANUET is a tablet that contains 2 prescription medicines, sitagliptin phosphate (**JANUVIA[®]**) and metformin, which lower blood sugar. Sitagliptin, a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and metformin, a member of the biguanide class of medicines, work together to control blood sugar levels in patients with type 2 diabetes mellitus, in whom this combination is appropriate.

JANUET, along with a recommended diet and exercise program is intended to lower blood sugar in patients with type 2 diabetes.

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. High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

2. BEFORE YOU TAKE JANUET

2.1 Do not take JANUET if:

Do not use this medicine if you:

- have type 1 diabetes mellitus.
- have kidneys which are not working properly.
- have diabetic ketoacidosis (increased ketone levels in the blood or urine: diabetes complication which includes high blood sugar, rapid weight loss, nausea or vomiting).
- are going to get an injection of dye or contrast agents for an x-ray procedure, **JANUET** will need to be stopped for a short time. Talk to your doctor about when you should stop **JANUET** and when you should start again (see section 3 "How do you use **JANUET**?").
- are allergic to any of the ingredients in **JANUET** (see section 6 for a complete list of ingredients in **JANUET**). Symptoms of a serious allergic reaction may include: rash, raised red patches on your skin (hives), or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.

2.2 Special warnings concerning use of JANUET

Before you take JANUET, tell your doctor if you:

- have or have had inflammation of your pancreas (pancreatitis). If you have had pancreatitis in the past, it is not known if you have a higher chance of getting pancreatitis while you take **JANUET** (see section 4 "Possible side effects").
- have kidney problems.
- have liver problems.
- Have or have had stones in your gallbladder.
- have high blood triglyceride levels.
- have heart problems, including congestive heart failure.
- are older than 80 years. If you are over 80 years you should not take **JANUET** unless your kidneys have been checked and they are normal.
- drink alcohol very often, or drink a lot of alcohol in short-term "binge" drinking. If you are or were addicted to alcohol.
- have any other medical conditions.
- are pregnant or plan to become pregnant (see section 2.5 "Pregnancy and breast-feeding").
- are breast-feeding or plan to breast-feed (see section 2.5 "Pregnancy and breast-feeding").

Stop taking **JANUET** and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

2.3 Taking other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.

JANUET may affect how well other drugs work and some drugs can affect how well **JANUET** works.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

2.4 Taking JANUET with food and drink

Take **JANUET** with meals to lower your chance of having an upset stomach.

2.5 Pregnancy and breast-feeding

- If you are pregnant or plan to become pregnant: It is not known if **JANUET** will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- If you are breast-feeding or plan to breast-feed: It is not known if **JANUET** will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking **JANUET**.

3. HOW DO YOU USE JANUET?

Always take **JANUET** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many **JANUET** tablets to take and when you should take them. Your doctor may change your dose of **JANUET** if needed.

Take **JANUET** with meals to help to lower your chance of an upset stomach.

Your doctor may tell you to take **JANUET** along with certain other diabetes medicines. Low blood sugar (hypoglycemia) can happen more often when **JANUET** is taken with certain other diabetes medicines (see section 4 "Possible side effects").

This medicine is not intended for administration to children under 18 years of age.

Do not break or cut **JANUET** tablets before swallowing. If you cannot swallow **JANUET** tablets whole, tell your doctor.

Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with **JANUET**.

- If you take too much **JANUET**, call your doctor right away.
- If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
- 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 2 doses of **JANUET** at the same time.

You may need to stop taking **JANUET** for a short time. Call your doctor for instructions if you:

- are dehydrated (have lost too much body fluids). Dehydration can occur if you are sick with severe vomiting, diarrhea or fever, or if you drink a lot less fluids than normal.
- plan to have surgery.
- are going to get an injection of dye or contrast agent for an x-ray procedure. See section 2.1 “Do not take **JANUET** if you” and section 4 “Possible Side Effects”.

When your body is under some types of stress, such as fever, trauma (such as a car accident), infection or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these problems and follow your doctor’s instructions.

Check your blood sugar as your doctor tells you to.

Stay on your prescribed diet and exercise program while taking **JANUET**.

Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.

Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

Continue to take **JANUET** as long as your doctor tells you.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **JANUET** can cause side effects, in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

Serious side effects can happen in people taking JANUET or the individual medicines in JANUET, including:

1. Lactic Acidosis. Metformin, one of the medicines in **JANUET**, can cause a rare but serious condition called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.

Stop taking JANUET and call your doctor right away if you get any of the following symptoms, which could be signs of lactic acidosis:

- You feel very weak or tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have unusual sleepiness or sleep longer than usual.
- You have sudden stomach or intestinal problems with nausea and vomiting or diarrhea.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a slow or irregular heartbeat.

You have a higher chance of getting lactic acidosis if you:

- Have kidney problems. People whose kidneys are not working properly should not take **JANUET**.
- Have liver problems.
- Have congestive heart failure that requires treatment with medicines.
- Drink alcohol very often, or drink a lot of alcohol in short-term “binge” drinking.
- Get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.

- Have certain x-ray tests with dyes or contrast agents that are injected into your body.
- Have surgery.
- Have a heart attack, severe infection, or stroke.
- Are 80 years of age or older and have not had your kidneys tested.

2. Pancreatitis (inflammation of the pancreas) which may be severe and lead to death.

Certain medical problems make you more likely to get pancreatitis.

Stop taking **JANUET** and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

3. Low blood sugar (hypoglycemia). If you take **JANUET** with another medicine that can cause low blood sugar, such as sulfonylureas or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you use **JANUET**.

Signs and symptoms of low blood sugar may include: headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heart beat, sweating, feeling jittery.

4. Serious allergic reactions can happen with **JANUET** or sitagliptin, one of the medicines in **JANUET**. Symptoms of a serious allergic reaction to **JANUET** may include: rash, raised red patches on your skin (hives), and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking **JANUET** and call your doctor right away. Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

5. Kidney problems, sometimes requiring dialysis.

6. Joint pain. Some people who take medicines called DPP-4 inhibitors, one of the medicines in **JANUET**, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.

The most common side effects of **JANUET** include:

- Stuffy or runny nose and sore throat.
- Upper respiratory infection.
- Diarrhea.
- Nausea and vomiting.
- Gas, upset stomach, indigestion.
- Weakness.
- Headache.
- Low blood sugar (hypoglycemia) when used in combination with certain medications, such as a sulfonylurea or insulin.

Taking **JANUET** with meals can help lessen the common stomach side effects of metformin that usually happen at the beginning of treatment. If you have unusual or sudden stomach problems, talk with your doctor. Stomach problems that start later during treatment may be a sign of something more serious.

JANUET may have other side effects, including:

- **Swelling of the hands or legs.** Swelling of the hands and legs can happen if you take **JANUET** in combination with rosiglitazone (Avandia®). Rosiglitazone is another type of diabetes medicine.
- Elevated liver enzymes
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- itching

These are not all the possible side effects of **JANUET**. For more information, ask your doctor.

Tell your doctor if you have any side effect that bothers you, is unusual, or does not go away.

If a side effect appears, if any of the side effects gets serious or if you notice side effects not mentioned in this leaflet, consult your doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by using the online form for reporting side effects in the homepage of the ministry of health website www.health.gov.il or by entering the following link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW TO STORE JANUET?

Avoid Poisoning! This medicine, as all other medicine, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not use **JANUET** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.

Store **JANUET** below 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**6.1 What JANUET contains?**

Active ingredients: sitagliptin and metformin.

In addition to the active ingredients, the medicine also contains:

Microcrystalline cellulose, polyvinylpyrrolidone (povidone), sodium lauryl sulfate, and sodium stearyl fumarate.

The tablet film coating contains the following inactive ingredients:

Polyvinyl alcohol, macrogol/polyethylene glycol, talc, titanium dioxide, iron oxide red, and iron oxide black.

6.2 What JANUET looks like and contents of the pack

JANUET tablets are available in three strengths:

JANUET 50 mg/500 mg are light pink, film-coated tablets, debossed '575' on one side and blank on the other.

JANUET 50 mg/850 mg are pink, film-coated tablets, debossed '515' on one side and blank on the other.

JANUET 50 mg/1000 mg are red, film-coated tablets, debossed '577' on one side and blank on the other.

Pack sizes:

JANUET 50 mg/500 mg: pack sizes of 7, 10, 14, 28, 30, 56 tablets.

JANUET 50 mg/850 mg: pack sizes of 7, 10, 14, 28, 30, 56 tablets.

JANUET 50 mg/1000 mg: pack sizes of 7, 10, 14, 28, 30, 56 tablets.

Not all pack sizes may be marketed.

Marketing authorization holder:

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O. Box 7121 Petah-Tikva 49170

This leaflet was checked and approved by the Ministry of Health in November 2015.

Drug registration no. listed in the official registry of the Ministry of Health:

JANUET 50 mg/500 mg: 139.89.31706

JANUET 50 mg/850 mg: 139.90.31902

JANUET 50 mg/1000 mg: 139.88.31705