

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

This medicine can be sold under doctor's prescription only

**JANUVIA<sup>®</sup> 25 mg**  
Tablets

**JANUVIA<sup>®</sup> 50 mg**  
Tablets

**JANUVIA<sup>®</sup> 100 mg**  
Tablets

**Each tablet contains:**

Sitagliptin (as monohydrate phosphate) 25 mg

Sitagliptin (as monohydrate phosphate) 50 mg

Sitagliptin (as monohydrate phosphate) 100 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 **JANUVIA**. 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 and adolescents under 18 years of age

**1. WHAT IS JANUVIA USED FOR?**

**JANUVIA** is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

**JANUVIA** is indicated as an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus

**THERAPEUTIC GROUP:** DPP-4 enzyme inhibitors.

**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. BEFORE YOU TAKE JANUVIA**

**2.1 Do not take JANUVIA if you:**

- have type 1 diabetes mellitus
- have diabetic ketoacidosis (increased ketones in the blood or urine: diabetes complication which includes high blood sugar, rapid weight loss, nausea or vomiting)
- are allergic (sensitive) to any of the ingredients of **JANUVIA** (see section 6 for a complete list of ingredients in **JANUVIA**).

Symptoms of a serious allergic reaction to **JANUVIA** 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 JANUVIA**

**Before starting treatment with JANUVIA, tell your doctor if you:**

- have or have had in the past pancreatitis (inflammation of the pancreas), gallstones, alcoholism or very high blood triglyceride levels. These medical conditions can increase your chance of getting pancreatitis (see "**POSSIBLE SIDE EFFECTS**", section 4)
- have kidney problems
- 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**")

### **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.**

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 JANUVIA with food and drink**

You can take **JANUVIA** with or without food.

### **2.5 Pregnancy and breast-feeding**

It is not known if **JANUVIA** will harm your unborn baby. If you are pregnant, or plan to become pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant. It is not recommended to take **JANUVIA** during pregnancy.

It is not known if **JANUVIA** will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking **JANUVIA**.

### **2.6 Driving and using machines**

This medicine has no known influence on the ability to drive and use machines. However, dizziness and drowsiness could occur, which may affect your ability to drive or use machines.

Taking **JANUVIA** in combination with medicines called sulfonylurea or with insulin, can cause hypoglycemia, which may affect your ability to drive and use machines.

## **3. HOW DO YOU USE JANUVIA?**

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

The dose and way of treatment will be determined by the doctor only. The usually recommended dose is 1 tablet, once a day.

**Do not exceed the recommended dose.**

You can take **JANUVIA** with or without food.

Swallow the medicine with a small amount of water.

No information is available regarding crushing/splitting/chewing of the tablets.

Your doctor may do blood tests from time to time to see how well your kidneys are working. Your doctor may change your dose of **JANUVIA** based on the results of your blood tests.

Your doctor may tell you to take **JANUVIA** along with other diabetes medicines. Low blood sugar can happen more often when **JANUVIA** is taken with certain other diabetes medicines (see "**POSSIBLE SIDE EFFECTS**").

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

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 conditions 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 **JANUVIA**.

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.

### **If you have accidentally taken a higher dose of JANUVIA**

If you take too much **JANUVIA**, 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 forget to take JANUVIA**

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 two doses of **JANUVIA** at the same time.

Continue to take this medicine as recommended by the doctor.

#### **How can you contribute to the success of the treatment?**

Complete the full course of treatment as instructed by the doctor.

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

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, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, taking **JANUVIA** 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 have happened in people taking JANUVIA:**

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

Certain medical problems make you more likely to get pancreatitis.

Before you start taking **JANUVIA**, tell your doctor if you have ever had pancreatitis, stones in your gallbladder (gallstones), a history of alcoholism, high blood triglyceride levels.

Stop taking **JANUVIA** 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. Low blood sugar (hypoglycemia).** If you take **JANUVIA** with another medicine that can cause low blood sugar, such as a sulfonylurea 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 **JANUVIA**. Signs and symptoms of low blood sugar may include: headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heart beat, sweating, feeling jittery.

##### **3. Serious allergic reactions.** Allergic reactions, which may be serious, including rash, hives (raised red patches on your skin), 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 **JANUVIA** 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.

##### **4. Kidney problems**, sometimes requiring dialysis.

##### **5. Joint pain.** Some people who take medicines called DPP-4 inhibitors like **JANUVIA**, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.

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

- Upper respiratory infection
- Stuffy or runny nose and sore throat and headache.

**JANUVIA** may have other side effects including:

- Stomach upset and diarrhea
- Swelling of the hands or legs, when **JANUVIA** is used with rosiglitazone (Avandia®). Rosiglitazone is another type of diabetes medicine
- Elevated liver enzymes
- Constipation
- Joint pain
- Muscle pain
- Arm or leg pain
- Back pain
- Vomiting
- Interstitial lung disease
- Osteoarthritis
- Dizziness
- Itching

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

If you get any side effect, 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](http://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 JANUVIA?**

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 **JANUVIA** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.

Store **JANUVIA** 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 JANUVIA contains?**

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

Microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, and sodium stearyl fumarate.

The tablet film coating contains the following inactive ingredients:

Polyvinyl alcohol, macrogol, talc, titanium dioxide, red iron oxide and yellow iron oxide.

### **6.2 What JANUVIA looks like and contents of the pack**

**JANUVIA** tablets are available in three strengths:

**JANUVIA** 25 mg are pink, round, biconvex, film-coated tablets, debossed "221" on one side and plain on the other.

**JANUVIA** 50 mg are light beige, round, biconvex, film-coated tablets, debossed "112" on one side and plain on the other.

**JANUVIA** 100 mg are beige, round, biconvex, film-coated tablets, debossed "277" on one side and plain on the other.

Pack sizes:

**JANUVIA** 25 mg: pack sizes of 7, 10, 14, 28, 30 tablets.

**JANUVIA** 50 mg: pack sizes of 7, 10, 14, 28, 30 tablets.

**JANUVIA** 100 mg: pack sizes of 7, 10, 14, 28, 30 tablets.

Not all pack sizes may be marketed.

**Manufacturer:** Merck Sharp & Dohme Corp., NJ, USA.

**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 October 2015.

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

**JANUVIA** 25 mg: 138.13.31554

**JANUVIA** 50 mg: 138.14.31555

**JANUVIA** 100 mg: 138.15.31556