

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

This medicine is marketed upon physician's prescription only

**JANUVIA® 25 mg**  
Film-coated tablets

**JANUVIA® 50 mg**  
Film-coated tablets

**JANUVIA® 100 mg**  
Film-coated tablets

**Each film-coated 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 "FURTHER INFORMATION". See also section 2.8 "Important information about some of the ingredients of the medicine".

**Read the entire leaflet carefully before using this medicine.**

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

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

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

**Important Limitations of Use:**

**JANUVIA** should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

**JANUVIA** has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using **JANUVIA**.

**Therapeutic group:** DPP-4 enzyme inhibitors.

**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.

**2. BEFORE USING JANUVIA**

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

- are allergic (sensitive) to any of the ingredients of **JANUVIA** (see section 6 "FURTHER INFORMATION" 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 regarding use of JANUVIA**

**Before starting treatment with JANUVIA, tell your doctor about all of your medical conditions, including 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 section 4 "**SIDE EFFECTS**")
- have kidney problems
- are pregnant or plan to become pregnant. (See section 2.6 "**Pregnancy and breastfeeding**")
- are breastfeeding or plan to breastfeed. (See section 2.6 "**Pregnancy and breastfeeding**")
- **have heart failure.** Heart failure means your heart does not pump blood well enough.

**Before you start taking JANUVIA**, tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing, especially when you lie down
- swelling or fluid retention, especially in the feet, ankles or legs
- an unusually fast increase in weight
- unusual tiredness

These may be symptoms of heart failure.

### **2.3 Tests and follow-up**

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

Check your blood sugar as your doctor tells you to.

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

### **2.4 Interactions with other medicines**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the 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.

### **2.5 Using JANUVIA with food**

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

### **2.6 Pregnancy and breastfeeding**

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**.

### **2.7 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.

### **2.8 Important information about some of the ingredients of the medicine**

**JANUVIA** contains sodium. This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

Always use **JANUVIA** according to the doctor's instructions.

You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.

The dosage and treatment regimen 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 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 section 4 "**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.

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.

#### **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.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine without 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 regarding the use of this product, consult with a doctor or a pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, **JANUVIA** may cause side effects in some users.

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

**JANUVIA can cause serious side effects, including:**

**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. Heart failure.** Heart failure means your heart does not pump blood well enough.

**Before you start taking JANUVIA**, tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor right away if you have any of the following symptoms: increasing shortness of breath or trouble breathing, especially when you lie down, swelling or fluid retention, especially in the feet, ankles or legs, an unusually fast increase in weight, unusual tiredness. These may be symptoms of heart failure.

**3. Kidney problems** (frequency not known), sometimes requiring dialysis.

**4. Low blood sugar (hypoglycemia).** Common (may affect up to 1 in 10 people). 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.

**5. Serious allergic reactions** (frequency not known). 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 or get emergency medical help. Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

**6. Joint pain** (frequency not known). 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.

7. **Skin reaction** (frequency not known). Some people who take medicines called DPP-4 inhibitors like **JANUVIA** may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking **JANUVIA**.

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 metformin and rosiglitazone. Rosiglitazone is another type of diabetes medicine
- Constipation
- Joint pain
- Muscle pain
- Arm or leg pain
- Back pain
- Vomiting
- Interstitial lung disease
- Osteoarthritis
- Dizziness
- Itching
- Blisters

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

**If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.**

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site ([www.health.gov.it](http://www.health.gov.it)) which refers to the online side effects reporting form, or by using the link:

<https://sideeffects.health.gov.it/>

## 5. HOW TO STORE JANUVIA?

- Avoid Poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight 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, sodium stearyl fumarate, and magnesium stearate.

The tablet film coating contains the following inactive ingredients:

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

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

**JANUVIA** film-coated 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 film-coated tablets.

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

**JANUVIA** 100 mg: pack sizes of 7, 10, 14, 28, 30 film-coated 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.

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**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