

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

The medicine is dispensed with a doctor's prescription only

Name of the medicine, its form and strength

Pioglitazone Inovamed 15 Tablets

Pioglitazone Inovamed 30 Tablets

Pioglitazone Inovamed 45 Tablets

Each Pioglitazone Inovamed 15 tablet contains:

Pioglitazone hydrochloride 15 mg

Each Pioglitazone Inovamed 30 tablet contains:

Pioglitazone hydrochloride 30 mg

Each Pioglitazone Inovamed 45 tablet contains:

Pioglitazone hydrochloride 45 mg

For the list of inactive and allergenic ingredients in the preparation, see "Further Information" in section 6. See also "Important information about some of the ingredients of the medicine" in section 2 of this leaflet.

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not intended for children and adolescents below the age of 18 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of type 2 diabetes (non-insulin dependent) in patients whose blood sugar level cannot be controlled by treatment with metformin alone.

Pioglitazone Inovamed is given as monotherapy in patients who are unable to take metformin and whose blood sugar level cannot be controlled by diet or exercise. Pioglitazone Inovamed is also given in combination with other medicines for the treatment of diabetes (such as metformin, sulphonylurea or insulin) when adequate control of blood sugar level has not been achieved.

Pioglitazone Inovamed helps control the blood sugar level by improving the response of the body's cells to insulin produced in the body.

Therapeutic group:

The medicine belongs to the thiazolidinedione group for the treatment of diabetes.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- There is known sensitivity to pioglitazone or to any of the ingredients of the medicine (see section 6 "Further information" and section 2 "Important information about some of the ingredients of the medicine").
- You suffer or have suffered in the past, from heart failure.
- You suffer from liver disease.
- You suffer from diabetic ketoacidosis, a complication of diabetes that causes rapid weight loss, nausea or vomiting.
- You suffer or have suffered in the past, from bladder cancer.
- You have blood in your urine that your doctor has not yet diagnosed.

Special warnings regarding use of the medicine

Before treatment with Pioglitazone Inovamed, tell the doctor if:

- You have known sensitivity to lactose, as the preparation contains lactose.
- You suffer from fluid retention in the body or from heart failure, especially in people above 75 years of age. If you are taking anti-inflammatory medicines that may also cause fluid retention and swelling, consult a doctor.
- You suffer from an eye disease typical of diabetes called macular edema (swelling in the back part of the eye).
- You suffer from polycystic ovary syndrome, as Pioglitazone Inovamed could cause ovulation and increase the chance of becoming pregnant. In order to prevent unplanned pregnancy, it is recommended to use contraceptives.
- You suffer from a liver or heart problem. Before starting treatment with Pioglitazone Inovamed, you should perform blood tests to assess liver function. It may be necessary to repeat the tests during treatment. Certain people who had suffered from diabetes for many years and from heart disease or stroke, who took Pioglitazone Inovamed and insulin, developed heart failure. Inform the doctor as soon as possible if you experience signs of heart failure such as: unusual shortness of breath or a sharp increase in body weight or localized edema (swelling).

Warnings

- If you take additional medicines for diabetes, precautionary measures should be taken to avoid the development of a condition of low blood sugar level (hypoglycemia).
- Blood tests should be performed at a frequency determined by your doctor, as there may be a reduction in blood count (anemia).
- A high number of bone fractures have been observed in patients treated with this medicine, particularly in women. Consult the doctor.

Drug interactions

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

In particular, if you are taking:

- Gemfibrozil (to lower cholesterol)
- Rifampicin (to treat tuberculosis and other infections)

In case you are taking either of these medicines, blood sugar levels should be tested in order to assess the appropriate dosage of Pioglitazone Inovamed.

Use of the medicine and food

Pioglitazone Inovamed can be taken with or without food. Swallow with a glass of water.

Pregnancy and breastfeeding

If you are pregnant, think you are pregnant or are planning a pregnancy, are breastfeeding or are planning to breastfeed, tell the doctor. He may recommend that you stop using the medicine.

Children and adolescents

This medicine is not recommended for use by children and adolescents below the age of 18 years.

Driving and operating machinery

The medicine does not impair the ability to drive or operate machinery, but exercise caution if you experience vision impairment during treatment.

Important information about some of the ingredients of the medicine

This medicine contains lactose monohydrate, which is a type of sugar. If you have been told by the doctor that you have an intolerance to lactose or you are unable to digest certain sugars, consult with a doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. Use this medicine at set times as determined by the attending doctor.

Dosage

The dosage and treatment regimen will be determined by the doctor only.

The usual directions for use are generally as follows:

One tablet of Pioglitazone Inovamed 15 or Pioglitazone Inovamed 30, once daily. If needed, the doctor will increase the dosage to a maximum of 45 mg once daily.

- If Pioglitazone Inovamed is taken in combination with other medicines for the treatment of diabetes (such as insulin, chlorpropamide, glibenclamide, gliclazide, tolbutamide), the doctor will determine whether a lower dosage of the medicines is required.
- The attending doctor will perform tests to assess the effectiveness of treatment with Pioglitazone Inovamed 3 to 6 months after commencement of treatment.
- If you are on a special diet for diabetics, adhere to it during treatment with Pioglitazone Inovamed.
- Routine blood tests should be performed for monitoring while using Pioglitazone Inovamed to check that liver function is normal.
- Your body weight should be monitored regularly. If your body weight increases, consult with the doctor.

Do not exceed the recommended dose.

Crushing/halving/chewing

Do not halve the tablets if there is no score line; there is no information about crushing.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Effects of overdose

Blood sugar levels could fall excessively. Blood sugar level can be increased by eating sugar. The patient is advised to carry food with him that contains sugar (such as: candies, sweets, cookies or sweetened juice).

If you forgot to take the medicine at the required time, take the next dose at the scheduled time. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Pioglitazone Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

- Heart failure may occur frequently (may affect up to 1 in 10 patients) in patients taking Pioglitazone Inovamed in combination with insulin. Typical symptoms are unusual shortness of breath or sharp increase in weight or localized swelling (edema). If you experience any of these effects, especially if you are over 65 years of age, seek medical assistance immediately.
- Bladder cancer may occur infrequently (may affect up to 1 in 100 patients) in patients taking Pioglitazone Inovamed. Signs and symptoms include blood in the urine, pain when urinating or a sudden urge to urinate. If you experience any of these effects, consult the doctor as soon as possible.
- Local swelling (edema) may occur very frequently (may affect more than 1 in 10 patients) in patients taking Pioglitazone Inovamed in combination with insulin. If you experience this effect, consult the doctor as soon as possible.
- Bone fractures have been reported frequently (may affect up to 1 in 10 patients) in cases in which women took Pioglitazone Inovamed, and at an unknown frequency in cases in which men took Pioglitazone Inovamed. In any case in which this side effect occurs, consult the doctor as soon as possible.
- Blurred vision due to swelling (or fluids) at the back part of the eye (unknown frequency). If you experience this effect for the first time, consult the doctor as soon as possible. If you suffer from blurred vision and the symptoms get worse, contact the doctor as soon as possible.
- Allergic reactions (unknown frequency). If you experience a severe allergic reaction, including skin allergy (hives) which can be accompanied by itching and swelling of the face, lips, tongue or throat that could cause difficulties breathing or swallowing, stop taking the medicine and consult with the doctor as soon as possible.

Additional side effects:

Common side effects – effects that occur in 1-10 users in 100:

- Respiratory tract infections
- Visual disturbances
- Weight gain
- Lack of sensation

Uncommon side effects – effects that occur in 1-10 users in 1,000:

- Inflammation of the sinuses (sinusitis)
- Insomnia

Side effects of unknown frequency (frequency cannot be determined from the existing data):

- Increase in liver enzymes
- Allergic reactions

Possible side effects if Pioglitazone Inovamed is taken in combination with other medicines for the treatment of diabetes:

Very common side effects – effects that occur in more than 1 user in 10:

- Hypoglycemia – decreased blood sugar levels

Common side effects – effects that occur in 1-10 users in 100:

- Headache
- Dizziness
- Joint pain
- Impotence
- Back pain
- Shortness of breath
- Mild decrease in red blood cell count
- Flatulence (release of gas from the digestive system)

Uncommon side effects – effects that occur in 1-10 users in 1,000:

- Sugar or protein in the urine
- Increase in enzyme levels
- Sensation of loss of balance (vertigo)
- Sweating
- Tiredness
- Increased appetite

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, should be kept 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 the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store this medicine at a temperature below 25°C.

6. FURTHER INFORMATION

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

Lactose monohydrate, Carmellose calcium, Hydroxypropylcellulose, Magnesium stearate.

What the medicine looks like and the contents of the package:

Pioglitazone Inovamed 15: White to off-white, round, biconvex, uncoated tablets debossed with '31' on one side and 'H' on the other side.

Pioglitazone Inovamed 30: White to off-white, round, flat faced, bevel edge, uncoated tablets debossed with '32' on one side and 'H' on the other side.

Pioglitazone Inovamed 45: White to off-white, round, flat faced, bevel edge, uncoated tablets debossed with '33' on one side and 'H' on the other side.

Pack size: Carton package containing 30 tablets in trays (blisters). The number of tablets in each package appears on the carton package.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Pioglitazone Inovamed 15: 167-54-35972

Pioglitazone Inovamed 30: 167-55-36002

Pioglitazone Inovamed 45: 167-56-36003

Manufacturer and Address:

Aurobindo Pharma Ltd., Plot #2, Maitrivihar, Ameerpet, Hyderabad, India.

Registration Holder and Importer:

Inovamed Ltd., 55 Be'er Ganim Street, P.O.B. 62, Even Yehuda 40500.

Revised in September 2021 according to MOH guidelines.