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

The medicine is dispensed with a doctor's prescription only

Actos® 15 mg Tablets

Actos® 30 mg Tablets

Actos® 45 mg Tablets

Composition

Active ingredients

Each tablet contains: Pioglitazone (as HCl) 15 mg	Each tablet contains: Pioglitazone (as HCl) 30 mg	Each tablet contains: Pioglitazone (as HCl) 45 mg

For a list of the inactive ingredients, see section 6 - "Further Information".

The medicine contains lactose, see section 2 **"Special warnings regarding use of the medicine"**.

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.

The medicine is not intended for children and adolescents under 18 years of age.

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.

Actos is given as monotherapy in patients who are unable to take metformin, and whose blood sugar level cannot be controlled by diet or exercise. Likewise, Actos may also be given in combination with other medicines for treatment of diabetes (such as metformin, sulphonylurea or insulin) in cases of inadequate control of the blood sugar level.

Actos helps control blood sugar levels by improving the response of the body cells to insulin produced in the body.

Therapeutic group:

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

2. BEFORE USING THE MEDICINE

☒ Do not use the preparation if:

There is known sensitivity to pioglitazone or to any of the ingredients of the medicine listed in section 6.

You suffer or have suffered in the past from heart failure.

You suffer from a liver disease.

You suffer from diabetic ketoacidosis, a complication of diabetes leading to 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 beginning treatment, inform the doctor if:

- You have a known sensitivity to lactose, since the preparation contains lactose.
- You suffer from fluid retention in the body or from heart failure, particularly in people above 75 years of age. If you are taking anti-inflammatory medicines that may also cause fluid retention and swelling, you should consult the doctor.
- You suffer from an eye disease typical of diabetics, called macular edema (swelling of the back part of the eye).
- You suffer from polycystic ovary syndrome, as Actos may cause ovulation and increase the chances of becoming pregnant. It is recommended to use contraceptive preparations in order to avoid an unplanned pregnancy.
- You suffer from a liver or heart problem. Before starting treatment with Actos, you should perform blood tests to assess liver function. It may be necessary to repeat the tests during treatment. Certain people with long-standing diabetes, as well as heart diseases or stroke, who took Actos 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 sharp increase in body weight or localized edema (swelling).

❗ Warnings

- If you are taking other medicines for diabetes, precautionary measures should be taken to avoid the development of situations of low blood sugar levels (hypoglycemia).
- You should perform blood tests at a frequency that will be determined by the attending 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.

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

In particular, inform the doctor if you are taking the following medicines:

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

In case you are taking any of these medicines, check your blood sugar levels, in order to estimate the appropriate Actos dosage.

❗ Use of the medicine and food

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

❗ Use in children

This medicine is not recommended for use in children and adolescents under 18 years of age.

❗ Driving and operating machinery

The medicine does not impair your ability to drive or operate machinery, but take care if you experience vision impairment during treatment.

❗ Important information about some of the ingredients of the medicine

This medicine contains lactose. If you are sensitive to lactose, consult the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage is according to the doctor only.

Use this medicine at specific time intervals as determined by the attending doctor.

Dosage:

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

The usual recommended directions for use are as follows:

One tablet of Actos 15 mg or 30 mg once daily. If necessary, the doctor will increase the dosage to a maximum of 45 mg once daily. Do not halve the tablets without a score line; there is no information about crushing.

- When Actos is taken in combination with other medicines for treatment of diabetes (such as insulin, chlorpropamide, glibenclamide, gliclazide, tolbutamide), the doctor will determine whether a lower dosage of your medicines is required.
- The attending doctor will perform tests to assess the effectiveness of the treatment with Actos, 3 to 6 months after commencement of treatment.
- If you are on a special diet for diabetics, persist with it while taking Actos.

Do not exceed the recommended dose

Tests and follow-up

- You should perform routine blood tests while using Actos in order to monitor for normal liver functioning.
- Your weight should be monitored regularly. If there is an increase in body weight, consult the doctor.

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 recommended to carry with him some sugary food (such as: candies, sweets, biscuits or sweetened juice).

If you forgot to take the medicine at the required time, take the next dose at the usual time. Do not take two doses together to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor, even if your medical condition has improved. Do not stop treatment without consulting the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Actos 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 can occur frequently (may affect up to 1 in 10 patients) in patients taking Actos 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 attention immediately.
- Bladder cancer may occur infrequently (may affect up to 1 in 100 patients) in patients taking Actos. Signs and symptoms include blood in the urine, pain upon urinating or a sudden urge to urinate. If you experience any of these effects, consult the doctor as soon as possible.
- Localized swelling (edema) may occur very frequently (may affect more than 1 in 10 patients) in patients taking Actos in combination with insulin. If you experience this effect, consult the doctor as soon as possible.
- Bone fractures have been frequently reported (may affect up to 1 in 10 patients) in women taking Actos, and at an unknown frequency in men taking Actos. Whenever 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 worsen, refer to the doctor as soon as possible.
- Allergic reactions (unknown frequency): If you experience a serious allergic reaction, including skin allergy (hives) which can be accompanied by itching and swelling of the face, lips, tongue or throat that may cause difficulty in breathing or swallowing, stop taking the medicine and consult the doctor as soon as possible.

Additional side effects:

Common side effects (may affect up to 1 in 10 patients):

- Respiratory track infections
- Visual disturbances
- Weight gain
- Numbness

Uncommon side effects (may affect up to 1 in 100 patients):

- Inflammation of the sinuses (sinusitis)
- Insomnia

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Increase in liver enzymes
- Allergic reactions

Possible side effects when Actos is taken in combination with other medicines for treatment of diabetes:

Very common side effects (may affect more than 1 in 10 patients):

- Hypoglycemia - decreased blood sugar levels

Common side effects (may affect up to 1 in 10 patients):

- Headache
- Dizziness
- Joint pain
- Impotence
- Back pain
- Shortness of breath
- Slight decrease in red blood cell count
- Flatulence

Uncommon side effects (may affect up to 1 in 100 patients):

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

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

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

Do not use the medicine after the expiry date (Expiry date) that appears on the package. The expiry date refers to the last day of that month.

Store in a dry place, below 25°C.

6. FURTHER INFORMATION

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

Lactose monohydrate, Carmellose calcium, Hydroxypropylcellulose, Magnesium stearate

Each Actos 15 mg tablet contains: 93 mg lactose monohydrate

Each Actos 30 mg tablet contains: 76.3 mg lactose monohydrate

Each Actos 45 mg tablet contains: 114.5 mg lactose monohydrate

What the medicine looks like and contents of the package

The package contains 28 tablets in trays (blisters).

Actos 15 mg: white ,round convex tablets. "15" appears on one side and ACTOS appears on the other side.

Actos 30 mg: white ,round flat tablets. "30" appears on one side and ACTOS appears on the other side.

Actos 45 mg: white ,round flat tablets. "45" appears on one side and ACTOS appears on the other side.

License Holder

Abic Marketing Ltd., P.O.B. 8077, Netanya

Manufacturer Name and its Address

Takeda Pharma A/S, Denmark

This leaflet was checked and approved by the Ministry of Health in July 2017

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

Actos 15 mg: 149.69.33828.00

Actos 30 mg: 149.70.33829.00

Actos 45 mg: 149.71.33830.00