

**Actos® 15 mg, 30 mg and 45 mg Tablets**

Pioglitazone hydrochloride

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See "Possible side effects".

The product is known by the name above but will be referred to as Actos throughout the rest of this leaflet.

**In this leaflet:**

1. What Actos is and what it is used for
2. What you need to know before you take Actos
3. How to take Actos
4. Possible side effects
5. How to store Actos
6. Contents of the pack and other information

**1. What Actos is and what it is used for**

Actos contains pioglitazone. It is an anti-diabetic medicine used to treat type 2 (non-insulin dependent) diabetes mellitus in adults, when metformin is not suitable or has failed to work adequately. This is the diabetes that usually develops in adulthood. Actos helps control the level of sugar in your blood when you have type 2 diabetes by helping your body make better use of the insulin it produces. Your doctor will check whether Actos is working 3 to 6 months after you start taking it. Actos may be used on its own in patients who are unable to take metformin, and where treatment with diet and exercise has failed to control blood sugar or may be added to other therapies (such as metformin, sulphonylurea or insulin) which have failed to provide sufficient control of blood sugar.

**2. What you need to know before you take Actos****Do not take Actos**

- If you are allergic to pioglitazone or any of the other ingredients of this medicine (listed in Section 6).
- If you have heart failure or have had heart failure in the past.
- If you have liver disease.
- If you have had diabetic ketoacidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting).
- If you have or have ever had bladder cancer.
- If you have blood in your urine that your doctor has not checked.

**Warnings and Precautions**

- Talk to your doctor or pharmacist before taking Actos (also see Section 4).
- If you retain water (fluid retention) or have heart failure problems, in particular if you are over 75 years old. If you take anti-inflammatory medicines which can also cause fluid retention and swelling, you must also tell your doctor.
- If you have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye).
- If you have cysts on your ovaries (polycystic ovary syndrome). There may be an increased possibility of becoming pregnant because you may ovulate again when you take Actos. If this applies to you, use appropriate contraception to avoid the possibility of an unplanned pregnancy.
- If you have a problem with your liver or heart. Before you start taking Actos you will have a blood sample taken to check your liver function. This check may be repeated at intervals. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with Actos and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- If you take Actos with other medicines for diabetes, it is more likely that your blood sugar could fall below the normal level (hypoglycaemia).
- You may also experience a reduction in blood count (anaemia).
- Broken bones: A higher number of bone fractures was seen in patients, particularly women taking pioglitazone. Your doctor will take this into account when treating your diabetes.

**Children and adolescents**

Use in children and adolescents under 18 years is not recommended.

**Other medicines and Actos**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. You can usually continue to take other medicines whilst you are being treated with Actos. However, certain medicines are especially likely to affect the amount of sugar in your blood:

- Gemfibrozil (used to lower cholesterol)
  - Rifampicin (used to treat tuberculosis and other infections)
- Tell your doctor or pharmacist if you are taking any of these. Your blood sugar will be checked, and your dose of Actos may need to be changed.

**Actos with food and drink**

You may take your tablets with or without food. You should swallow the tablets with a glass of water.

**Pregnancy and breast-feeding**

Tell your doctor if:

- You are, you think you might be or are planning to become pregnant.
  - You are breast-feeding or if you are planning to breast-feed your baby.
- Your doctor will advise you to discontinue this medicine.

**Driving and using machines**

This medicine will not affect your ability to drive or use machines but take care if you experience abnormal vision.

**Actos contains lactose monohydrate**

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Actos.

**3. How to take Actos**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose is one tablet of 15 mg or of 30 mg of pioglitazone to be taken once daily. Your doctor may increase the dose to a maximum of 45 mg once a day. Your doctor will tell you the dose to take.

If you have the impression that the effect of Actos is too weak, talk to your doctor.

When Actos is taken in combination with other medicines used to treat diabetes (such as insulin, chlorpropamide, glibenclamide, gliclazide, tolbutamide) your doctor will tell you whether you need to take a smaller dose of your medicines.

Your doctor will ask you to have blood tests periodically during treatment with Actos. This is to check that your liver is working normally.

If you are following a special diet for diabetes, you should continue with this while you are taking Actos.

Your weight should be checked at regular intervals; if your weight increases, inform your doctor.

**If you take more Actos than you should**

If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately. Your blood sugar could fall below the normal level and can be increased by taking sugar. It is recommended that you carry some sugar lumps, sweets, biscuits or sugary fruit juice.

**If you forget to take Actos**

Take Actos daily as prescribed. However if you miss a dose, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Actos**

Actos should be used every day to work properly. If you stop using Actos, your blood sugar may go up. Talk to your doctor before stopping this treatment.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**In particular, patients have experienced the following serious side effects:**

Heart failure has been experienced commonly (may affect up to 1 in 10 people) in patients taking Actos in combination with insulin. Symptoms are unusual shortness of breath or rapid increase in weight or localised swelling (oedema). If you experience any of these, especially if you are over the age of 65, seek medical advice straight away.

Bladder cancer has been experienced uncommonly (may affect up to 1 in 100 people) in patients taking Actos. Signs and symptoms include blood in your urine, pain when urinating or a sudden need to urinate. If you experience any of these, talk to your doctor as soon as possible.

Localised swelling (oedema) has also been experienced very commonly (may affect more than 1 in 10 people) in patients taking Actos in combination with insulin. If you experience this side effect, talk to your doctor as soon as possible.

Broken bones have been reported commonly (may affect up to 1 in 10 people) in female patients taking Actos and have also been reported in male patients (frequency cannot be estimated from the available data) taking Actos. If you experience this side effect, talk to your doctor as soon as possible.

Blurred vision due to swelling (or fluid) at the back of the eye (frequency cannot be estimated from the available data) has also been reported in patients taking Actos. If you experience this symptom for the first time, talk to your doctor as soon as possible. Also, if you already have blurred vision and the symptom gets worse, talk to your doctor as soon as possible.

Allergic reactions have been reported (frequency cannot be estimated from the available data) in patients taking Actos. If you have a serious allergic reaction, including hives and swelling of the face, lips, tongue, or throat that may cause difficulty in breathing or swallowing stop taking this medicine and talk to your doctor as soon as possible.

**The other side effects that have been experienced by some patients taking Actos are:****Common (may affect up to 1 in 10 people)**

- Respiratory infection
- Abnormal vision
- Weight gain
- Numbness

**Uncommon (may affect up to 1 in 100 people)**

- Inflammation of the sinuses (sinusitis)
- Difficulty sleeping (insomnia)

**Not known (frequency cannot be estimated from the available data)**

- Increase in liver enzymes
- Allergic reactions

**The other side effects that have been experienced by some patients when Actos is taken with other antidiabetic medicines are:****Very common (may affect more than 1 in 10 people)**

- Decreased blood sugar (hypoglycaemia)

**Common (may affect up to 1 in 10 people)**

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

**Uncommon (may affect up to 1 in 100 people)**

- Sugar in urine, proteins in urine
- Increase in enzymes
- Spinning sensation (vertigo)
- Sweating
- Tiredness
- Increased appetite

**5. How to store Actos**

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton after Exp Date. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What Actos contains**

The active substance is pioglitazone hydrochloride. Each tablet of Actos 15 mg, 30 mg and 45 mg Tablets contain pioglitazone hydrochloride equivalent to 15 mg, 30 mg or 45 mg pioglitazone; respectively.

The other ingredients are lactose, carmellose calcium, hydroxypropyl cellulose and magnesium stearate.

**What Actos looks like and contents of the pack**

Actos 15 mg Tablets are white to off white, round, convex tablets debossed with "15" on one face and with "ACTOS" on the other.

Actos 30 mg Tablets are white to off white, round, flat tablets debossed with "30" on one face and with "ACTOS" on the other.

Actos 45 mg Tablets are white to off white, round, flat tablets debossed with "45" on one face and with "ACTOS" on the other.

The tablets are supplied in bottle packs of 30 tablets.

**Marketing Authorization Holder and Manufacturer**

The Arab Pharmaceutical Manufacturing PSC

P.O. Box 42

Sult, Jordan

Tel: + (962-5) 3492200

Fax: + (962-5) 3492203

**Under licensed from**

Takeda Pharmaceutical Company Ltd.,

Osaka-Japan

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder:

• Jordan

Tel: 00962 6 580 5430 Ext: 11651.

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**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

• Jordan

Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance department

Tel: + (962-6) 5632000, e-mail: jpsc@jfd.a.jo, Website: www.jfd.a.jo

Smart phones application: JFDA, Paper reporting form: Yellow card

**Council of Arab Health Ministers, Union of Arab Pharmacists****THIS IS A MEDICAMENT**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

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