

PACKAGE LEAFLET: INFORMATION FOR THE USER

Actos® 15 mg tablets
Actos® 30 mg tablets
Pioglitazone

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What *actos*® is and what it is used for
2. Before you take *actos*®
3. How to take *actos*®
4. Possible side effects
5. How to store *actos*®
6. Further 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. 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.

actos® may be used on its own or in combination with metformin and / or a sulphonylurea which are also oral anti-diabetic medicines.

2. BEFORE YOU TAKE ACTOS®

Do not take *actos*®

- if you are hypersensitive (allergic) to pioglitazone or any of the other ingredients of *actos*®.
- if you have heart failure or have had heart failure in the past.
- if you have liver disease.
- if you have or have ever had bladder cancer.
- if you have blood in your urine that your doctor has not checked.
- if you have type 1 diabetes – this needs different treatment.
- if you have acute or chronic metabolic acidosis (a complication of diabetes causing rapid weight loss, nausea or vomiting).

Take special care with *actos*[®]

Tell your doctor before you start to take this medicine

- if you retain water (fluid retention) or have heart failures problems in particular if you are over 75 years old.
- 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 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 women (but not in men) taking pioglitazone. Your doctor will take this into account when treating your diabetes.

Children

Use in children under 18 years is not recommended.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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.

Taking *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 breastfeeding

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

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

Important information about some of the ingredients of *actos*[®]

This medicine 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*[®]

One tablet of 15 mg or 30 mg of pioglitazone should be taken once daily. If necessary your doctor may tell you to take a different dose.

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 diabetic diet, 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, **actos**[®] 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 (1 to 10 users in 100) 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 (1 to 10 users in 1000) 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 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 (1 to 10 users in 100) in women patients 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 not known) 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ACTOS[®]

Keep out of the reach and sight of children.

Do not use **actos**[®] after the expiry date which is stated on the carton and the blister pack after the word "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage precautions.

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 What ACTOS[®] contains

The active substance is pioglitazone. Each tablet contains 15 mg or 30 mg of pioglitazone (as hydrochloride).

Product Registrant

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