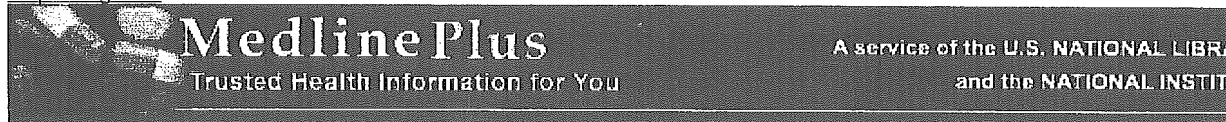


	<ul style="list-style-type: none"> ・α-グルコシダーゼ阻害剤(ボグリボース(商品名:ベイスン)やアカルボース(商品名:グルコバイ)などの糖分の吸収を遅らせる薬)との併用により低血糖症状が起こった時にはブドウ糖をとるようにしてください。 ・指示された食事療法、運動療法をきちんと守ってください。
この薬を飲んだ あと、気をつけ て いただくこと (副作用)	<p>薬は人によって、目的の効果以外に、望ましくない作用が出る場合もあります。</p> <p>◆次のような症状に気づいたら、使用をやめて、すぐに主治医に相談してください。</p> <p>顔や手足がむくむ、顔や手足が腫れる、急に体重が増える、心臓がドキドキする、息切れする、熱が出る、食欲がなくなる、はきけを伴い体がひどくなる、疲れやすい、冷や汗が出る、急に異常な空腹感が起こる、力の抜けた感じがする、皮ふや白目が黄色くなる、発しんやかゆみなどの皮ふ症状があらわれる、手足がふるえる、胃が痛い、便が黒くなる、はく、おなかが痛い、尿が茶色になる、息苦しい、しびれ。</p> <p>◇次のような症状に気づいたら、なるべく早めに主治医に相談してください。</p> <p>顔色が悪い、立ちくらみがする、おなかがはる、便秘になる、食欲が出る、関節が痛くなる、ふるえ。</p> <ul style="list-style-type: none"> ・ほかにも何か変だなと感じたら、主治医または薬剤師に相談してください。
その他 (コメント)	
主治医の連絡先	薬局の連絡先

※ここには、知っておいて頂きたい主な事柄だけが書いてあります。更にくわしく知りたいときは、主治医または薬剤師におたずねください。



Last updated:2004/04

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Pioglitazone (Systemic)

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Contents of this page:

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Brand Names

In the U.S.—

- [Actos](#)

Category

- [Antidiabetic agent](#)

Description

Pioglitazone (pye-oh-GLI-ta-zone) is used to treat a certain type of diabetes mellitus (sugar diabetes) called type 2 diabetes. It may be used alone, with insulin, or with metformin or another type of oral diabetes medicine called a sulfonylurea. Pioglitazone is to be used when diet and exercise plus another diabetes medicine do not result in good blood sugar control.

This medicine is available only with your doctor's prescription, in the following dosage form:

Oral

- [Tablets \(U.S. and Canada\)](#)

Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For pioglitazone, the following should be considered:

Allergies—Tell your doctor if you have ever had any unusual or allergic reaction to pioglitazone. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

Pregnancy—Pioglitazone has not been studied in pregnant women. However, it is easier during pregnancy to control your blood sugar by using injections of insulin, rather than by taking pioglitazone. Close control of your blood sugar can reduce the chance of your baby gaining too much weight, having birth defects, or having high blood sugar before birth. Pioglitazone should be used during pregnancy only if the potential benefit outweighs the potential risk. Be sure to tell your doctor if you plan to become pregnant or you think you are pregnant.

Breast-feeding—It is not known whether pioglitazone passes into the breast milk of humans. However, pioglitazone is not recommended during breast-feeding.

Children—Studies on this medicine have been done only in adult patients, and there is no specific information comparing use of pioglitazone in children with use in other age groups.

Older adults—This medicine has been tested in a limited number of patients 65 years of age or older and has not been shown to cause different side effects or problems in older people than it does in younger adults.

Other medicines—Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking pioglitazone, it is especially important that your health care professional know if you are taking the following:

- Ketoconazole—Use of this medicine with pioglitazone may decrease the effect of pioglitazone

Other medical problems—The presence of other medical problems may affect the use of pioglitazone. Make sure you tell your doctor if you have any other medical problems, especially

- Diabetic ketoacidosis (ketones in the blood) or
- Type 1 diabetes—Insulin is needed to control these conditions
- Heart disease or
- Liver disease—Pioglitazone may make these conditions worse
- Problems with fluid retention or swelling— may make these conditions worse
- Hypersensitivity to pioglitazone or any ingredients in pioglitazone.

Proper Use of This Medicine

Follow carefully the special meal plan your doctor gave you. This is the most important part of controlling your condition, and is necessary if the medicine is to work properly. Also, exercise

regularly and test for sugar in your blood or urine as directed.

Pioglitazone may be taken with or without food.

Certain women may be at an increased risk for pregnancy while taking pioglitazone. Adequate contraception is recommended.

Dosing—

The dose of pioglitazone will be different for different patients. *Follow your doctor's orders or the directions on the label. If your dose is different, do not change it unless your doctor tells you to do so.*

- For oral dosage form (tablets):
 - For type 2 diabetes:
 - Pioglitazone alone:
 - Adults: At first, the dose is 15 or 30 milligrams (mg) once daily with or without meals. Your doctor may later increase your dose up to 45 mg once daily.
 - Children: Use and dose must be determined by your doctor.
 - Pioglitazone with insulin:
 - Adults: At first, the dose is 15 or 30 mg once daily with or without meals.
 - Children: Use and dose must be determined by your doctor.
 - Pioglitazone with metformin:
 - Adults: At first, the dose is 15 or 30 mg once daily with or without meals.
 - Children: Use and dose must be determined by your doctor.
 - Pioglitazone with a sulfonylurea:
 - Adults: At first, the dose is 15 or 30 mg once daily with or without meals.
 - Children: Use and dose must be determined by your doctor.

Missed dose—

If you miss a dose of this medicine, take it as soon as you remember. However, if you do not remember it until it is time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage—

To store this medicine:

- Keep out of the reach of children.
- Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- Store away from heat and direct light.
- Do not keep outdated medicine or medicine no longer needed. Ask your health care professional how you should dispose of any medicine you do not use. Be sure that any discarded medicine is out of the reach of children.

Precautions While Using This Medicine

If you experience abdominal or stomach pain, dark urine, loss of appetite, nausea or vomiting, unusual tiredness or weakness, or yellow eyes or skin, check with your doctor immediately. These may be symptoms of liver problems.

It is very important that your doctor check your progress at regular visits to make sure that this medicine is working properly and to check for unwanted effects

It is very important to follow carefully any instructions from your health care team about

- Alcohol—Drinking alcohol may cause severe low blood sugar. Discuss this with your health care team.
- Other medicines—Do not take other medicines during the time you are taking pioglitazone unless they have been discussed with your doctor. This especially includes nonprescription medicines such as aspirin, and medicines for appetite control, asthma, colds, cough, hay fever, or sinus problems.
- Counseling—Other family members need to learn how to prevent side effects or help with side effects if they occur. Also, diabetic patients may need special counseling about diabetes medicine dosing changes that might occur because of lifestyle changes, such as changes in exercise and diet. Furthermore, counseling on contraception and pregnancy may be needed because of the problems that can occur during pregnancy in patients with diabetes .
- Travel—Keep a recent prescription and your medical history with you. Be prepared for an emergency as you would normally. Make allowances for changing time zones and keep your meal times as close as possible to your usual meal times.
- *In case of emergency*—There may be a time when you need emergency help for a problem caused by your diabetes. You need to be prepared for these emergencies. It is a good idea to wear a medical identification (ID) bracelet or neck chain at all times. Also, carry an ID card in your wallet or purse that says that you have diabetes and a list of all of your medicines.
- Symptoms of fluid retention—Know what to do if you start to retain fluid. Fluid retention may worsen or lead to heart problems.
- *This medicine does not cause hypoglycemia (low blood sugar). However, low blood sugar can occur* when you take pioglitazone with other medicines that can lower blood sugar, such as insulin, metformin, or a sulfonylurea. Low blood sugar also can occur if you delay or miss a meal or snack, exercise more than usual, drink alcohol, or cannot eat because of nausea or vomiting.
- *Symptoms of low blood sugar include* anxiety; behavior change similar to being drunk; blurred vision; cold sweats; confusion; cool, pale skin; difficulty in thinking; drowsiness; excessive hunger; fast heartbeat; headache (continuing); nausea; nervousness; nightmares; restless sleep; shakiness; slurred speech; or unusual tiredness or weakness.
- If symptoms of low blood sugar occur, *eat glucose tablets or gel, corn syrup, honey, or sugar cubes; or drink fruit juice, nondiet soft drink, or sugar dissolved in water to relieve the symptoms.* Also, check your blood for low blood sugar. *Glucagon is used in emergency situations when severe symptoms such as seizures (convulsions) or unconsciousness occur.* Have a glucagon kit available, along with a syringe and needle, and know how to use it. Members of your family also should know how to use it.

Hyperglycemia (high blood sugar) may occur if you do not take enough or skip a dose of your antidiabetic medicine, overeat or do not follow your meal plan, have a fever or infection, or do not exercise as much as usual.

Symptoms of high blood sugar include blurred vision; drowsiness; dry mouth; flushed, dry skin; fruit-like breath odor; increased urination (frequency and amount); ketones in urine; loss of appetite; stomachache, nausea, or vomiting; tiredness; troubled breathing (rapid and deep);

unconsciousness; or unusual thirst.

If symptoms of high blood sugar occur, *check your blood sugar level and then call your doctor for instructions.*

Side Effects of This Medicine

Side Effects of This Medicine

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

- *More common*
 - Problems with teeth

- *Less common*

- Swelling

- *Incidence Unknown*
 - Unexplained, rapid weight gain

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

- *More common*

- Blurred vision; cough ; dry mouth; fatigue; flushed, dry skin; fruit like breath odor; headache; increased hunger; increased thirst; increased urination; loss of consciousness; muscle soreness; nausea; runny or stuffy nose; sore throat; stomachache; sweating; troubled breathing; unexplained weight loss; vomiting

- *Less Common*
 - Pale skin; trouble breathing with activity ; unusual bleeding or bruising; unusual tiredness or weakness

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

Developed: 1/20/2000

Revised: 12/19/2003

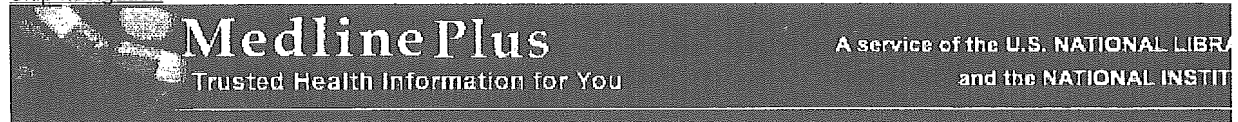
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Pioglitazone


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(pye oh gli' ta zone)

Brand name(s): Actos

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- [How should this medicine be used?](#)
- [Other uses for this medicine](#)
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- [What should I do if I forget a dose?](#)
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Why is this medication prescribed?

Pioglitazone is used, alone or in combination with other medications, to treat type 2 diabetes in people whose diabetes cannot be controlled by diet and exercise alone. Pioglitazone is in a class of drugs called thiazolidinediones. It works by increasing your body's sensitivity to insulin, a substance your body produces to help control blood sugar levels.

How should this medicine be used?

Pioglitazone comes as a tablet to take by mouth. It is usually taken once daily with or without meals. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take pioglitazone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Pioglitazone controls type 2 diabetes but does not cure it. Continue to take pioglitazone even if you feel well. Do not stop taking pioglitazone without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking pioglitazone,

- tell your doctor and pharmacist if you are allergic to pioglitazone, rosiglitazone, troglitazone, or any other drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially ketoconazole (Nizoral), oral contraceptives, other medications for type 2 diabetes, and vitamins or herbal products. Tell your doctor and pharmacist if you have ever taken troglitazone (Rezulin).
- tell your doctor if you have or have ever had heart failure, liver disease (including cirrhosis and hepatitis), swollen ankles or feet (edema), high cholesterol, or a history of alcohol abuse.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking pioglitazone, call your doctor immediately.
- you should know that pioglitazone can restart ovulation in women taking oral contraceptives or those with polycystic ovary disease. You are at risk for pregnancy if adequate birth control is not used. You should discuss a reliable form of birth control with your doctor. If you are taking birth control pills, your doctor may choose to adjust your dose.

What special dietary instructions should I follow?

Pioglitazone should be taken with the same meals every day. Be sure to follow all exercise and dietary recommendations made by your doctor or dietitian. Calorie reduction, weight loss, and exercise will help control your diabetes and will also make pioglitazone work better. It is important to eat a healthy diet.

Alcohol increases blood sugar; ask your doctor for information on how much alcohol is safe to drink.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Pioglitazone does not usually cause hypoglycemia (low blood sugar) when used alone, but it may cause low blood sugar when used with other medications for diabetes. If you have any of the following symptoms, eat or drink a food or beverage with sugar in it, such as hard candy or fruit juice, and call your doctor immediately. Symptoms of low blood sugar include:

- shakiness
- dizziness
- rapid heartbeat
- sweating
- confusion
- blurred vision
- headache
- numbness or tingling of the mouth
- weakness
- tiredness

- pale color
- sudden hunger

If you have any of the following symptoms of hyperglycemia (high blood sugar), call your doctor immediately:

- thirst
- dry mouth
- tiredness
- flushing
- dry skin
- frequent urination
- loss of appetite
- trouble breathing

Although side effects from pioglitazone are not common, they can occur. Tell your doctor if any of these symptoms are severe or do not go away:

- sinus or respiratory infection
- headache
- muscle pain
- tooth or mouth pain
- sore throat
- weight gain
- swelling of the ankles or feet

If you experience any of the following symptoms, call your doctor immediately:

- difficulty breathing
- rapid weight gain
- swelling of the ankles or feet that happens very quickly
- seizures
- loss of consciousness
- upset stomach
- vomiting
- stomach pain
- excessive tiredness
- dark urine
- yellowing of the skin or whites of the eyes

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your blood sugar and glycosolated hemoglobin should be checked regularly to determine your response to pioglitazone.

Rare cases of liver injury and failure have occurred during therapy with troglitazone, a drug similar to pioglitazone. The potential risk of liver injury with pioglitazone is not known at this time. It is important that you keep all appointments with your doctor and the laboratory. Your doctor will order certain laboratory tests before and during your treatment to check your response to pioglitazone. You will have these tests before you begin to take pioglitazone, and then every 2 months for the first year of therapy. After the first year, these tests will be done less frequently.

Call your doctor during periods of stress, such as fever, trauma, infection, or prolonged illness. Your medications may need to be adjusted.

Pioglitazone may cause a slight decrease in red and white blood cells. Before you have any laboratory test, tell the laboratory personnel and your doctor that you take this medication.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

Last Revised - 01/01/2003



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Actos	
Brand Name:	Actos
Active Ingredient:	pioglitazone
Strength(s):	15 mg, 30 mg, and 45 mg
Dosage Form(s):	Tablets
Company Name:	Takeda Chemical Industries, Ltd.
Availability:	Prescription only
*Date Approved by the FDA:	July 15, 1999
<i>*Approval by FDA does not mean that the drug is available for consumers at this time.</i>	

What is Actos used for? Actos, in addition to diet and exercise, improves blood sugar control in patients with type 2 diabetes (non-insulin dependent diabetes). Actos can be used alone or in combination with a sulfonylurea, metformin, or insulin when diet, exercise, and one of these agents or diet, exercise, plus Actos alone are not enough to control blood sugar.

Who should not take Actos?

- Do not take Actos for Type 1 diabetes (juvenile diabetes) or diabetic ketoacidosis.
- If you have heart failure, fluid retention or active liver disease your health care provider will evaluate you to decide if Actos is right for you.

General Precautions with Actos:

- In drug testing, Actos did not cause liver toxicity or an increase in liver enzymes. However, Actos is in the same class of drugs as Rezulin, which has been associated with rare but serious liver injury, including liver failure leading to transplant or death.
- Because the liver safety profile of Actos is not fully determined yet, your doctor will do blood tests that evaluate your liver before starting you on Actos. These blood tests should be repeated every two months for the first year, then regularly after that.
- Call your health care provider right away if you develop nausea, vomiting, stomach pain, a feeling of tiredness, or having no energy, loss of appetite, dark urine, or jaundice (yellow coloring of eyes and skin). These may be the symptoms of liver problems.
- When taking Actos with insulin or certain other oral diabetes medicines, there is a risk

of your blood sugar becoming dangerously low. Ask your health care provider about symptoms of low blood sugar, conditions that make low blood sugar more likely, and what to do if you get it. Make sure to explain to family members.

- If you are a woman who has not reached menopause but have not had menstrual periods; you may become pregnant unless you use an effective method of birth control. Actos, like other drugs in this class, may cause insulin resistant women to start ovulating again.
- Women should tell their doctor if they notice any changes in their monthly menstrual cycle.
- During periods of stress on the body, such as fever, trauma, infection, or surgery, your medication requirements may change; contact your health care provider promptly.

What should I tell my doctor or health care provider?

Women taking oral birth control pills should talk to their health care provider when taking Actos, because the effectiveness of oral birth control pills can be reduced.

Tell your health care provider if you are trying to become pregnant, are already pregnant, or are breast-feeding.

Because certain other medications may interact with Actos, review all medications that you are taking with your health care provider, including those that you take without a prescription.

What are some possible side effects of Actos? *(This list is NOT a complete list of side effects reported with Actos. Your health care provider can discuss with you a more complete list of side effects.)*

- Cough or cold
- Headache
- Inflammation of the sinuses or throat
- Muscle pain
- Swelling or fluid retention

For more detailed information about Actos, ask your health care provider.

[Actos' Approved Label](#) 

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Posted: 3/28/00
Revised: 3/14/01

INFORMATION FOR
CONSUMERS

Consumer Medicine Information



ACTOS[®]

pioglitazone hydrochloride

What is in this leaflet

This leaflet answers some common questions about ACTOS. It does not contain all the available information and does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ACTOS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with this medicine. You may need to read it again.

What ACTOS is used for

ACTOS is used in the management of type 2 diabetes mellitus not controlled by diet. Type 2 diabetes mellitus is the 'adult onset' type of diabetes and is controlled by diet, certain oral medications and occasionally insulin. ACTOS helps to control the level of glucose in your blood by improving the action of the body's naturally produced insulin.

This medicine is also called pioglitazone hydrochloride and belongs to a group of medicines called glitazones. Glitazones decrease insulin resistance.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

The use of ACTOS has not been studied in children.

Before you take ACTOS

When you must not take it

Do not take ACTOS if you have an allergy to:

- any medicine containing pioglitazone hydrochloride
- any of the ingredients listed at the end of this leaflet (see 'Product description')
- other similar medicines (thiazolidinediones)

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take ACTOS if you have type 1 diabetes mellitus.

Do not take ACTOS if you have heart disease with shortness of breath after minimal physical activity

(New York Heart Association Class III) or heart disease with severe symptoms at rest (New York Heart Association Class IV).

Do not take ACTOS if you are pregnant.

Do not breast feed if you are taking ACTOS.

Do not take this medicine after the date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetic ketoacidosis (loss of appetite, weight loss, nausea, stomach pain, difficulty breathing, unusual muscle pain or feeling tired, weak or uncomfortable)
- heart disease that limits your physical activity
- problems with your liver
- swelling of hands, ankles or feet
- some women who do not have monthly periods and have not been through menopause may restart their periods when taking ACTOS. These women may be at increased risk of pregnancy.

Tell your doctor if you are using another medicine for diabetes. ACTOS can enhance the action of other medicines. You may be at risk of low blood sugar (hypoglycaemia). If this happens, your doctor may need to adjust the dose of your other medicines.

Tell your doctor if you suffer from lactose intolerance (because ACTOS tablets contain lactose).

If you have not told your doctor about any of the above, tell him/her before you start taking ACTOS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and ACTOS may interfere with each other. These include:

- oral contraceptives
- chlorpropamide
- glibenclamide
- gliclazide
- tolbutamide
- metformin
- insulin

These medicines may be affected by ACTOS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking this medicine.

How to take ACTOS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many ACTOS tablets you should take. The dose your doctor will prescribe for you will usually be in the range of 15 mg to 45 mg per day.

ACTOS tablets should be taken once a day as advised by your doctor. Your doctor may increase or decrease your dose in order to find the appropriate dose for your condition.

How to take it

ACTOS tablets should be swallowed whole with a glass of water.

When to take it

Take your medicine at about the same time each day. This will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do NOT take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the New Zealand National Poisons (0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much ACTOS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking ACTOS

Things you must do

It is important that you remember to take ACTOS daily and at the dose prescribed by your doctor.

Tell any other doctors, dentists and pharmacists who treat you that you are taking ACTOS.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ACTOS.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

You doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you have had unusual weight gain since taking ACTOS. Improved blood sugar control may be associated with weight gain.

Things you must not do

Do not take ACTOS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

ACTOS alone is unlikely to affect your ability to drive or operate machinery. However, be careful driving or operating machinery when using ACTOS in combination with other diabetes medicines.

Side effects

Tell your doctor or pharmacist as soon as possible if you experience any undesirable effect or feel unwell while you are taking ACTOS.

This medicine helps most people with type 2 diabetes not controlled by diet, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Some side effects may be related to the dose of ACTOS. Accordingly, it is important that you tell your doctor as soon as possible about any unwanted effects. Your doctor may then decide to adjust the dose of ACTOS you are taking.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- weight gain
- sore throat and discomfort when swallowing
- cold symptoms
- tooth disorder

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- fluid retention, particularly with swelling of your hands, feet and ankles
- symptoms of hypoglycaemia such as sweating; weakness; hunger; dizziness; trembling; headache; flushing or paleness; numbness; a fast, pounding heart
- urinary tract infection
- shortness of breath with swelling of feet or legs

- nausea; vomiting; loss of appetite; generally feeling unwell; fever; itching; yellowing of the skin and eyes; dark coloured urine

The above list includes serious side effects, which may require medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After using ACTOS

Storage

Keep your tablets in the aluminium blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 30–C.

Do not store ACTOS or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ACTOS or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

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

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

ACTOS is presented in aluminium blister packs containing 28 tablets.

Ingredients

ACTOS contains 15 mg, 30 mg or 45 mg of pioglitazone hydrochloride as the active ingredient. It also contains:

- lactose
- hydroxypropylcellulose
- carmellose calcium
- magnesium stearate

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

ACTOS is supplied in New Zealand by:

Eli Lilly and Company (NZ) Limited

9 Gladding Place, Manukau City
PO Box 97-046, SAMC,
AUCKLAND 1730

⊚ Registered Trademark
This leaflet was prepared in May 2002.



PACKAGE LEAFLET
ACTOS 15 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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Actos 15 mg tablets are and what they are used for
2. Before you take Actos 15 mg tablets
3. How to take Actos 15 mg tablets
4. Possible side effects
5. Storing Actos 15 mg tablets

Actos 15 mg tablets
(Pioglitazone)

The active substance in Actos 15 mg tablets is pioglitazone. Each tablet contains 15 mg pioglitazone. The other ingredients are lactose monohydrate, hydroxypropylcellulose, carmellose calcium and magnesium stearate.

Marketing authorisation holder: Takeda Europe R & D Centre Limited, Savannah House, 11-12 Charles II Street, London SW1Y 4QU, United Kingdom.

Manufacturer: Takeda Ireland Limited, Bray Business Park, Kilruddery, County Wicklow, Ireland. Lilly S.A, Avda. de la Industria 30, 28108 Alcobendas (Madrid), Spain

1. WHAT ACTOS 15 MG TABLETS ARE AND WHAT THEY ARE USED FOR

Actos 15 mg tablets are white to off white, round, convex tablets marked 15 on one face. The tablets are supplied in blister packs of 14, 28, 50, 56 or 98 tablets.

Actos 15 mg tablets are an anti-diabetic medicine used to treat type 2 (non-insulin dependent) diabetes mellitus. This is the diabetes that usually develops in adulthood.

Actos 15 mg tablets 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 15 mg tablets should be used only with metformin or a sulphonylurea which are also oral anti-diabetic medicines.

2. BEFORE YOU TAKE ACTOS 15 MG TABLETS

Do not take Actos 15 mg tablets:

- If you are hypersensitive (allergic) to pioglitazone or any of the other ingredients of Actos 15 mg tablets.
- If you have heart failure.
- If you have liver disease.
- If you are also taking insulin.