

Patient Information

DUETACT™ (doo-et' -ăct)

(pioglitazone hydrochloride and glimepiride) tablets

Read the Patient Information that comes with DUETACT before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment. Always follow the directions given by your doctor.

What is the most important information I should know about DUETACT?

DUETACT may cause or worsen congestive heart failure (“CHF”) in some people. Be sure and tell your doctor if you have congestive heart failure. People with the most serious form of congestive heart failure, called New York Heart Association Class III or IV should not start taking DUETACT. If you have less serious congestive heart failure, called New York Heart Association Class I or II heart failure, your doctor will observe you carefully while taking DUETACT. If you are taking DUETACT and develop serious congestive heart failure, your doctor will decide whether you need to discontinue.

What is DUETACT?

DUETACT contains 2 prescription anti-diabetic medicines, pioglitazone hydrochloride (ACTOS®) and glimepiride (Amaryl®), a sulfonylurea. DUETACT is used with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes who are:

- already taking pioglitazone hydrochloride (ACTOS) and a medicine called a sulfonylurea together
- or
- taking a medicine called a sulfonylurea alone and it is not controlling blood sugar

It is important to eat the right foods, lose weight if needed, and exercise regularly in order to manage your type 2 diabetes. Diet, weight loss, and exercise are the main treatment for type 2 diabetes and they also help your anti-diabetic medicines work better for you.

DUETACT has not been studied in children and is not recommended for children.

Who should not take DUETACT?

Do not take DUETACT if you:

- **have a condition called diabetic ketoacidosis.** Diabetic ketoacidosis should be treated with insulin.
- **are allergic to pioglitazone hydrochloride (ACTOS) or glimepiride.** See the end of this leaflet for a complete list of ingredients in DUETACT.

What should I tell my doctor before taking DUETACT?

Tell your doctor about all of your medical conditions, especially if you:

- **have heart problems or heart failure, especially Class III/IV heart failure since DUETACT can not be started with this condition**
- **have kidney problems**
- **have liver problems**
- **have a type of diabetic eye disease called macular edema** (swelling of the back of the eye).
- **are pregnant or planning to become pregnant.** It is not known if DUETACT can harm your unborn baby. DUETACT is not recommended for pregnant women. Talk to your doctor about the best way to control your blood sugar levels while pregnant.
- **are breastfeeding.** It is not known if DUETACT passes into your milk and if it can harm your baby. You should not take DUETACT if you breastfeed your baby. Talk to your doctor about the best way to control your blood sugar levels while breastfeeding.
- **are a premenopausal woman, even if you do not have regular or any monthly periods.** DUETACT may increase your chances of becoming pregnant. Talk to your doctor about birth control choices while taking DUETACT.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. DUETACT and some of your other medicines can interact with each other. You may need to have your dose of DUETACT or certain other medicines adjusted. Certain other medicines can affect your blood sugar control. Know the medicines you take. Keep a list of them to show your doctor and pharmacist. Talk to your doctor before you start any new medicine.

How should I take DUETACT?

- Take DUETACT exactly as prescribed. Your doctor may need to change your dose to control your blood sugar. Do not change your dose unless told to do so by your doctor.
- DUETACT should be taken once a day with the first main meal.
- Stay on your exercise and diet programs and test your blood sugar regularly while taking DUETACT.
- Your doctor should monitor your diabetes through regular blood tests. Your doctor should also do blood tests before starting DUETACT and from time to time to check your liver, kidneys, and blood cells. Your doctor will also do a regular blood test called a hemoglobin A1C to check how well your blood sugar is controlled.

If you miss a dose of DUETACT, take your tablet as soon as you remember unless it is time to take your next dose. Take your next dose at the usual time. Do not take a double dose to make up for a missed dose.

If you take too much DUETACT, call your doctor or poison control center right away.

What are the possible serious side effects of DUETACT?

- **Heart failure.** DUETACT can cause your body to hold fluid. This can lead to heart failure or make heart failure you already have worse. Call your doctor right away if you have:
 - swelling in your ankles or legs
 - shortness of breath or trouble breathing, especially when you lie down
 - unusual tiredness
 - a sudden increase in weight
- **Due to the sulfonylurea component of DUETACT, there could be an increased chance of death from heart or blood vessel problems** when used instead of treatment with diet alone or diet and insulin to control your high blood sugar levels from diabetes.
- **Low blood sugar (hypoglycemia).** Call your doctor if you get lightheaded, dizzy, shaky, or hungry. These can happen if you skip meals, use another medicine that lowers blood sugar, or if you have certain medical problems. Your dose of DUETACT may need to be changed if these symptoms are a problem for you.
- **Swelling (edema).** DUETACT can cause your body to hold fluid and swell. This can be a problem for people who already have edema.
- **Weight gain.** This is probably due to swelling from extra fluid in your body and extra fat gain.
- **Liver problems.** In rare cases, DUETACT may cause serious liver problems. Your doctor should do blood tests to check your liver before you start DUETACT and regularly during treatment. Call your doctor right away if you get unexplained symptoms such as:
 - nausea or vomiting
 - stomach pain
 - unusual or unexplained tiredness
 - loss of appetite
 - dark urine
 - yellowing of your skin or whites of your eyes
- **Bone fractures.** Some people, particularly women, are at higher risk of having bone fractures while taking DUETACT. Talk to your doctor for advice on how to keep your bones healthy.

Some common side effects of DUETACT are cold-like symptoms, headache, urinary tract infection, diarrhea, nausea, arm or leg pain, and decreased red cell count.

These are not all the side effects of DUETACT. For more information, ask your doctor or pharmacist.

How should I store DUETACT?

Store DUETACT at room temperature, 68° to 77°F, in its original container. Keep container tightly closed and protect from moisture and humidity.

Keep DUETACT and all medicines out of the reach of children.

General information about DUETACT

Medicines are sometimes prescribed for purposes other than those listed in the patient information leaflet. Do not use DUETACT for a condition for which it is not prescribed. Do not share your medicine with other people even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about DUETACT. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DUETACT that is written for health care professionals. You can also get this "prescribing information" by visiting www.actos.com or calling 1-877-825-3327.

What are the ingredients in DUETACT?

Active Ingredients: pioglitazone hydrochloride and glimepiride

Inactive Ingredients: povidone USP, croscarmellose sodium NF, lactose monohydrate NF, magnesium stearate NF, hydroxypropyl cellulose NF, polysorbate 80 NF, and microcrystalline cellulose NF.

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September 2007