

הודעה על החמרה (מידע בטיחות)
(מעודכן 3102.50)

בעלון לרופא

תאריך ___November 27, 2013___

שם תכשיר באנגלית ומספר הרישום : ACTOS Tablets 15, 30 and 45 mg + Actos 15 mg

149 69 33828 00; 30 mg: 149 70 33829 00; 45mg: 149 71 33830 00

שם בעל הרישום Abic Marketing Ltd., POBox 8077, Kiryat Nordau, Netanya, Israel

טופס זה מיועד לפרוט החמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
		Contraindications
		Posology, dosage & administration
<p><i>Fluid retention and cardiac failure</i></p> <p>Pioglitazone can cause fluid retention, which may exacerbate or precipitate heart failure. When treating patients who have at least one risk factor for development of congestive heart failure (e.g. prior myocardial infarction or symptomatic coronary artery disease or the elderly), physicians should start with the lowest available dose and increase the dose gradually. Patients should be observed for signs and symptoms of heart failure, weight gain or oedema; particularly those with reduced cardiac reserve. There have been post-marketing cases of cardiac failure reported when pioglitazone was used in combination with insulin or in patients with a history of cardiac failure. Patients should be observed for signs and symptoms of heart failure, weight gain and oedema when pioglitazone is used in combination with insulin. Since insulin and pioglitazone are both associated with fluid retention, concomitant administration may increase the risk of oedema.</p> <p>Post marketing cases of peripheral oedema and cardiac failure have also been reported in patients with concomitant use of pioglitazone and nonsteroidal anti-inflammatory drugs, including selective COX-2 inhibitors. Pioglitazone should be discontinued if any deterioration in cardiac status occurs.</p> <p>Some epidemiological studies have suggested a similarly increased risk of fracture in both men and women.</p>	<p><i>Fluid retention and cardiac failure</i></p> <p>Pioglitazone can cause fluid retention, which may exacerbate or precipitate heart failure. When treating patients who have at least one risk factor for development of congestive heart failure (e.g. prior myocardial infarction or symptomatic coronary artery disease or the elderly), physicians should start with the lowest available dose and increase the dose gradually. Patients should be observed for signs and symptoms of heart failure, weight gain or oedema; particularly those with reduced cardiac reserve. There have been post-marketing cases of cardiac failure reported when pioglitazone was used in combination with insulin or in patients with a history of cardiac failure. Patients should be observed for signs and symptoms of heart failure, weight gain and oedema when pioglitazone is used in combination with insulin. Since insulin and pioglitazone are both associated with fluid retention, concomitant administration may increase the risk of oedema. Pioglitazone should be discontinued if any deterioration in cardiac status occurs.</p>	Special Warnings and Special Precautions for Use

		Interaction with Other Medicaments and Other Forms of Interaction
		Fertility, Pregnancy and Lactation
<p>⁴ In controlled clinical trials the incidence of reports of heart failure with pioglitazone treatment was the same as in placebo, metformin and sulphonylurea treatment groups, but was increased when used in combination therapy with insulin. In an outcome study of patients with pre-existing major macrovascular disease, the incidence of serious heart failure was 1.6% higher with pioglitazone than with placebo, when added to therapy that included insulin. However, this did not lead to an increase in mortality in this study. In this study in patients receiving pioglitazone and insulin, a higher percentage of patients with heart failure was observed in patients aged ≥ 65 years compared with those less than 65 years (9.7% compared to 4.0%). In patients on insulin with no pioglitazone the incidence of heart failure was 8.2% in those ≥ 65 years compared to 4.0% in patients less than 65 years. Heart failure has been reported rarely with marketing use of pioglitazone, but more frequently when pioglitazone was used in combination with insulin or in patients with a history of cardiac failure.</p>	<p>In controlled clinical trials the incidence of reports of heart failure with pioglitazone treatment was the same as in placebo, metformin and sulphonylurea treatment groups, but was increased when used in combination therapy with insulin. In an outcome study of patients with pre-existing major macrovascular disease, the incidence of serious heart failure was 1.6% higher with pioglitazone than with placebo, when added to therapy that included insulin. However, this did not lead to an increase in mortality in this study. Heart failure has been reported rarely with marketing use of pioglitazone, but more frequently when pioglitazone was used in combination with insulin or in patients with a history of cardiac failure.</p>	Adverse events

בעלון לצרכן

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
		התוויות
		מתי אין להשתמש בתכשיר?
<p>בחולים המטופלים בתרופה זו, במיוחד בנשים, המטופלות בתרופה זו נצפה מספר גבוה של שברים בעצמות. יש להתייעץ עם הרופא</p>	<p>בנשים, המטופלות בתרופה זו נצפה מספר גבוה של שברים בעצמות. יש להתייעץ עם הרופא</p>	<p>אזהרות מיוחדות הנוגעות לשימוש בתרופה:</p>
<p>אם הינך סובל מאצירת נוזלים בגוף או אם הינך סובל מאי ספיקת לב, במיוחד באנשים מעל גיל 75 שנה. במידה והינך נוטל תרופות נוגדי דלקות העלולות גם לגרום לאצירת נוזלים ולנפיחות עליך גם להיוועץ ברופא.</p>	<p>אם הינך סובל מאצירת נוזלים בגוף או אם הינך סובל מאי ספיקת לב, במיוחד באנשים מעל גיל 75 שנה.</p>	<p>אין להשתמש בתרופה מבלי להיוועץ ברופא לפני התחלת הטיפול:</p>
		תגובות בין תרופתיות:
		הריון והנקה:
		כיצד תשתמש בתרופה:
		תופעות לוואי: