Before prescribing Pioglitazone Actavis Group, please read the Summary of Product Characteristics (SmPC)

Educational pack for Pioglitazone Actavis Group

Pioglitazone Actavis Group 15 mg, 30 mg and 45 mg tablets

A review of a possible increased risk of bladder cancer with pioglitazone by the European Medicines Agency (EMA) concluded that, although there is a small risk of bladder cancer with pioglitazone, its benefits continue to outweigh its risks in a limited population of type 2 diabetic patients. A number of recommendations have been made regarding the management of this risk through careful patient selection and ongoing monitoring for efficacy in individual patients.

The {Name of Local medicines agency} has requested that an Educational Pack is provided to all physicians and healthcare professionals expected to prescribe/use Pioglitazone Actavis Group in {Name of country}. This pack provides information on appropriate patient selection, based on the EMA review, the Summary of Product Characteristics (SmPC) and the Package Leaflet.

Healthcare professionals are requested to familiarise themselves with the Summary of Product Characteristics (SmPC) contained in this pack to ensure they are fully aware of ALL risks involved, and to optimise the benefit-risk margin for each patient.

actavis

Risk Minimisation Advice

Bladder cancer, heart failure and use in the elderly

The following information from the Pioglitazone Actavis Group SmPC advises on the selected risks of heart failure and bladder cancer with pioglitazone, and also discusses use in the elderly. Before prescribing Pioglitazone Actavis Group the full SmPC should be consulted (SmPC for Pioglitazone Actavis Group {strength} is included in this pack).

Does the patient suffer from heart failure or have a history of heart failure (NYHA stages I to IV)?

Risk Minimisation Advice (see sections 4.3, 4.4 and 4.8 in SmPC):
- Pioglitazone Actavis Group is contraindicated in patients with cardiac failure or a history of cardiac failure (NYHA stages I to IV).

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.

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.

Does the patient suffer from bladder cancer or have a history of bladder cancer?

Risk Minimisation Advice (see sections 4.3, 4.4 and 4.8 in SmPC):
- Pioglitazone Actavis Group is contraindicated in patients with current bladder cancer or a history of bladder cancer.

Risk factors for bladder cancer should be assessed before initiating pioglitazone treatment (risks include age, smoking history, exposure to some occupational or chemotherapy agents e.g. cyclophosphamide or prior radiation treatment in the pelvic region).

Does the patient have blood in their urine (macroscopic haematuria)?

Risk Minimisation Advice (see sections 4.3 and 4.4 in SmPC):
- Pioglitazone Actavis Group is contraindicated in patients with uninvestigated macroscopic haematuria

Due to its potential association with bladder cancer, any macroscopic haematuria should be investigated before starting pioglitazone therapy. Patients should be advised to promptly seek the attention of their physician if macroscopic haematuria or other symptoms such as dysuria or urinary urgency develop during treatment.

Is the patient over 65 years of age?

Risk Minimisation Advice (see sections 4.2 and 4.4 in SmPC):

In light of age-related risks (especially bladder cancer, fractures and heart failure), the balance of benefits and risks should be considered carefully both before and during treatment in the elderly.

No dose adjustment is necessary for elderly patients. Physicians should start treatment with the lowest available dose and increase the dose gradually, particularly when pioglitazone is used in combination with insulin. Combination use with insulin should be considered with caution in the elderly because of increased risk of serious heart failure (see above precautions for heart failure).

Pioglitazone prescribing guide

After initiation of therapy with pioglitazone, **patients should be reviewed after 3 to 6 months to assess adequacy of responses to treatment** (e.g. reduction in HbA1c). **In patients who fail to show an adequate response, pioglitazone should be discontinued. In light of potential risks with prolonged therapy, prescribers should confirm at subsequent routine reviews that the benefit of pioglitazone is maintained (section 4.1, SmPC).**

Pioglitazone

Pioglitazone should not be used as first line therapy.

Therapeutic indications (section 4.1, SmPC):

Pioglitazone is indicated as second or third line treatment of type 2 diabetes mellitus as described below:

as monotherapy

- in adult patients (particularly overweight patients) inadequately controlled by diet and exercise for whom metformin is inappropriate because of contraindications or intolerance.

as dual oral therapy in combination with

- metformin, in adult patients (particularly overweight patients) with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin.
- a sulphonylurea, only in adult patients who show intolerance to metformin or for whom metformin is contraindicated, with insufficient glycaemic control despite maximal tolerated dose of monotherapy with a sulphonylurea.

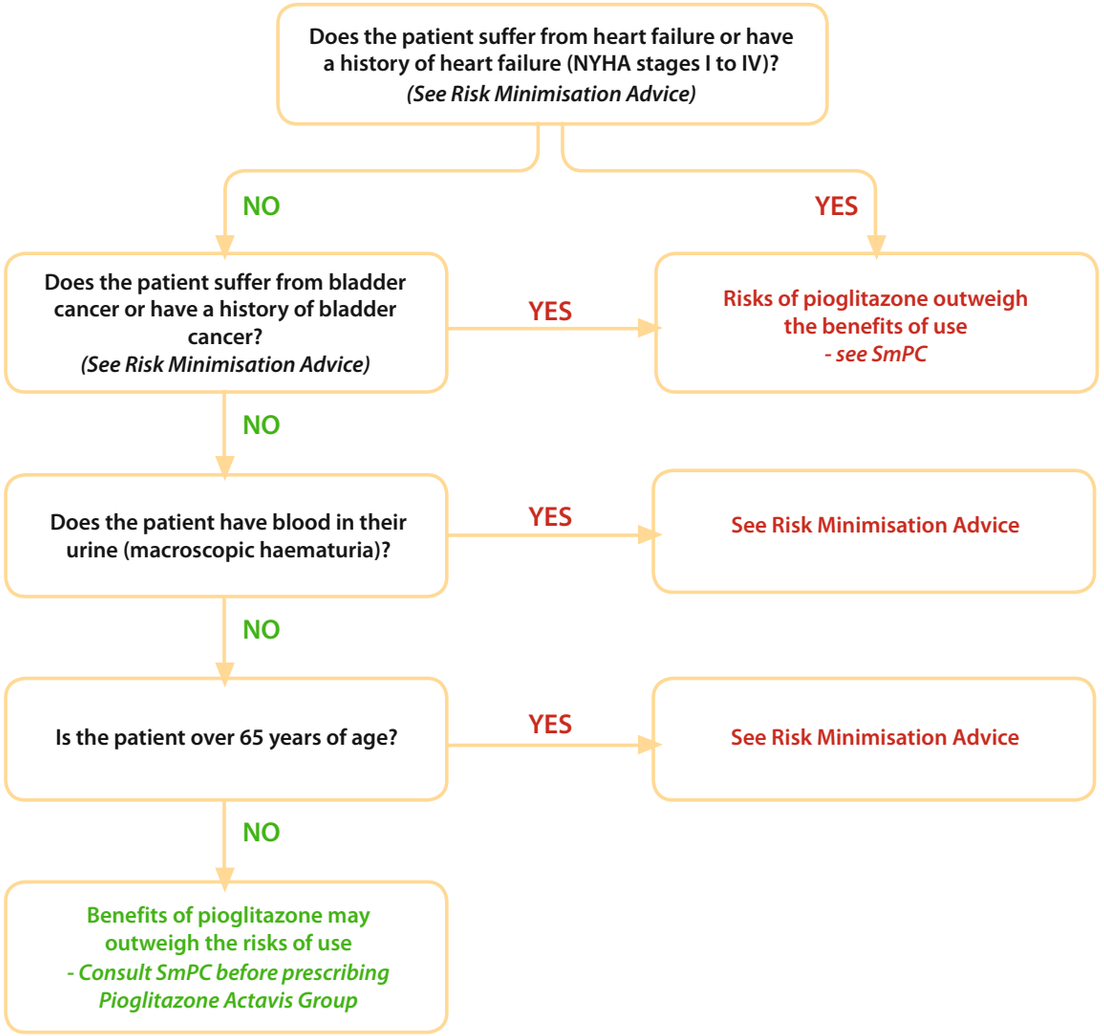
as triple oral therapy in combination with

- metformin and a sulphonylurea, in adult patients (particularly overweight patients) with insufficient glycaemic control despite dual oral therapy.

- Pioglitazone is also indicated for combination with insulin in type 2 diabetes mellitus adult patients with insufficient glycaemic control on insulin for whom metformin is inappropriate because of contraindications or intolerance.

Contraindications (section 4.3, SmPC):

For full set of contraindications, see section 4.3 in the SmPC.



<This educational pack can be downloaded from:
{Local representative website}>

<Adverse events should be reported.><Reporting forms and information can be found at {Local authority website}.> <Adverse events should <also> be reported to <Name of local representative of the MAH><Address><Telephone number> or <e-mail>.>

Marketing Authorisation Holder:
Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland