19 January 2012
EMA/CHMP/644013/2011, rev 1
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Sepioglin

pioglitazone

On 19 January 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted a revised positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sepioglin 15, 30, 45 mg tablet intended for the treatment of type 2 diabetes mellitus. The revision amends the wording of the product information to ensure that the terms of the marketing authorisation are in line with the outcome of the referral of the reference medicinal product. The applicant for this medicinal product is Vaia S.A.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Sepioglin 15, 30, 45 mg tablet is pioglitazone, a drug used in diabetes, blood glucose lowering drugs, excl. insulins (A10BG03) and appears to act via activation of specific nuclear receptors (peroxisome proliferator activated receptor gamma) leading to increased insulin sensitivity of liver, fat and skeletal muscle cells in animals. Treatment with pioglitazone has been shown to reduce hepatic glucose output and to increase peripheral glucose disposal in the case of insulin resistance.

Sepioglin 15, 30, 45 mg tablet is a generic of Actos, which has been authorised in the EU since 13 October 2000. Studies have demonstrated the satisfactory quality of Sepioglin 15, 30, 45 mg tablet and its bioequivalence with the reference product Actos. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Sepioglin 15, 30, 45 mg tablet will be implemented as part of the marketing authorisation.

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

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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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.

After initiation of therapy with pioglitazone, patients should be reviewed after 3 to 6 months to assess adequacy of response 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.

Pioglitazone is contraindicated in patients with:

- hypersensitivity to the active substance or to any of the excipients
- cardiac failure or history of cardiac failure (NYHA stages I to IV)
- hepatic impairment
- diabetic ketoacidosis
- current bladder cancer or a history of bladder cancer
- uninvestigated macroscopic haematuria

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Sepioglin 15, 30, 45 mg tablet and therefore recommends the granting of the marketing authorisation.