BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

JANUVIA 50 mg and XELEVIA 50 mg (sitagliptin), DPP-4 inhibitor

In type 2 diabetics with renal impairment, low actual benefit in monotherapy and in combination with a sulfonylurea
Insufficient actual benefit in combination with insulin

Main points
- In type 2 diabetics with moderate renal impairment for whom metformin is contraindicated, JANUVIA 50 mg and XELEVIA 50 mg have Marketing Authorisation to improve glycaemic control in monotherapy, in dual therapy in combination with a sulfonylurea or with insulin.
- For patients with moderate renal impairment (CrCl ≥ 30 to < 50 ml/min), the dosage is 50 mg sitagliptin once daily.
- In dual therapy with insulin or a sulfonylurea, in the absence of any clinical data, the efficacy/adverse effect ratio of JANUVIA 50 mg and XELEVIA 50 mg is poorly established in type 2 diabetics with moderate renal impairment. Sitagliptin 50 mg can possibly be combined with a sulfonylurea, but is not recommended with insulin.

Other dosage
- There is a 100 mg presentation of JANUVIA and XELEVIA.
- This summary does not cover this indication.

Therapeutic use

The objective of the management of patients with type 2 diabetes and renal impairment is to reduce morbidity and mortality in type 2 diabetes through glycaemic control and through control of the associated cardiovascular risk factors. Poor glycaemic control is a risk factor for progression of the renal disease.

Role of the medicinal product in the therapeutic strategy
- In type 2 diabetic patients with moderate renal impairment for whom metformin is contraindicated, sitagliptin in a dose of 50 mg in monotherapy may be an alternative, particularly where there is a contraindication to sulfonylureas and before the initiation of insulin. In patients placed on dual therapy from the outset on account of poor glycaemic control, the combination of sitagliptin 50 mg + sulfonylurea can be considered before the initiation of insulin with, as an alternative, the combination of insulin + sulfonylurea.
- If moderate renal impairment develops in patients already treated and stabilised on sitagliptin 100 mg in combination with a sulfonylurea, the dose of sitagliptin can be reduced to 50 mg.
- In the absence of any clinical data and any role in the therapeutic strategy for JANUVIA 50 mg and XELEVIA 50 mg in view of the recommended combinations in dual therapy with insulin, namely metformin (except in patients with renal impairment) or a sulfonylurea, JANUVIA and XELEVIA cannot be recommended.

Clinical data
- There are no clinical data on the use of sitagliptin 50 mg in dual therapy in combination with a sulfonylurea or an insulin in type 2 diabetics with chronic moderate renal impairment.
Benefit of the medicinal product

- The actual benefit* of JANUVIA 50 mg and XELEVIA 50 mg is low in monotherapy and in dual oral therapy in combination with a sulfonylurea, and is insufficient in dual therapy with insulin to justify reimbursement by National Health Insurance.

---

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

© Haute Autorité de Santé 2016