HAUTE AUTORITÉ DE SANTÉ

DIABETOLOGY
New indication
October 2014

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

ONGLYZA (saxagliptin),
KOMBOGLYZE (saxagliptin/metformin), antidiabetic

No clinical benefit demonstrated for saxagliptin in combination with metformin and a sulfonylurea

Main points

- ONGLYZA has Marketing Authorisation in combination with metformin and a sulfonylurea when dual therapy with these medicines, diet and exercise have not provided adequate glycaemic control in adult patients with type 2 diabetes.
- The fixed-dose combination KOMBOGLYZE has Marketing Authorisation in combination with a sulfonylurea, in patients not controlled by dual therapy.
- As there are no direct comparisons with validated and available triple therapies, none can be recommended in preference to any of the others.

Pre-existing indications

- ONGLYZA already has Marketing Authorisation in adult patients aged 18 years and older with type 2 diabetes to improve glycaemic control: as monotherapy, as oral dual therapy, as oral triple therapy, in combination with insulin.
- KOMBOGLYZE has Marketing Authorisation in adult patients aged 18 years and older with type 2 diabetes to improve glycaemic control, as an adjunct to diet and exercise, in patients inadequately controlled by the maximum tolerated dose of metformin alone, or those already being treated with the combination of saxagliptin and metformin as separate tablets, in combination with insulin.
- This summary does not cover these indications.

Therapeutic use

- The generally recommended use is first of all monotherapy with metformin, then dual therapy with the combination of metformin and sulfonylurea.
- **Role of the medicinal product in the therapeutic strategy**
  ONGLYZA is a treatment option that can be added to dual therapy with sulfonylurea and metformin, in patients in whom metformin combined with diet and exercise has not provided adequate glycaemic control.

  The fixed-dose combination KOMBOGLYZE is used in combination with a sulfonylurea when dual therapy with metformin and sulfonylurea, plus diet and exercise, has not provided adequate glycaemic control. This proprietary medicinal product is suitable for patients treated with a maximum dosage of 1000 mg metformin administered twice daily.

Clinical data

- A randomised, double-blind, placebo-controlled, parallel-group study evaluated the efficacy and safety over 24 weeks of the addition of saxagliptin (5 mg/day) to treatment with sulfonylurea and metformin which did not provide adequate glycaemic control. A reduction in the HbA1c level showed, by comparison with placebo, a difference between saxagliptin and placebo of -0.66% 95% CI [-0.86; -0.47%] p < 0.0001.
- The adverse events most commonly reported in the saxagliptin group were infections (primarily nasopharyngitis, upper respiratory tract infection and urinary tract infection), gastrointestinal disorders and hypoglycaemic episodes.

Benefit of the medicinal product

- The actual benefit* of ONGLYZA and KOMBOLYZE is substantial.
- As there are no direct comparisons with the validated triple therapies available, ONGLYZA does not provide any clinical added value** (CAV V, none) in the management of patients with type 2 diabetes on triple oral therapy, namely in combination with metformin and a sulfonylurea when dual therapy with these medicines plus diet and exercise do not provide adequate glycaemic control.
- As there are no direct comparisons with the validated triple therapies available and no clinical trials conducted with the fixed-dose combination, KOMBOGLYZE does not provide any clinical added value (CAV V, none) in the management of type 2 diabetes patients as triple oral therapy in combination with a sulfonylurea.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 23 July 2009 (CT-13848 and CT-13849) and is available at **www.has-sante.fr**

[i] * 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 by the National Health Insurance.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".