BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

GALVUS/JALRA (vildagliptin),
EUCREAS/ICANDRA (vildagliptin/metformin), antidiabetics

No clinical added value demonstrated for vildagliptin combined with metformin and a sulfonylurea by comparison with triple therapy in the management of type 2 diabetes

Main points

- GALVUS/JALRA has Marketing Authorisation in combination with metformin and a sulfonylurea when dual therapy with these medicines, diet and exercise do not provide adequate glycaemic control.
- The fixed-dose combination EUCREAS/ICANDRA is indicated in combination with a sulfonylurea (i.e. triple therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulfonylurea.
- 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

- GALVUS/JALRA has Marketing Authorisation in the treatment of type 2 diabetes mellitus in adults as monotherapy, as oral dual therapy.
- EUCREAS/ICANDRA has Marketing Authorisation in the treatment of type 2 diabetes mellitus in adults who have inadequate glycaemic control with the maximum tolerated dose of metformin in monotherapy, in patients already being treated with the combination of vildagliptin and metformin in the form of separate tablets.
- 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 a sulfonylurea.
- **Role of the medicinal product in the therapeutic strategy**
  GALVUS/JALRA 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 sufficient glycaemic control.

The fixed-dose combination EUCREAS/ICANDRA 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 study evaluated the efficacy and safety over 24 weeks of the addition of vildagliptin (50 mg x 2/day) to treatment with sulfonylurea (glimepiride) and metformin which did not provide adequate glycaemic control. It showed a reduction in the HbA1c level in favour of vildagliptin by comparison with placebo, with a difference between vildagliptin and placebo of -0.76% 95% CI [-0.98; -0.53%] \( p < 0.001 \). The mean baseline HbA1c was 8.7% in the vildagliptin group and 8.8% in the placebo group.
- The most commonly reported adverse events in the vildagliptin group were dizziness, hyperhidrosis and urinary tract infections. The incidence of hypoglycaemic episodes was 5.1% in the vildagliptin group versus 1.9% in the placebo group.
Benefit of the medicinal product

- The actual benefit* of GALVUS/JALRA and EUCREAS/ICANDRA is substantial.
- As there are no direct comparisons with the validated triple therapies available, GALVUS/JALRA does not provide any clinical added value** (CAV V, none) in the management of patients with type 2 diabetes mellitus as 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 studies conducted with the fixed-dose combination, the Transparency Committee considers that EUCREAS/ICANDRA does not provide any clinical added value (CAV V, none) in the management of patients with type 2 diabetes mellitus 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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* 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”.

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