HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
8 JULY 2020

The legally binding text is the original French opinion version

insulin aspart
FIASP 100 U/ml solution for injection

New indication

Key points

Favourable opinion for reimbursement in the treatment of diabetes mellitus in adolescents and children aged 1 year and above.

What therapeutic improvement?

No clinical added value compared to NOVORAPID (insulin aspart) in the treatment of diabetes mellitus in adolescents and children aged 1 year and above.

Role in the care pathway?

Type 1 diabetes

Children and adolescents with type 1 diabetes require insulin therapy and nutritional management. There are a number of possible insulin therapy regimens:
- treatment with 2 injections/d: injection of a mixture of fast-acting insulin (or fast-acting analogue) and intermediate-acting insulin,
- treatment with 3, 4 or 5 injections/d: a mixture of fast-acting insulin (or fast-acting analogue) and intermediate-acting insulin is combined with a fast-acting insulin (or fast-acting analogue),

- “basal-bolus” treatment with 3, 4 or 5 injections/d: an intermediate-acting “basal insulin” (twice/d) or a long-acting insulin analogue (once to twice/d) is combined with a fast-acting “prandial insulin” (or fast-acting analogue) injected as a bolus before each of the main meals (3 times/d),
- treatment using a subcutaneous portable pump (continuous infusion with a fixed or variable basic flow rate depending on the time of day or night and bolus at mealtimes). Pump administration requires the use of fast-acting insulin (or fast-acting analogue).

The choice of insulin therapy regimen is dependent on the glycaemic targets for each child and adolescent, their preferences and lifestyle, and those of their family.

Type 2 diabetes

The initial treatment of type 2 diabetes in children and adolescents focuses on lifestyle changes, since type 2 diabetes in children and adolescents is mainly related to being overweight. If these lifestyle changes are not effective, medicinal treatment with metformin (MA in children from 10 years of age and adolescents), and sometimes insulin, may be initiated. In some cases, it may be necessary to temporarily initiate insulin at the start of treatment in the event of severe hyperglycaemia symptoms at the time of diagnosis.

Role of the medicinal product in the care pathway

In the treatment of type 1 diabetes in adolescents and children aged 1 year and above, FIASP (insulin aspart) is a first-line treatment in the context of a basal-bolus regimen.

As a fast-acting insulin, the role of FIASP (insulin aspart) in the care pathway for the treatment of type 2 diabetes in adolescents and children aged 1 year and above is as follows:

- following the failure of lifestyle changes, medicinal treatment with metformin (MA in children from 10 years of age and adolescents,) and sometimes insulin, may be initiated.
- in some cases, it may be necessary to temporarily initiate insulin at the start of treatment in the event of severe hyperglycaemia symptoms at the time of diagnosis.

In the study available, the higher incidence of severe or confirmed nocturnal hypoglycaemia in the FIASP group, particularly with postmeal administration, compared to the NOVORAPID group, with both containing the same active substance (insulin aspart), raises the question of the benefit of its use compared to NOVORAPID (insulin aspart) in a paediatric population.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Diabetes is a chronic disease with potentially serious complications, particularly cardiovascular.
◗These proprietary medicinal products are part of a symptomatic treatment regimen for hyperglycaemia.
◗ The efficacy/adverse effects ratio of these medicinal products is high.
◗ There are therapeutic alternatives.
◗ In the treatment of type 1 diabetes in adolescents and children aged 1 year and above, FIASP (insulin aspart) is a first-line treatment in the context of a basal-bolus regimen.
As a fast-acting insulin, the role of FIASP (insulin aspart) in the care pathway for the treatment of type 2 diabetes in adolescents and children aged 1 year and above is as follows:

- following the failure of lifestyle changes, medicinal treatment with metformin (MA in children from 10 years of age and adolescents,) and sometimes insulin, may be initiated.
- in some cases, it may be necessary to temporarily initiate insulin at the start of treatment in the event of severe hyperglycaemia symptoms at the time of diagnosis.

Public health impact

Considering:

- the seriousness of the disease,
- its prevalence,
- the met medical need,
- the absence of demonstration of an additional impact on morbidity and mortality and on quality of life and hence the absence of an additional response to the already met medical need,
- the absence of data relative to the organisation of care or quality of life and the lack of a demonstrated impact on the patient's care and/or life pathway,

FIASP (insulin aspart) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of FIASP (insulin aspart) is substantial in the treatment of diabetes mellitus in adolescents and children aged 1 year and above.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the treatment of diabetes mellitus in adolescents and children aged 1 year and above and at the MA dosages.

Clinical Added Value

Considering:

- **the demonstration of the non-inferiority and then the superiority of mealtime FIASP (insulin aspart) compared to NOVORAPID (insulin aspart), as well as the non-inferiority of postmeal FIASP (insulin aspart) compared to NOVORAPID (insulin aspart), in terms of change in HbA1c after 26 weeks of treatment (primary endpoint) in a study conducted in children and adolescents with type 1 diabetes,**
- **the availability of efficacy results for an intermediate endpoint only, and the absence of morbidity and mortality data,**
- **the safety profile of FIASP (insulin aspart), which appears to be similar to NOVORAPID (insulin aspart), with, however, more episodes of severe or blood glucose-confirmed hypoglycaemia, particularly for postmeal administration, compared to the NOVORAPID (insulin aspart) group in this same study,**
- **and the absence of quality of life data,**

the Transparency Committee considers that FIASP (insulin aspart) provides no clinical added value (CAV V) compared to NOVORAPID (insulin aspart) in the management of diabetes mellitus in adolescents and children aged 1 year and above.