Key points on this medicine

- **Fiasp®**:  
  - is insulin aspart (NovoRapid®) in a new formulation for the treatment of adults with diabetes who require mealtime insulin
  - has a faster onset of action (onset of appearance in bloodstream is twice as fast) than NovoRapid®, and a greater early glucose-lowering effect compared with NovoRapid® but with similar potency
  - FlexTouch® has price parity with NovoRapid® FlexPen®, offering improved efficacy at no additional cost
  - offers flexible dosing time, and may be administered up to 2 minutes before a meal or up to 20 minutes after starting a meal without compromising HbA₁c

*Fiasp® (post-meal) when compared with NovoRapid® (pre-meal)*

Mode of action

- Fiasp® is a fast-acting insulin aspart formulation; the primary activity of Fiasp® is the regulation of glucose metabolism by binding to insulin receptors. Receptor-bound insulin facilitates cellular uptake of glucose into skeletal muscle and adipose tissue and inhibits the output of glucose from the liver.

Evidence for use

- Fiasp® improved glycaemic control in adults with:
  - type 1 diabetes, demonstrating a statistically significantly greater reduction in HbA₁c and superior PPG control when dosed with a meal vs NovoRapid®, and without an increased risk of hypoglycaemia or weight gain
  - type 2 diabetes, showing non-inferiority to NovoRapid® regarding change in HbA₁c and a statistically significant benefit in 1-hour PPG control vs NovoRapid®, without an increased risk of hypoglycaemia or weight change

  - Compared with NovoRapid®, Fiasp®:
    - has an earlier onset of appearance in the bloodstream (4.9 vs 11.2 minutes)
    - takes less time to reach 50% maximum concentration in the bloodstream (20.7 vs 31.6 minutes).

Clinical considerations

- The 2015/16 National Diabetes Audit revealed that 70.8% of people with type 1 diabetes and 34.3% of people with type 2 diabetes in England and Wales failed to achieve an HbA₁c target of ≤58 mmol/mol (≤7.5%)  

  - In 2015, national HbA₁c targets were lowered to 48 mmol/mol (6.5%) in type 1 diabetes and 53 mmol/mol (7.0%) in type 2 diabetes, which may mean that now even more people are not achieving their targets.

Guidance

SMC

- Following an abbreviated submission, insulin aspart (Fiasp®) is accepted for use within NHS Scotland for the treatment of diabetes mellitus in adults.

AWMSG

- Fiasp® is a new formulation of NovoRapid® with no budget impact, therefore the AWMSG has excluded Fiasp® from formal appraisal.

---

*The potency of insulin analogues, including Fiasp®, is expressed in units; 1 unit of Fiasp® corresponds to 1 international unit of human insulin or 1 unit of other fast-acting insulin analogues*
Mealtime insulin for subcutaneous administration up
FlexPen®
Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd,
Vial
uncommon (≥1/1000 to <1/100)—hypersensitivity,
very common (≥1/10)— hypoglycaemia

Formulation
£14.08
NICE guidance

- NICE recommends the following:
  - (for adults with type 1 diabetes) offer rapid-acting
    insulin analogues injected before meals, rather than
    rapid-acting soluble human or animal insulins, for
    mealtime insulin replacement
  - (for adults with type 2 diabetes) consider starting
    insulin therapy with both NPH and short-acting insulin
    (particularly if the person’s HAβp is 75 mmol/mol
    [9.0%] or higher), administered either: separately or as
    a pre-mixed (biphasic) human insulin preparation.

Undesirable effects

- Adverse reactions:¹
  - very common (≥1/10)—hypoglycaemia
  - common (≥1/100 to <1/10)—allergic skin
    manifestations, injection/infusion site reactions
  - uncommon (≥1/1000 to <1/100)—hypersensitivity,
    lipodystrophy
  - Please refer to the SPC at: www.medicines.org.uk/emc
    for a complete list of precautions and side-effects.¹

References

1. Novo Nordisk Limited. FlexPen 100 units/mL solution for injection—summary of product
3. Monthly Index of Medical Specialities website. MIMS. www.mims.co.uk (accessed 13
   March 2017).
9. NICE. Type 1 diabetes in adults: diagnosis and management. NICE Guideline 17. NICE,
   2015. Available at: www.nice.org.uk/ng17
    Available at: www.nice.org.uk/ng28
12. All Wales Medicines Strategy Group. Medicines excluded by AWMSG and for
    health board consideration of local formulary inclusion (February 2017). Available at:
    www.awmsg.org/awmsgonline/app/reportawmsgexclusion?execution=e6s1

Cost implications³

<table>
<thead>
<tr>
<th>Fiasp®</th>
<th>NovoRapid®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation</td>
<td>Cost</td>
</tr>
<tr>
<td>FlexTouch® (5 x 3 ml pre-filled pen)</td>
<td>£30.60</td>
</tr>
<tr>
<td>Penfill® (5 x 3 ml cartridges)</td>
<td>£28.31</td>
</tr>
<tr>
<td>Vial (1 x 10 ml vial)</td>
<td>£14.08</td>
</tr>
</tbody>
</table>

There are some variations in the clinical indications and licensed ages of these products. See each individual SPC for further information at: www.medicines.org.uk/emc

Fiasp®, FlexTouch®, NovoTwist® and NovoFine® are trademarks owned by Novo Nordisk A/S.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

¹ Please refer to the SPC at: www.medicines.org.uk/emc
² Undesirable effects: Very common (≥1/10): Hypoglycaemia. Common (≥1/100 to <1/10): Allergic skin
   manifestations, injection/infusion site reactions. Uncommon (≥1/1000 to <1/100)—Hypersensitivity,
   Lipodystrophy