

SHARED CARE GUIDELINE ON THE USE OF FIASP® FOR THE MANAGEMENT OF TYPE 1 DIABETES IN ADULTS

INDICATION

Fiasp® is indicated for the treatment of diabetes mellitus in adults.

Special Note: **DMAG has approved the use of Fiasp® for adult patients only where NovoRapid® has been tried and proven to be ineffective.**

[NICE guideline NG17](#); Type 1 diabetes in adults: diagnosis and management states:

'Offer rapid-acting insulin analogues injected before meals, rather than rapid-acting soluble human or animal insulins, for mealtime insulin replacement for adults with T1DM.'

According to the manufacturer Fiasp® has a faster onset of action than NovoRapid®, which improves efficacy by more closely matching the physiological response of endogenous insulin in healthy individuals, and therefore reducing post-prandial hyperglycaemia.

Post-prandial glucose contributes significantly to overall glycaemic control, with a greater relative effect observed when patients are nearing HbA1c levels of 7% (53 mmol/mol). Effective management to avoid post-prandial hyperglycaemia is an important factor for achieving HbA1c targets, reducing the risk of diabetes-related complications. Epidemiological studies have shown a strong association between post-prandial hyperglycaemia and an increased risk of all-cause and cardiovascular-related mortality and increased risk of retinopathy.

Fiasp® effectively improves post-prandial glycaemic control in patients with type 1 diabetes, with a statistically significantly greater reduction in HbA1c when dosed with a meal versus NovoRapid®, and without an apparent increased risk of hypoglycaemia or weight change, the manufacturer claims.

Fiasp® can also be used in insulin pumps, being suitable for insulin infusion.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Fiasp® can be shared between the specialist setting and the patient's GP (if different). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Initiation of Fiasp® should be undertaken by a healthcare professional with experience in prescribing rapid acting insulin with the support of a multi-disciplinary team capable of educating the patient on how to administer and titrate doses.

Initiation would be for:

- Use as an alternative treatment option for adults with type 1 diabetes who require treatment with a mealtime (bolus) insulin, particularly a rapid-acting insulin analogue such as NovoRapid®.

Specialist Responsibilities

1	To assess the patient and the ongoing management of their Type 1 diabetes, determine a management strategy and ensure appropriate follow-up in conjunction with the GP.
2	The specialist will: <ul style="list-style-type: none"> • initiate and stabilise treatment with Fiasp® • obtain consent from the patient's GP to continue prescribing once treatment has been established • monitor the patient and their therapy at least annually
3	To provide the GP with appropriate prescribing information and any additional information requested.
4	To be available for advice if the patient's condition changes.
5	To ensure that procedures are in place for the rapid re-referral of the patient by the GP.
6	To ensure the patient has given informed consent to their treatment.
7	To liaise with the GP on any suggested changes in prescribed therapy.

General Practitioner Responsibilities

1	Initially refer the patient with type 1 diabetes for specialist advice if they are not already under the care of the Specialist Diabetes Team in secondary care.
2	Where appropriate, to continue to prescribe Fiasp® as part of a shared care arrangement, after treatment has been initiated.
3	Deal with general health issues of the patient.
4	Monitor concordance with therapy and raise concerns with the specialist team as appropriate.

Patient's role (or that of carer)

1	Ensure regular monitoring of blood glucose levels to aid titration of insulin dosing and minimise risk of hypoglycaemia.
2	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3	Attend appropriate GP and other follow up appointments.
4	Share any concerns in relation to treatment with Fiasp®
5	Use written and other information provided with the medication and by the healthcare team.
6.	Seek help urgently for episodes of severe hypoglycaemia, or if suspecting adverse effects, or otherwise unwell.

SUPPORTING INFORMATION

Monitoring

Education on how to administer rapid acting insulin analogues is essential prior to commencing therapy, with an understanding of how to titrate insulin according to blood glucose levels.

Dosage and Administration

Fiasp[®] is recommended to be administered subcutaneously in the abdominal wall or the upper arm. Fiasp[®] can be used for CSII in pumps suitable for insulin infusion and will cover both the bolus insulin requirement (approximately 50%) and basal insulin. It can be administered in accordance with the instructions provided by the pump manufacturer, preferably in the abdomen. Infusion site should be rotated within the same region to reduce the risk of lipodystrophy. When used with an insulin infusion pump, it should not be diluted or mixed with any other insulin medicinal products.

The recommended starting dose of Fiasp[®] in insulin naive patients with T1DM is approximately 50% of the total daily insulin dose (i.e., both basal and bolus insulin) and should be divided between the meals based on the size and composition of the meals. The remainder of the total daily insulin dose should be administered as intermediate-acting or long-acting insulin. Generally, 0.2 to 0.4 units of insulin per kilogram of body weight can be used to calculate the initial total daily insulin dose in insulin naive patients with T1DM.

Converting from another mealtime insulin can be done on a unit-to-unit basis. Due to the earlier onset of insulin action, Fiasp[®] should be injected just before (0-2 minutes) the start of the meal, with the option to administer within 20 minutes after starting the meal. Transferring a patient from another type, brand or manufacturer of insulin to Fiasp[®] must be done under medical supervision and may require a change in dosage.

Contraindications

Hypersensitivity to active substance or excipients.

Cautions

The safety of Fiasp[®] has been investigated as part of the onset[®] programme, involving more than 2,100 people with T1DM or T2DM. The safety profile of Fiasp[®] is similar to that of NovoRapid[®]. The NovoRapid[®] molecule has a well-known tolerability profile based on more than 17 years of clinical experience.

Special warnings and precautions for use

Hypoglycaemia

Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement.

Patients, whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia and should be advised accordingly. Usual warning symptoms may disappear in patients with long-standing diabetes. The timing of hypoglycaemia usually reflects the time-action profile of the administered insulin formulation. Hypoglycaemia may occur earlier after an injection/infusion when compared to other mealtime insulins due to the earlier onset of action of Fiasp[®]. Since Fiasp[®] should be administered up to 2 minutes before the start of the meal with the option to administer up to 20 minutes after starting the meal, the time to onset of action must be considered when prescribing to patients with concomitant diseases or treatment where a delayed absorption of food might be expected.

Paediatric population

Hyperglycaemia

The use of inadequate doses or discontinuation of treatment, especially in patients requiring insulin, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. Insulin pump or infusion set malfunctions can lead to a fast onset of hyperglycaemia and ketosis. Prompt identification and correction of the cause of hyperglycaemia or ketosis is necessary. Interim therapy with subcutaneous injection may be required.

Skin and subcutaneous tissue disorders

Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site from an affected to an unaffected area, and dose adjustment of antidiabetic medications may be considered.

Transfer from other insulin medicinal products

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type, origin (animal, human insulin or human insulin analogue) and/or method of manufacture (recombinant DNA versus animal source insulin) may result in the need for a change in dose. Patients transferred to Fiasp® from another type of insulin may require a change in dose from that used with their usual insulin medicinal products

Combination of thiazolidinediones and insulin medicinal products

Cases of congestive heart failure have been reported when thiazolidinediones were used in combination with insulin, especially in patients with risk factors for development of congestive heart failure. This should be kept in mind if treatment with the combination of thiazolidinediones and insulin medicinal products is considered. If the combination is used, patients should be observed for signs and symptoms of congestive heart failure, weight gain and oedema. Thiazolidinediones should be discontinued if any deterioration in cardiac symptoms occurs.

Concomitant illness

Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirements. Concomitant diseases in the kidney, liver or affecting the adrenal, pituitary or thyroid gland may require changes in the insulin dose.

Insulin initiation and glucose control intensification

Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, acute painful peripheral neuropathy, and peripheral oedema. However, long-term glycaemic control decreases the risk of diabetic retinopathy and neuropathy.

Insulin antibodies

Insulin administration may cause insulin antibodies to form. In rare cases, the presence of such insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyper- or hypoglycaemia.

Avoidance of accidental mix-ups/medication errors

Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between this medicinal product and other insulin medicinal products. Patients must visually verify the units of the dose prior to administering. Therefore, the requirement for

patients to self-administer is that they can read the dose scale. Patients, who are blind or have poor vision, must be instructed to always get assistance from another person who has good vision and is trained in administration of insulins.

Considerations in specific populations:

Elderly patients 65 years old: The safety and efficacy of Fiasp[®] has been established in elderly patients aged 65-75 years.

Renal and hepatic impairment: Renal or hepatic impairment may reduce the patient's insulin requirements. Glucose monitoring should be intensified, and the dose adjusted on an individual basis.

Paediatric population: The efficacy and safety of Fiasp[®] has not been established in children and adolescents below 18 years.

Pregnancy: Fiasp[®] can be used in pregnancy.

Side effects

Very common (1/10): Hypoglycaemia. Common (1/100 to <1/10): Allergic skin manifestations, injection/infusion site reactions. Uncommon (1/1,000 to <1/100): Hypersensitivity, lipodystrophy. Anaphylactic reactions have not been reported with Fiasp[®]. With insulin preparations in general, anaphylactic reactions may occur. The Summary of Product Characteristics should be consulted for a full list of adverse reactions.

Interactions

Fiasp[®] to be used as part of basal-bolus regimen with a long-acting basal insulin analogue in the management of type 1 diabetes. Precautions must be undertaken with sensible titration of insulin dosing to avoid hypoglycaemia when using combination insulin therapy.

Several medicinal products are known to interact with the glucose metabolism.

The following substances may reduce insulin requirement:

Oral antidiabetics, monoamine oxidase inhibitors (MAOis), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids, sulphonamides and GLP-1 receptor agonist.

The following substances may increase insulin requirement:

Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

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Beta-blocking agents may mask the symptoms of hypoglycaemia. Octreotide/lanreotide may either increase or decrease the insulin requirement. Alcohol may intensify or reduce the hypoglycaemic effect of insulin

This list is not exhaustive. The manufacturer’s summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Drug costs:

Fiasp® in the FlexTouch® pen is the same price as NovoRapid® in the FlexPen®. Fiasp® Penfill® cartridges and 10mL vials are also available, at the same price as NovoRapid® Penfill® cartridges and 10mL vials.

Cost per pack: Dm+d accessed April 2021

- Fiasp® vial 100 units/mL, solution for injection in vial 10 mL £14.08
- Fiasp® Penfill® 100 units/mL, solution for injection in cartridge 5 x 3 mL £28.31
- Fiasp® FlexTouch® 100 units/mL, solution for injection in pre-filled pen 5 x 3 mL £30.60

References

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Contact for This Policy	Diabetes and Endocrinology Working Group via medicine.question@dorsetccg.nhs.uk	