Dulaglutide (Trulicity®)

Prescribing Information Sheet – Updated November 20

This document provides general prescribing information on the use of Dulaglutide. For the most up to date information, consult the summary of product characteristics

For information on Bedfordshire and Luton Joint Prescribing Committee (JPC) recommendations on place in therapy, prescribing and monitoring requirements and responsibilities, please consult the 'Overarching Shared Care Guideline for the use of Glucagon-like peptide 1 (GLP 1) agonists.' document.

Licensed Indication	Dulaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see SPC .
Drug dose	*Monotherapy* The recommended dose is 0.75 mg once weekly. *Add-on therapy* The recommended dose is 1.5 mg once weekly. For potentially vulnerable populations 0.75 mg once weekly can be considered as a starting dose. For additional glycaemic control, • the 1.5 mg dose may be increased after at least 4 weeks to 3 mg once weekly. • the 3 mg dose may be increased after at least 4 weeks to 4.5 mg once weekly. The maximum dose is 4.5 mg once weekly.
Dose modifications in Special Populations	**Elderly** • No dose adjustments are necessary based on age. **Renal Impairment** • No dose adjustments are necessary in mild, moderate or severe renal impairment but limited experience in patients with end stage renal disease (<15ml/min/1.73m^2), hence it is not recommended in this population. **Hepatic Impairment**

	• No dose adjustments are necessary in Hepatic impairment **Added to other hypoglycaemic agents** When dulaglutide is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued. When dulaglutide is added to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy, the current dose of metformin and/or SGLT2i can be continued. When it is added to existing therapy of a sulphonylurea or insulin, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. The use of dulaglutide does not require blood glucose self-monitoring. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea or insulin, particularly when dulaglutide therapy is started and insulin is reduced. A stepwise approach to insulin dose reduction is recommended.
Administration details	• Dulaglutide is to be injected subcutaneously in the abdomen, thigh or upper arm. • It should not be administered intravenously or intramuscularly. • The dose can be administered at any time of day, with or without meals. • If a dose is missed, it should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If less than 3 days (72 hours) remain before the next scheduled dose, the missed dose should be skipped and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule. • The day of weekly administration can be changed if necessary, as long as the last dose was administered 3 or more days (72 hours) before.
Formulations	Injection, dulaglutide, 4 × 0.75 mg/0.5 mL, pre-filled pen; 4 × 1.5 mg/0.5 mL pre-filled pen
Duration of Action	Dulaglutide starts working after the first administration and this is sustained throughout the once weekly dosing interval.
Contra-indications / Cautions	Dulaglutide is contraindicated in patients who have experienced hypersensitivity to the active substance or to any of the excipients; Dulaglutide is contra-indicated in severe gastro-intestinal disease. Clinicians should refer to the Summary of Product Characteristics (SPC's) or the current electronic BNF for full details. **Cautions** • Dulaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Dulaglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. • Dehydration, sometimes leading to acute renal failure or worsening renal impairment, has been reported in patients treated with dulaglutide, especially at the initiation of treatment.

	Many of the reported adverse renal events occurred in patients who had experienced nausea, vomiting, diarrhoea, or dehydration. **Patients treated with dulaglutide should be advised of the potential risk of dehydration, particularly in relation to gastrointestinal side-effects and take precautions to avoid fluid depletion** • Risk of developing acute pancreatitis with dulaglutide. If pancreatitis is suspected, dulagutide should be discontinued. If pancreatitis is confirmed, dulaglutide should not be restarted • Risk of hypoglycaemia in patients on sulphonylurea or insulin
Side effects	Clinicians should refer to the Summary of Product Characteristics and current electronic BNF for full details. Common or very common side-effects:- Appetite decreased; atrioventricular block; burping; constipation; diarrhoea; fatigue; gastrointestinal discomfort; gastrointestinal disorders; hypoglycaemia; nausea; sinus tachycardia; vomiting The most frequently reported adverse reactions in clinical trials were gastrointestinal, including nausea, vomiting and diarrhoea. In general these reactions were mild or moderate in severity and transient in nature. Results from the long-term cardiovascular outcome study with 4949 patients randomised to dulaglutide and followed for a median of 5.4 years were consistent with these findings. Rarely dulaglutide can cause acute pancreatitis in which case treatment should be discontinued. **Patients should be told how to recognise signs and symptoms of this and to seek medical attention if symptoms such as persistent, severe abdominal pain develop.** **MHRA warning (June 2019)** – GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued. Report all suspected reactions to established drugs that are serious, medically significant, or result in harm to the MHRA using the yellow card scheme. http://yellowcard.mhra.gov.uk/
Drug Interactions	In the clinical pharmacology studies described within the SPC, dulaglutide did not affect the absorption of the orally administered medications tested to any clinically relevant degree. However, for patients receiving oral medicinal products requiring rapid gastrointestinal absorption or prolonged release formulations the potential for altered drug exposure should be considered Clinicians should check the Summary of Product Characteristics (SPC) and the current electronic BNF for a full list of potential drug interactions before starting any new medication or when stopping any existing medication.

Alcohol	There is no specific interaction between dulaglutide and alcohol, however, for general health reasons it recommended that both men and women should drink no more than 14 units / week and they should also have at least two alcohol-free days during the week.
Pregnancy and Breastfeeding	There are no or limited amount of data from the use of dulaglutide in pregnant women. Studies in animals have shown reproductive toxicity. Therefore, the use of dulaglutide is not recommended during pregnancy. It is unknown whether dulaglutide is excreted in human milk. A risk to newborns/infants cannot be excluded. Dulaglutide should not be used during breast-feeding.
Storage Conditions	It is initially necessary to refrigerate dulaglutide (2 °C – 8 °C) but once in use, it may be stored unrefrigerated for up to 14 days below 30 °C.

References:-

1. Summary of Product Characteristics for Trulicity® (Dulaglutide), accessed 29/10/20
2. eBNF, accessed 29/10/20
3. Drug Safety Update, MHRA, June 2019