

Liraglutide (Victoza®)

Prescribing Information Sheet – Updated November 2020

This document provides general prescribing information on the use of liraglutide. For the most up to date information, consult the [summary of product characteristics](#).

For information 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. **NB. Although liraglutide is licensed for use in adults, adolescents and children aged 10 years and above, the JPC recommendations and shared care guidelines apply to use in adults only at the current time.**

Licensed Indication	<p>Liraglutide is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise</p> <ul style="list-style-type: none">• as monotherapy when metformin is considered inappropriate due to intolerance or contraindications• in addition to other medicinal products for the treatment of diabetes. <p>For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see SPC.</p>
Drug dose	<p>Initially 0.6 mg once daily, increased after at least 1 week to 1.2 mg once daily, further increased if necessary after an interval of at least 1 week to max. 1.8 mg once daily. NB – if considering an increase in dose above 1.2 mg – refer to the Specialist Diabetology Team for advice <u>before</u> increasing the dose.</p> <p>Added to other hypoglycaemic agents</p> <p>When liraglutide is added to sulfonylurea therapy or insulin, a reduction in the dose of sulfonylurea or basal insulin should be considered to reduce the risk of hypoglycaemia. Combination therapy with sulfonylurea is only valid for adult patients.</p> <p>Self-monitoring of blood glucose is not needed in order to adjust the dose of liraglutide.</p> <p>Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin, particularly when liraglutide therapy is started and insulin is reduced. A stepwise approach to insulin does reduction is recommended.</p>
Drug modifications in Special Populations	<p>Elderly (>65 years old)</p> <ul style="list-style-type: none">• No dose adjustment is required based on age. <p>Renal Impairment</p> <ul style="list-style-type: none">• No dose adjustment is needed for patients with mild, moderate or severe renal impairment.• There is no therapeutic experience in patients with end-stage renal disease, and liraglutide is therefore not recommended for use in these patients. <p>Hepatic Impairment</p>

	<ul style="list-style-type: none"> No dose adjustment is needed for patients with mild or moderate hepatic impairment The use of liraglutide in patients with severe hepatic impairment is not recommended. <p>Paediatric Population</p> <ul style="list-style-type: none"> No dose adjustment is required for adolescents and children aged 10 years and above No data are available for children below 10 years of age 	
Administration details	<ul style="list-style-type: none"> Liraglutide is administered once daily at any time, independent of meals, and can be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site and timing can be changed without dose adjustment. However, it is preferable that liraglutide is injected around the same time of the day, when the most convenient time of the day has been chosen. Liraglutide must not be administered intravenously or intramuscularly. 	
Formulations	Injection, liraglutide 6 mg/mL, 2 x 3-mL prefilled pens, 3 x 3-mL prefilled pens. Each 3 mL prefilled pen provides 15 doses of 1.2mg, 30 doses of 0.6mg or 10 doses of 1.8mg.	
Contra-indications / Cautions	<p>Clinicians should refer to the current electronic BNF or Summary of Product Characteristics (SPC's) for full details.</p> <p>Contraindications:- severe congestive heart failure—no information available; diabetic ketoacidosis; inflammatory bowel disease; diabetic gastroparesis.</p> <p>Cautions: -; Acute pancreatitis -discontinue if symptoms of acute pancreatitis (persistent, severe abdominal pain) develop; thyroid disease; increased risk of hypoglycaemia when liraglutide is given in combination with insulin or sulfonylurea; dehydration; Liraglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis; Liraglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin.</p> <table border="1" data-bbox="619 1406 1474 1727"> <tr> <td> <p>Acute pancreatitis</p> <p>Patients should be told how to recognise signs and symptoms of acute pancreatitis and advised to seek immediate medical attention if symptoms such as persistent, severe abdominal pain develop.</p> <p>Further advice for patients</p> <p>Manufacturer advises patients and their carers should be informed of the potential risk of dehydration in relation to gastro-intestinal side-effects and advised to take precautions to avoid fluid depletion; they should also be informed of the symptoms of cholelithiasis and cholecystitis, and of increased heart rate.</p> </td> </tr> </table>	<p>Acute pancreatitis</p> <p>Patients should be told how to recognise signs and symptoms of acute pancreatitis and advised to seek immediate medical attention if symptoms such as persistent, severe abdominal pain develop.</p> <p>Further advice for patients</p> <p>Manufacturer advises patients and their carers should be informed of the potential risk of dehydration in relation to gastro-intestinal side-effects and advised to take precautions to avoid fluid depletion; they should also be informed of the symptoms of cholelithiasis and cholecystitis, and of increased heart rate.</p>
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Side effects	<p>Clinicians should refer to the Summary of Product Characteristics (SPC) and current electronic BNF for full details.</p> <p>The most frequently reported adverse reactions during clinical trials were gastrointestinal disorders: nausea and diarrhoea were very common, whereas vomiting, constipation, abdominal pain, and dyspepsia were common. At the beginning of the therapy, these gastrointestinal adverse reactions may occur more frequently. These reactions usually diminish within a few days or weeks on continued</p>	

	<p>treatment. Headache and nasopharyngitis were also common. Hypoglycaemia was common, and very common when liraglutide is used in combination with a sulfonylurea. Severe hypoglycaemia has primarily been observed when combined with a sulfonylurea.</p> <p>If symptoms of acute pancreatitis occur (persistent, severe abdominal pain), then liraglutide should be discontinued.</p> <p>MHRA warning (June 2019) – GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued.</p> <p>Overall, frequency, type and severity of adverse reactions in adolescents and children aged 10 years and above were comparable to that observed in the adult population.</p> <p>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/</p>
Drug Interactions	<p>The small delay of gastric emptying with liraglutide may influence absorption of concomitantly administered oral medicinal products. However, interaction studies did not show any clinically relevant delay of absorption and therefore no dose adjustment is required. Few patients treated with liraglutide reported at least one episode of severe diarrhoea. Diarrhoea may affect the absorption of concomitant oral medicinal products.</p> <p>Paediatric population – interaction studies have only been performed in adults.</p> <p>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.</p>
Pregnancy and breast feeding	<p>Contra-indicated in pregnancy and breast feeding.</p> <p>There are no adequate data from the use of liraglutide in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Liraglutide should not be used during pregnancy, and the use of insulin is recommended instead. If a patient wishes to become pregnant, or pregnancy occurs, treatment with liraglutide should be discontinued.</p> <p>It is not known whether liraglutide is excreted in human milk. Animal studies have shown that the transfer of liraglutide and metabolites of close structural relationship into milk is low. Non-clinical studies have shown a treatment-related reduction of neonatal growth in suckling rat pups (see section). Because of lack of experience, liraglutide should not be used during breast-feeding.</p>
Storage	<p>Liraglutide should be stored in a refrigerator at a temperature between 2°C - 8°C until first use.</p> <p>After the first use, liraglutide can be stored below 30°C or in a refrigerator (for 1 month) but should not be frozen.</p> <p>The cap of the pen should be kept on at all times when it is not in use, in order to protect the drug from light.</p>

References:-

1. [Summary of Product Characteristics for Victoza®](#) (Liraglutide), accessed 29/10/20.
2. [eBNF](#), accessed 29/10/20.
3. [Drug Safety Update, MHRA, June 2019](#)