Prescribing Information
Victoza® Liraglutide.

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

Victoza® 6 mg/ml pre-filled pen
1 ml of solution contains 6 mg of liraglutide. One pre-filled pen contains 18 mg liraglutide in 3 ml.
Indication: 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 SmPC sections 4.4, 4.5 and 5.1.
Posology and administration: Victoza® is administered once daily by subcutaneous injection and at any time independent of meals however it is preferable to inject around the same time of day. Victoza® should not be administered intravenously or intramuscularly. Recommended starting dose is 0.6 mg daily, after at least one week, the dose should be increased to a maintenance dose of 1.2 mg. Based on clinical response, after at least one week the dose can be increased to 1.8 mg. Daily doses higher than 1.8 mg are not recommended. When Victoza® is added to sulfonylurea or insulin, a reduction in dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia. Victoza® can be used in the elderly (>65 years) without dose adjustment. No dose adjustment for patients with mild, moderate or severe renal impairment. There is no therapeutic experience in patients with end-stage renal disease. No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Victoza® is not recommended for use in patients with end-stage renal disease, patients with severe hepatic impairment or children and adolescents <18 years.
Contraindications: Hypersensitivity to the active substance or any of the excipients.
Special warnings and Precautions for use: Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Victoza® is not a substitute for insulin. No experience in patients with New York Heart Association (NYHA) IV and Victoza® is not recommended for use in these patients. Due to limited experience Victoza® is not recommended in patients with inflammatory bowel disease and diabetic gastroparesis since it is associated with transient gastrointestinal (GI) adverse reactions, including nausea, vomiting and diarrhoea. Acute pancreatitis has been observed with the use of GLP-1 receptor agonists; patients should be informed of symptoms of acute pancreatitis. If pancreatitis is suspected, Victoza® should be discontinued. If acute pancreatitis is confirmed, Victoza® should not be restarted. Thyroid adverse events, such as goitre have been reported in clinical trials particularly in patients with pre-existing thyroid disease and Victoza® should be used with caution. Risk of dehydration in relation to GI side effects; take precautions to avoid fluid depletion. Victoza® has no or negligible influence on the ability to drive and use machines. Patients advised to take precautions to avoid hypoglycaemia while driving and using machines, in particular when Victoza® is used in combination with sulfonylurea or insulin. In the absence of compatibility studies Victoza® must not be mixed with other medicinal products.
Fertility, pregnancy and lactation: If a patient wishes to become pregnant, pregnancy occurs or is breast feeding, treatment with Victoza® should be discontinued. Apart from a slight decrease in number of live implants in animal studies no harmful effects on fertility observed.
Undesirable effects: The most frequently observed adverse reactions from long term phase 3a controlled trials, the LEADER trial (a long-term cardiovascular outcome trial) and spontaneous (post-marketing) reports were: Very common (≥1/10): nausea, diarrhoea, hypoglycaemia when used in combination with sulfonylureas. ***Common (≥1/100 to <1/10):*** vomiting, constipation, abdominal pain, discomfort and distension, dyspepsia, gastritis, flatulence, gastroesophageal reflux disease, increased heart rate, toothache, headache, dizziness, nasopharyngitis, bronchitis, hypoglycaemia, anorexia, appetite decreased, fatigue, rash, injection site reactions, increased lipase, increased amylase; GI adverse reactions are more frequent at start of therapy but are usually transient. Patients >70 years or with mild and moderate renal impairment (CrCl 60-90 ml/min and 30-59 ml/min, respectively) may experience more GI effects. Few cases of cholelithiasis and cholecystitis have been reported in phase 3a clinical trials. Dehydration, renal impairment, acute renal failure and malaise were uncommonly reported (≥1/1,000 to <1/100) and intestinal obstruction reported rarely (≥1/10,000 to <1/1,000). Consistent with medicinal products containing proteins/peptides, patients may develop anti-liraglutide antibodies following treatment but this has not been associated with reduced efficacy of Victoza®. Few cases of: angioedema (0.05%), acute pancreatitis (<0.2%), injection site reactions (usually mild, approx. 2%). Allergic reactions (including urticaria, rash and pruritus) and a few cases of anaphylactic reactions (with additional symptoms such as hypotension, palpitations, dyspnoea and oedema) have been reported from marketed use of Victoza®. The Summary of Product Characteristics should be consulted for a full list of side effects.
MA numbers and Basic NHS Price:
2 x 3 ml pre-filled pens EU/1/09/529/002 £78.48;
3 x 3 ml pre-filled pens EU/1/09/529/003 £117.72.
Legal Category: POM.
Further prescribing information can be obtained from: Novo Nordisk Limited, 3 City Place, Beehive Ring Road, Gatwick, West Sussex, RH6 0PA.
Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.