13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84
18	30.00	30.00

4.2 Posology and method of administration

Posology

Adults

The starting dose is 0.6 mg once daily. The dose should be increased to 3.0 mg once daily in increments of 0.6 mg with at least one-week intervals to improve gastro-intestinal tolerability (see table 2). If escalation to the next dose step is not tolerated for two consecutive weeks, consider discontinuing treatment. Daily doses higher than 3.0 mg are not recommended.

Table 2 Dose escalation schedule

	Dose	**Weeks**
Dose escalation 4 weeks	**0.6 mg**	**1**
	1.2 mg	**1**
	1.8 mg	**1**
	2.4 mg	**1**
Maintenance dose	**3.0 mg**	

Adolescents (≥12 years)

For adolescents from the age of 12 to below 18 years old a similar dose escalation schedule as for adults should be applied (see table 2). The dose should be increased until 3.0 mg (maintenance dose) or maximum tolerated dose has been reached. Daily doses higher than 3.0 mg are not recommended.

Missed doses

If a dose is missed within 12 hours from when it is usually taken, the patient should take the dose as soon as possible. If there is less than 12 hours to the next dose, the patient should not take the missed dose and resume the once-daily regimen with the next scheduled dose. An extra dose or increase in dose should not be taken to make up for the missed dose.

Patients with type 2 diabetes mellitus

Saxenda should not be used in combination with another GLP-1 receptor agonist.

When initiating Saxenda, it should be considered to reduce the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of insulin or insulin-secretagogues (see section 4.4).

Special populations

Elderly (≥65 years old)

No dose adjustment is required based on age. Therapeutic experience in patients ≥75 years of age is limited and use in these patients is not recommended (see sections 4.4 and 5.2).

Renal impairment
No dose adjustment is required for patients with mild or moderate renal impairment (creatinine clearance ≥30 ml/min). Saxenda is not recommended for use in patients with severe renal impairment (creatinine clearance <30 ml/min) including patients with end-stage renal disease (see sections 4.4, 4.8 and 5.2).

Hepatic impairment
No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Saxenda is not recommended for use in patients with severe hepatic impairment and should be used cautiously in patients with mild or moderate hepatic impairment (see sections 4.4 and 5.2).

Paediatric population

No dose adjustment is required for adolescents from the age of 12 years and above.
The safety and efficacy of Saxenda in children below 12 years of age has not been established (see section 5.1).

Method of administration

Saxenda is for subcutaneous use only. It must not be administered intravenously or intramuscularly.

Saxenda is administered once daily at any time, independent of meals. It should be injected in the abdomen, thigh or upper arm. The injection site and timing can be changed without dose adjustment. However, it is preferable that Saxenda is injected around the same time of the day, when the most convenient time of the day has been chosen.

For further instructions on administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to liraglutide or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Patients with heart failure

There is no clinical experience in patients with congestive heart failure New York Heart Association (NYHA) class IV, and liraglutide is therefore not recommended for use in these patients.

Special populations

The safety and efficacy of liraglutide for weight management have not been established in patients:
- aged 75 years or more,
- treated with other products for weight management,
- with obesity secondary to endocrinological or eating disorders or to treatment with medicinal products that may cause weight gain,
- with severe renal impairment,
- with severe hepatic impairment.

Use in these patients is not recommended (see section 4.2).