SUMMARY OF PRODUCT CHARACTERISTICS
SEGLIA SC Injection (Semaglutide 1.34 mg/ml Solution for Injection)

1. NAME OF THE MEDICINAL PRODUCT

SEGLIA SC Injection (Semaglutide 1.34 mg/ml Solution for Injection, pre-filled pen)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains 1.34 mg semaglutide. Each dose contains 0.5 mg semaglutide in 0.37 ml solution. For use only with the Biopen flexi pen device. The pen delivers doses of 0.25 mg (19 units) or 0.5 mg (37 units).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection).

Clear, colourless or almost colourless, isotonic solution; pH 7.4.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SEGLIA SC 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.

4.2 Posology and method of administration

Dosing

Starting dose: 0.25 mg semaglutide once weekly. After 4 weeks, increase to 0.5 mg once weekly. After at least 4 weeks at 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control. After at least 4 weeks at 1 mg once weekly, the dose can be increased to 2 mg once weekly if required. 0.25 mg is not a maintenance dose. Weekly doses higher than 2 mg are not recommended.

When semaglutide is added to existing metformin, thiazolidinedione or SGLT2 inhibitor therapy, the current dose of those agents can be continued unchanged. When added to a sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia. A stepwise approach to insulin reduction is recommended.

Missed dose

Administer as soon as possible within 5 days of the missed dose. If more than 5 days have passed, skip the missed dose and resume the regular once-weekly schedule.

Changing the dosing day

The day of weekly administration can be changed as long as the time between two doses is at least 3 days (>72 hours).

Special populations

Elderly: No dose adjustment required based on age alone; therapeutic experience in patients ≥75 years is limited. Renal impairment: No dose adjustment required in mild, moderate or severe renal impairment; semaglutide is not recommended in end-stage renal disease. Hepatic impairment: No dose adjustment required; caution in severe hepatic impairment. Paediatric population: Safety and efficacy in children and adolescents below 18 years have not been established.

Method of administration

Subcutaneous injection in the abdomen, thigh or upper arm. The injection site can be changed without dose adjustment. Semaglutide should not be administered intravenously or intramuscularly. Administer once weekly at any time of day, with or without meals.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

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

Type 1 diabetes and DKA

Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Semaglutide is not a substitute for insulin. DKA has been reported in insulin-dependent patients following rapid discontinuation or dose reduction of insulin when GLP-1 receptor agonist treatment was started.

Heart failure NYHA class IV

There is no experience in patients with NYHA class IV heart failure; semaglutide is not recommended in these patients.

Gastrointestinal effects

GLP-1 receptor agonists may cause gastrointestinal adverse reactions. This should be considered in patients with impaired renal function as nausea, vomiting and diarrhoea may cause dehydration and deterioration of renal function.

Acute pancreatitis

Acute pancreatitis has been observed with GLP-1 receptor agonists. If pancreatitis is suspected, semaglutide should be discontinued; if confirmed, it should not be restarted. Caution should be exercised in patients with a history of pancreatitis.

Hypoglycaemia

Patients treated with semaglutide in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk can be lowered by reducing the dose of sulfonylurea or insulin.

Diabetic retinopathy

In patients with diabetic retinopathy treated with insulin and semaglutide, an increased risk of developing diabetic retinopathy complications has been observed. Caution should be exercised and these patients should be monitored closely. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Semaglutide 2 mg is not recommended in patients with uncontrolled or potentially unstable diabetic retinopathy.

4.5 Interaction with other medicinal products and other forms of interaction

Semaglutide delays gastric emptying and may impact the rate of absorption of concomitantly administered oral medicinal products. Semaglutide should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption.

Paracetamol:

AUC0-60min and Cmax of paracetamol were decreased by 27% and 23% with semaglutide 1 mg. Total paracetamol exposure (AUC0-5h) was not affected. No dose adjustment of paracetamol is necessary.

Oral contraceptives:

Semaglutide did not change ethinylestradiol exposure to a clinically relevant degree; a 20% increase in levonorgestrel exposure was observed at steady state. No dose adjustment is necessary.

Atorvastatin:

Semaglutide did not change the overall AUC of atorvastatin; Cmax was decreased by 38% (assessed as not clinically relevant).

Warfarin:

Semaglutide did not change overall R- or S-warfarin exposure; INR was not clinically relevantly affected. However, upon initiation, frequent INR monitoring is recommended in patients on warfarin or other coumarin derivatives.

Digoxin and metformin:

No clinically meaningful interaction observed.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Women of childbearing potential are recommended to use contraception when treated with semaglutide.

Pregnancy

Animal studies have shown reproductive toxicity. There are limited data from the use of semaglutide in pregnant women. Semaglutide should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, semaglutide should be discontinued at least 2 months before a planned pregnancy (due to the long half-life of approximately 1 week).

Breast-feeding

In lactating rats, semaglutide was excreted in milk. As a risk to a breast-fed child cannot be excluded, semaglutide should not be used during breast-feeding.

Fertility

The effect of semaglutide on fertility in humans is unknown. In female rats, an increase in oestrous length and a small reduction in number of ovulations were observed at doses associated with maternal body weight loss; male fertility was unaffected.

4.7 Effects on ability to drive and use machines

Semaglutide has no or negligible influence on the ability to drive or use machines. When used in combination with a sulfonylurea or insulin, patients should take precautions to avoid hypoglycaemia while driving and using machines.

4.8 Undesirable effects

Summary of the safety profile

In phase 3a trials (n=4,792 patients exposed to semaglutide up to 1 mg), the most frequently reported adverse reactions were gastrointestinal disorders including nausea (very common), diarrhoea (very common) and vomiting (common). These reactions were generally mild or moderate in severity and of short duration.

System Organ Class	Very common	Common	Uncommon	Rare	Not known
Immune system			Hypersensitivity	Anaphylactic reaction	
Metabolism	Hypoglycaemia (with insulin/SU)	Hypoglycaemia (other OADs); decreased appetite			
Nervous system		Dizziness	Dysgeusia		
Eye disorders		Diabetic retinopathy complications			
Cardiac			Increased heart rate		
Gastrointestinal	Nausea, diarrhoea	Vomiting, abdominal pain, distension, constipation, dyspepsia, gastritis, GERD, eructation, flatulence	Acute pancreatitis; delayed gastric emptying		
Hepatobiliary		Cholelithiasis			
Skin					Angioedema
General		Fatigue	Injection site reactions		
Investigations		Increased lipase, increased amylase, weight decreased			

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Overdoses of up to 4 mg in a single dose and up to 4 mg in a week have been reported in clinical trials; the most commonly reported adverse reaction was nausea, and all patients recovered without complications. There is no specific antidote. In the event of overdose, appropriate supportive treatment should be initiated. A prolonged period of observation may be necessary, taking into account the long half-life of approximately 1 week.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in diabetes, glucagon-like peptide-1 (GLP-1) analogues. ATC code: A10BJ06.

Semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1. It acts as a GLP-1 receptor agonist, selectively binding to and activating the GLP-1 receptor. GLP-1 has multiple actions in glucose and appetite regulation and in the cardiovascular system. Semaglutide reduces blood glucose in a glucose-dependent manner by stimulating insulin secretion and lowering glucagon secretion when blood glucose is high. It also reduces body weight and body fat mass through lowered energy intake, and reduces preference for high-fat foods.

SUSTAIN programme: In six phase 3a trials (4,107 patients treated with semaglutide), semaglutide 0.5 mg and 1 mg demonstrated sustained, statistically superior and clinically meaningful reductions in HbA1c and body weight for up to 2 years compared to placebo, sitagliptin, insulin glargine, exenatide ER and dulaglutide. SUSTAIN FORTE: Semaglutide 2 mg demonstrated statistically superior HbA1c reduction vs semaglutide 1 mg at week 40 (-2.2% vs -1.9%). SUSTAIN 6 (cardiovascular outcomes trial): In 3,297 patients at high cardiovascular risk over 104 weeks, semaglutide reduced the composite primary outcome of cardiovascular death, non-fatal MI or non-fatal stroke by 26% vs placebo (HR 0.74, $p<0.001$ for non-inferiority; $p=0.02$ for superiority).

5.2 Pharmacokinetic properties

Absorption

Semaglutide has a prolonged half-life of approximately 1 week due to albumin binding, which reduces renal clearance and protection from metabolic degradation. Maximum concentration is reached 1–3 days post-dose; steady-state exposure achieved after 4–5 weeks of once-weekly administration. Mean steady-state concentrations following 0.5 mg and 1 mg are approximately 16 nmol/L and 30 nmol/L, respectively. Absolute bioavailability of subcutaneous semaglutide is 89%. Similar exposure is achieved with subcutaneous administration in the abdomen, thigh or upper arm. Administration with food has no clinically significant impact.

Distribution

Mean volume of distribution approximately 12.5 L. Extensively bound to plasma albumin (>99%).

Biotransformation

Extensively metabolised through proteolytic cleavage of the peptide backbone and sequential beta-oxidation of the fatty acid side chain. The enzyme neutral endopeptidase (NEP) is expected to be involved.

Elimination

Approximately 2/3 of semaglutide-related material is excreted in urine and approximately 1/3 in faeces; approximately 3% of the dose is excreted as intact semaglutide via urine. Clearance approximately 0.05 L/h. With an elimination half-life of approximately 1 week, semaglutide will be present in the circulation for about 5 weeks after the last dose.

Special populations

Age, gender, race and ethnicity have no clinically significant effect on semaglutide pharmacokinetics. Body weight affects exposure (higher body weight results in lower exposure). Renal impairment does not impact semaglutide pharmacokinetics in a clinically relevant manner. Hepatic impairment does not affect semaglutide exposure.

5.3 Preclinical safety data

Non-lethal thyroid C-cell tumours observed in rodents are a class effect for GLP-1 receptor agonists; the relevance to humans is considered low but cannot be completely excluded. In embryo-foetal development studies in rats, semaglutide caused embryotoxicity at clinically relevant exposures, including major skeletal and visceral malformations; this mechanism (GLP-1 receptor-mediated impairment of nutrient supply via rat yolk sac) is considered unlikely to be relevant to humans. In rabbits and cynomolgus monkeys, increased pregnancy loss and slightly increased foetal abnormalities were observed at clinically relevant exposures. In juvenile rats, semaglutide caused delayed sexual maturation without impact on subsequent fertility. Semaglutide had no genotoxic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol, disodium phosphate dihydrate, phenol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

18 months. After first use: use within 6 weeks.

6.4 Special precautions for storage

Store in a refrigerator (2°C–8°C). Do not freeze. Keep the pen cap on to protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container

3 ml glass cartridge (Type I glass) assembled into a disposable pre-filled pen device. The pen is for use by one person only. To be used only with the Biopen flexi pen device.

6.6 Special precautions for disposal and other handling

The patient should be advised to discard the injection needle after each injection and store the pen without a needle attached. This prevents blocked needles, contamination, infection, leakage and inaccurate dosing. Needles and other waste material should be disposed of in accordance with local requirements.

Do not use if the solution does not appear clear and colourless or almost colourless. Do not use if the product has been frozen.

7. MARKETING AUTHORISATION HOLDER

DAWA LIMITED

Plot No. 7879/8, Baba Dogo Road, Ruaraka,

P.O. Box 16633-00620, Nairobi, Kenya.

Manufacturer: ADVANCED CHEMICAL INDUSTRIES LIMITED

7, Hajeegonj Road, Godnyle, Narayanganj, Bangladesh.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12458/25863

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

17.01.2026

10. DATE OF REVISION OF THE TEXT

17.01.2026