***Public Assessment Report***

**WEGOVY®**

## INFORMASI PRODUK

| | | |
|---|---|---|
| Nama Obat | : | **WEGOVY®** |
| Zat Aktif | : | Tiap ml mengandung:<br>Semaglutide 0,68 mg<br>Semaglutide 1,34 mg<br>Semaglutide 2,27 mg<br>Semaglutide 3,2 mg |
| Bentuk Sediaan | : | Larutan injeksi |
| Kemasan | : | 1. Dus, 1 cartridge @ 1,5 ml *in pre-filled pen* (FlexTouch®) (0,25 mg/dosis) + 4 jarum NovoFine® Plus<br>2. Dus, 1 cartridge @ 1,5 ml *in pre-filled pen* (FlexTouch®) (0,5 mg/dosis) + 4 jarum NovoFine® Plus<br>3. Dus, 1 cartridge @ 3 ml *in pre-filled pen* (FlexTouch®) (1 mg/dosis) + 4 jarum NovoFine® Plus<br>4. Dus, 1 cartridge @ 3 ml *in pre-filled pen* (FlexTouch®) (1,7 mg/dosis) + 4 jarum NovoFine® Plus<br>5. Dus, 1 cartridge @ 3 ml *in pre-filled pen* (FlexTouch®) (2,4 mg/dosis) + 4 jarum NovoFine® Plus |
| Pendaftar | : | PT Beta Pharmacon, Karawang |
| Produsen | : | Novo Nordisk A/S, Bagsvaerd, Denmark |
| Kategori Registrasi | : | Registrasi produk biologi dengan indikasi dan posologi baru |
| Indikasi yang diajukan: | : | *Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of:*<br>• *≥ 30 kg/m2 (obesity), or*<br>• *≥ 27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.* |
| Posologi yang diajukan | : | *The maintenance dose of semaglutide 2.4 mg once-weekly is reached by starting with a dose of 0.25 mg. To reduce the likelihood of gastrointestinal symptoms, the dose should be escalated over a 16-week period to a maintenance dose of 2.4 mg once weekly (see Table 1). In case of significant gastrointestinal symptoms, consider delaying dose escalation or lowering to the previous dose until symptoms have improved.* |

*Table 1 Dose escalation schedule*

| ***Dose escalation*** | ***Weekly dose*** |
|---|---|
| *Week 1–4* | *0.25 mg* |
| *Week 5–8* | *0.5 mg* |
| *Week 9–12* | *1 mg* |
| *Week 13–16* | *1.7 mg* |
| ***Maintenance dose*** | *2.4 mg* |

*Weekly doses higher than 2.4 mg are not recommended.*

*Patients with type 2 diabetes*

*When initiating semaglutide in patients with type 2 diabetes, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia,*

*see section 4.4.*

*Missed dose*
*If a dose is missed, it should be administered as soon as possible and within 5 days after the missed dose. If more than 5 days have passed, 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. If more doses are missed, reducing the starting dose for re-initiation should be considered.*

*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 greater sensitivity of some older individuals cannot be excluded.*

*Patients with renal impairment*
*No dose adjustment is required for patients with mild or moderate renal impairment. Experience with the use of semaglutide in patients with severe renal impairment is limited. Semaglutide is not recommended for use in patients with severe renal impairment (eGFR < 30 mL/min/1.73m$^2$) including patients with end-stage renal disease (see sections 4.4, 4.8 and 5.2).*

*Patients with hepatic impairment*
*No dose adjustment is required for patients with mild or moderate hepatic impairment. Experience with the use of semaglutide in patients with severe hepatic impairment is limited. Semaglutide 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*
*The safety and efficacy of semaglutide in children and adolescents below 18 years have not yet been established. No data are available.*

*Method of administration*
*Subcutaneous use.*
*Wegovy® is administered once weekly at any time of the day, with or without meals.*
*It is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site can be changed. It should not be administered intravenously or intramuscularly.*
*The day of weekly administration can be changed if necessary, as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once-weekly dosing should be continued.*
*When administering Wegovy®, the pen should be pressed firmly against the skin until the yellow bar has stopped moving. The injection takes about 5–10 seconds.*
*Patients should be advised to read the 'Instructions on how to use Wegovy® pen' on the other side of this leaflet carefully before administering the medicinal product.*
*For further information before administration see section 6.6.*

**PENGANTAR**

Semaglutide merupakan suatu analog *glucagon-like peptide-1* (GLP-1) dengan 94% sekuen homolog dengan GLP-1 manusia. Injeksi semaglutide telah disetujui di Indonesia dengan nama produk Ozempic® untuk indikasi diabetes mellitus tipe 2. Saat ini injeksi semaglutide kembali didaftarkan dengan nama produk yang baru yaitu Wegovy® dengan indikasi dan posologi yang baru. Adapun persamaan dan perbedaan antara Ozempic® dan Wegovy® adalah sebagai berikut.

| | **Ozempic®** | **Wegovy®** |
|---|---|---|
| Zat Aktif | Semaglutide | Semaglutide |
| Kekuatan | • 1,34 mg/ml (2 mg/1,5 ml)<br>• 1,34 mg/ml (4 mg/3 ml) | • 0,68 mg/ml (1 mg/1,5 ml)<br>• 1,34 mg/ml (2 mg/1,5 ml)<br>• 1,34 mg/ml (4 mg/3 ml)<br>• 2,27 mg/ml (6,8 mg/3 ml)<br>• 3,2 mg/ml (9,6 mg/3 ml) |
| Kemasan | • Dus, 1 cartridge @ 1,5 ml *in pre-filled pen* (0,25 mg; 0,5 mg/dosis) + 6 jarum NovoFine® Plus<br>• Dus, 1 cartridge @ 3 ml *in prefilled pen* (1 mg/dosis) + 4 jarum NovoFine® Plus | • Dus, 1 cartridge @ 1,5 ml *in pre-filled pen* (FlexTouch®) (0,25 mg/dosis) + 4 jarum NovoFine® Plus<br>• Dus, 1 cartridge @ 1,5 ml *in pre-filled pen* (FlexTouch®) (0,5 mg/dosis) + 4 jarum NovoFine® Plus<br>• Dus, 1 cartridge @ 3 ml *in pre-filled pen* (FlexTouch®) (1 mg/dosis) + 4 jarum NovoFine® Plus<br>• Dus, 1 cartridge @ 3 ml *in pre-filled pen* (FlexTouch®) (1,7 mg/dosis) + 4 jarum NovoFine® Plus<br>• Dus, 1 cartridge @ 3 ml *in pre-filled pen* (FlexTouch®) (2,4 mg/dosis) + 4 jarum NovoFine® Plus |
| Pendaftar | PT Beta Pharmacon | PT Beta Pharmacon |
| Produsen Zat Aktif | Novo Nordisk A/S, Kalundborg, Denmark<br>Novo Nordisk A/S, Bagsvaerd, Denmark | Novo Nordisk A/S, Kalundborg, Denmark<br>Novo Nordisk A/S, Bagsvaerd, Denmark |
| Produsen Produk Jadi | Novo Nordisk A/S, Bagsvaerd, Denmark | Novo Nordisk A/S, Bagsvaerd, Denmark |
| Indikasi yang Disetujui | *Ozempic® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise in addition to metformin, metformin and sulphonylurea, metformin and basal insulin, or sodium-glucose cotransporter 2 (SGLT2) inhibitor.*<br><br>*For trial results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied,* see *sections 4.4, 4.5 and 5.1* | *Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of*<br>• *≥30 kg/m2 (obesity), or*<br>• *≥27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.*<br><br>*<u>Limitation of Use</u>*<br>*Wegovy® contains semaglutide and should not be co-administered with other semaglutide containing products or with any other GLP-1 receptor agonist.* |

**Dirilis Badan POM 18 Juni 2024**

<table>
<tr><th></th><th>Ozempic®</th><th>Wegovy®</th></tr>
<tr><td></td><td></td><td>The safety and effectiveness of Wegovy® in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.<br>Wegovy® has not been studied in patients with a history of pancreatitis (see section 4.4)</td></tr>
<tr><td>Posologi yang Disetujui</td><td>The starting dose is 0.25 mg semaglutide once weekly. After 4 weeks the dose should be increased to 0.5 mg once weekly. After at least 4 weeks with a dose of 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control.<br><br>Semaglutide 0.25 mg is not a maintenance dose. Weekly doses higher than 1 mg are not recommended.<br><br>When Ozempic® is added to existing metformin therapy or to a SGLT2 inhibitor, the current dose of metformin or SGLT2 inhibitor can be continued unchanged.<br><br>When Ozempic® is added to existing therapy of sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia (see sections 4.4 and 4.8).<br><br>Self-monitoring of blood glucose is not needed in order to adjust the dose of Ozempic®. Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin, particularly when Ozempic® is started and insulin is reduced. A stepwise approach to insulin reduction is recommended.<br><br><u>Missed dose</u><br>If a dose is missed, it should be administered as soon as possible and within 5 days after the missed dose. If more than 5 days have passed, 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.</td><td>The maintenance dose of semaglutide 2.4 mg once-weekly is reached by starting with a dose of 0.25 mg. To reduce the likelihood of gastrointestinal symptoms, the dose should be escalated over a 16-week period to a maintenance dose of 2.4 mg once weekly (see Table 1). In case of significant gastrointestinal symptoms, consider delaying dose escalation or lowering to the previous dose until symptoms have improved.<br><br>Table 1 Dose escalation schedule<br><table><tr><td>Dose escalation</td><td>Weekly dose</td></tr><tr><td>Week 1 – 4</td><td>0.25 mg</td></tr><tr><td>Week 5 – 8</td><td>0.5 mg</td></tr><tr><td>Week 9 – 12</td><td>1 mg</td></tr><tr><td>Week 13 – 16</td><td>1.7 mg</td></tr><tr><td>Maintenance dose</td><td>2.4 mg</td></tr></table><br>Weekly doses higher than 2.4 mg are not recommended.<br><br>Patients with type 2 diabetes<br>When initiating semaglutide in patients with type 2 diabetes, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia, see section 4.4.<br>Clinical data on efficacy and safety are limited to 68 weeks.<br><br>Missed dose<br>If a dose is missed, it should be administered as soon as possible and within 5 days after the missed dose. If more than 5 days have passed, 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. If more doses are missed, reducing the starting dose for re-initiation should be considered.</td></tr>
</table>

| | Ozempic® | Wegovy® |
|---|---|---|
| | *Changing the dosing day*<br>*The day of weekly administration can be changed if necessary, as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once-weekly dosing should be continued.*<br><br>*Special populations*<br>*Elderly*<br>*No dose adjustment is required based on age. Therapeutic experience in patients ≥ 75 years of age is limited (see section 5.2).*<br><br>*Renal impairment*<br>*No dose adjustment is required for patients with mild, moderate or severe renal impairment. Experience with the use of semaglutide in patients with severe renal impairment is limited. Semaglutide is not recommended for use in patients with end-stage renal disease (see section 5.2).*<br><br>*Hepatic impairment*<br>*No dose adjustment is required for patients with hepatic impairment. Experience with the use of semaglutide in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with semaglutide (see section 5.2).*<br><br>*Paediatric population*<br>*The safety and efficacy of semaglutide in children and adolescents below 18 years have not yet been established. No data are available.*<br><br>*Method of administration*<br>*Subcutaneous use.*<br>*Ozempic® is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site can be changed without dose adjustment. Ozempic® should not be administered intravenously or intramuscularly.*<br>*Ozempic® is to be administered once weekly at any time of the day, with or without meals.*<br>*For further information on administration, see section 6.6.* | *Special populations*<br>*Elderly (≥65 years old)*<br>*No dose adjustment is required based on age. Therapeutic experience in patients ≥75 years of age is limited, and greater sensitivity of some older individuals cannot be excluded.*<br><br>*Patients with renal impairment*<br>*No dose adjustment is required for patients with mild or moderate renal impairment. Experience with the use of semaglutide in patients with severe renal impairment is limited. Semaglutide is not recommended for use in patients with severe renal impairment (eGFR <30 mL/min/1.73m2) including patients with end-stage renal disease (see sections 4.4, 4.8 and 5.2).*<br><br>*Patients with hepatic impairment*<br>*No dose adjustment is required for patients with mild or moderate hepatic impairment. Experience with the use of semaglutide in patients with severe hepatic impairment is limited. Semaglutide 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).*<br><br>*Paediatric population*<br>*The safety and efficacy of semaglutide in children and adolescents below 18 years have not yet been established. No data are available.*<br><br>*Method of administration*<br>*Subcutaneous use.*<br>*Wegovy® is administered once weekly at any time of the day, with or without meals. It is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site can be changed. It should not be administered intravenously or intramuscularly.*<br>*The day of weekly administration can be changed if necessary, as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once-weekly dosing should be continued.*<br>*Patients should be advised to read the instruction for use included in the package* |

| | Ozempic® | Wegovy® |
|---|---|---|
| | | *leaflet carefully before administering the medicinal product.*<br>*For further information before administration see section 6.6.* |

**ASPEK MUTU**

Produk jadi Wegovy® tersedia dalam bentuk larutan injeksi yang mengandung 0,68 mg/ml; 1,34 mg/ml; 2,27 mg/ml dan 3,2 mg/ml semaglutide. Produk ini harus disimpan pada suhu 2-8°C (sebelum dibuka) dan jangan dibekukan. Wegovy® dikemas dalam sediaan *pre-filled pen* yang di dalamnya terdapat cartridge gelas tipe 1 ukuran 1,5 ml dan 3 ml. Obat jadi mengandung eksipien yang terdiri atas *disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid, sodium hydroxide* dan *water for injection.*

**Zat Aktif**

Zat aktif yang digunakan pada Wegovy® sama dengan zat aktif yang digunakan pada Ozempic®.

**Obat Jadi**

Proses produksi Wegovy® dilakukan di Novo Nordisk A/S, Denmark pada skala 300 L untuk semaglutide 0,68 mg/ml; 2,27 mg/ml dan 3,2 mg/ml, sedangkan untuk semaglutide 1,34 mg/ml pada skala 1000 L.

Proses produksi secara umum terdiri atas tahap *dissolution, volume adjustment, pH adjustment if necessary, volume adjustment, sterile filtration, filling* dan *cartridges closed*. Proses produksi diserahkan dengan rincian yang memadai. Tahapan kritis proses telah diidentifikasi dan kontrol beserta rentang penerimaannya telah ditetapkan. Validasi terhadap proses produksi telah dilakukan mencakup proses formulasi *bulk* produk jadi, *filling, assembly* dan validasi *media fill*. Hasil validasi menunjukan kemampuan proses menghasilkan obat jadi yang memenuhi kriteria penerimaan yang ditetapkan.

Spesifikasi obat jadi telah ditetapkan mencakup parameter uji, referensi metode uji serta kriteria penerimaannya. Prosedur uji telah divalidasi. Parameter dalam spesifikasi dipilih dengan mempertimbangkan antara lain hasil uji bets yang digunakan dalam uji klinik, data stabilitas jangka panjang, variabilitas proses produksi maupun metode analisis dan data pengembangan proses yang relevant.

Data stabilitas obat jadi mendukung penyimpanan obat jadi selama 36 bulan pada suhu 2-8°C dan jangan dibekukan.

Kesimpulan

Dari aspek mutu, Wegovy® dapat dipertimbangkan untuk diterima.

**ASPEK KHASIAT DAN KEAMANAN**

Efikasi dan keamanan semaglutide untuk menurunkan berat badan dapat ditunjukkan melalui studi NN9536-4153 (studi fase 2), NN9536-4373 (STEP 1), NN9536-4374 (STEP 2), NN9536-4375 (STEP 3), NN9536-4376 (STEP 4) dan NN9535-3744 (SUSTAIN 6) sebagai berikut:

1. Efikasi
   a. Berdasarkan hasil studi NN9536-4153, semaglutide dosis 0,2 mg; 0,3 mg dan 0,4 mg per hari lebih baik dibandingkan dengan liraglutide 3 mg per hari dalam menurunkan berat badan selama 52 minggu (*Estimated Treatment Difference (ETD)* semaglutide 0,2 mg – liraglutide 3 mg yaitu -3,83 (95% CI -6,18; -1,49), semaglutide 0,3 mg – liraglutide 3 mg yaitu -3,41 (95% CI -5,75; -1.06), semaglutide 0,4 mg – liraglutide 3 mg yaitu -6.08 (95% CI -8,41; -3,75)).
   b. Hasil studi NN9536-4373 (STEP 1) dan NN9536-4376 (STEP 4) menunjukkan efikasi semaglutide dengan dosis inisial 0,25 mg seminggu sekali yang dititrasi setiap 4 minggu selama 16 minggu hingga mencapai 2,4 mg seminggu sekali, yang disertai diet rendah kalori dan aktifitas fisik, menunjukkan penurunan berat badan yang lebih tinggi dari plasebo. Pemberian semaglutide selama 68 minggu (STEP 1) menunjukkan penurunan berat badan yang lebih tinggi

dibanding pemberian semaglutide selama 20 minggu (STEP 4). Hasil penurunan berat badan dari baseline pada semaglutide vs plasebo sebagai berikut:

- Studi NN9536-4373 (STEP 1): -14,85% vs -2,41% (ETD -12,44; 95% CI -13,37; -11,51)
- Studi NN9536-4376 (STEP 4): -7,88% vs 6,87% (ETD -14,75; 95% CI -16.00; -13,50)

c. Hasil studi NN9536-4375 (STEP 3) menunjukkan pada pemberian semaglutide 2,4 mg seminggu sekali selama 68 minggu yang disertai *Intensive Behavioural Therapy* (IBT) terjadi penurunan berat badan yang lebih tinggi dari plasebo yaitu -15,97% vs -5,70% (ETD -10,27; 95% CI -11.97; -8.57).

d. Hasil studi NN9536-4374 (STEP 2) menunjukkan pada pemberian semaglutide 2,4 mg seminggu sekali selama 68 minggu pada pasien diabetes mellitus tipe 2 dengan obesitas/*overweight*, terjadi penurunan berat badan yang lebih tinggi dibanding plasebo yaitu -9,64% vs -3,42% (ETD -6,21; 95% CI-7,28; -5,15).

2. Keamanan
   a. Profil keamanan secara keseluruhan dapat ditoleransi, dan tidak ada efek samping baru yang dilaporkan.
   b. Efek samping yang dilaporkan lebih dari 5% subjek pada studi fase IIIa (STEP 1, 2, 3 dan 4) lebih tinggi dibanding plasebo yaitu mual (38,3% vs 14,0%), muntah (21,8% vs 5,7%), nyeri perut (8.4% vs 4,0%), dispepsia (7,6% vs 2,7%), nyeri perut atas (7,1% vs 3,6%), *eructation* (6,5% vs 0,4%), distensi abdomen (6,3% vs 4,3%), kembung (5,3% vs 3,7%), diare (26,8% vs 14,3%), konstipasi (21,8% vs 10,2%).
   c. Hasil studi NN9535-3744 (SUSTAIN 6) yang menilai *cardiovascular outcome* semaglutide 0,5 mg dan 1 mg seminggu sekali pada pasien diabetes mellitus menunjukkan penurunan risiko *primary composite outcome of death* yang disebabkan *cardiovascular, non-fatal myocardial infarction,* atau *non-fatal stroke*. Namun studi *cardiovascular outcome* yang menggunakan dosis 2,4 mg seminggu sekali sesuai yang diajukan belum diserahkan.

3. Studi klinik yang diserahkan terbatas sampai 68 minggu.

4. Diketahui bahwa pankretitis akut, termasuk hemoragik fatal dan non-fatal, telah dilaporkan terjadi pada pasien yang mendapat agonis reseptor GLP-1, termasuk semaglutide. Namun demikian, belum ada studi Wegovy® pada pasien dengan riwayat pankreatitis untuk memastikan keamanan, termasuk peningkatan risiko, pada populasi pasien tersebut.

5. Terdapat studi klinik semaglutide pada subjek *overweight* dan obesitas yang masih berjalan dan belum diserahkan, termasuk:
   a. Studi untuk menilai *cardiovascular outcome* dengan dosis 2,4 mg seminggu sekali

6. Dipertimbangkan terdapat kebutuhan obat untuk obesitas atau *overweight* dengan faktor risiko ko-morbid karena obat yang tersedia masih terbatas dan jumlah populasi Indonesia dengan obesitas terus meningkat. Data dari Riset Kesehatan Dasar 2018 menunjukkan bahwa pada 2018 sebanyak 21,8% penduduk Indonesia mengalami obesitas, meningkat dibandingkan tahun 2013 yaitu 14,8%.

**KEPUTUSAN**
Mempertimbangkan data mutu, khasiat dan keamanan tersebut di atas, diputuskan registrasi Wegovy® larutan injeksi **dapat diterima dengan perbaikan indikasi dan posologi sebagai berikut.**

**Indikasi:**
*Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of:*

- *≥30 kg/m2 (obesity), or*
- *≥27 kg/m2 to < 30 kg/m2 (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.*

*Limitation of use*
*WEGOVY contains semaglutide and should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist.*
*The safety and effectiveness of WEGOVY in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established. WEGOVY has not been studied in patients with a history of pancreatitis [see Warnings and Precautions (5.2)].*

**Posologi:**
*The maintenance dose of semaglutide 2.4 mg once-weekly is reached by starting with a dose of 0.25 mg. To reduce the likelihood of gastrointestinal symptoms, the dose should be escalated over a 16- week period to a maintenance dose of 2.4 mg once weekly (see Table 1). In case of significant gastrointestinal symptoms, consider delaying dose escalation or lowering to the previous dose until symptoms have improved.*

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*Weekly doses higher than 2.4 mg are not recommended.*

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*Clinical data on efficacy and safety are limited to 68 weeks.*

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*Elderly (≥ 65 years old) No dose adjustment is required based on age. Therapeutic experience in patients ≥ 75 years of age is limited, and greater sensitivity of some older individuals cannot be excluded.*

*Patients with renal impairment*
*No dose adjustment is required for patients with mild or moderate renal impairment. Experience with the use of semaglutide in patients with severe renal impairment is limited. Semaglutide is not recommended for use in patients with severe renal impairment (eGFR < 30 mL/min/1.73m2) including patients with end-stage renal disease (see sections 4.4, 4.8 and 5.2).*

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*Subcutaneous use.*
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*When administering Wegovy®, the pen should be pressed firmly against the skin until the yellow bar has stopped moving. The injection takes about 5–10 seconds.*
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