



Saxenda® Same Will New Way

Benefits of long-term weight management with Saxenda® and NovoFine® Needle

LINDA, teacher; Age 40 BMI: 36
Patient portrayal

AGENDA

▶ Obesity

- Obesity as a chronic disease

▶ Introducing Saxenda®

- Indication
- Weight loss clinical efficacy
- Benefits beyond weight loss
- Mechanism of action
- Get your patients off to a good start

▶ Introducing NovoFine® needle

▶ Summary

▶ Q&A

▶ Reference

Obesity



Obesity is a chronic disease that requires long-term management³⁻⁵



Recognised by health organisations as a disease including World Obesity Federation, The Obesity Society, and European Association for the study of Obesity.³⁻⁵

Classification based on BMI⁶

CLASSIFICATION	Normal range	Overweight	Obesity
BMI	≥18.5 and <25	≥25 and <30	≥30

BMI (body mass index) provides a convenient population-level measure of obesity.⁶

Waist circumference⁷

Waist circumference cut-offs to identify increased relative risk for development of weight-related complication

Men	>102 cm (>40 in)
Women	>88 cm (>35 in)

Waist circumference can be used alongside BMI to assess a person's risk for developing weight-related complications.⁷

A larger waist circumference is associated with an increased risk of developing weight-related complications and mortality.⁷

BMI=the weight in kilograms divided by the square of the height in meters (kg/m²).⁶

Obesity is a chronic disease that requires long-term management³⁻⁵



Recognised by health organisations as a disease including Korean Society for the Study of Obesity*

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BMI (body mass index) provides a convenient population-level measure of obesity.⁶

Waist circumference*

Waist circumference cut-offs to identify increased relative risk for development of weight-related complication

Men	≥90 cm
Women	≥85 cm

Waist circumference can be used alongside BMI to assess a person's risk for developing weight-related complications.⁷

A larger waist circumference is associated with an increased risk of developing weight-related complications and mortality.⁷

* 대한비만학회 홈페이지 <http://www.kosso.or.kr/>

BMI=the weight in kilograms divided by the square of the height in meters (kg/m²).⁶

Obesity is associated with **more than 195 complications**⁸⁻¹⁰



Sleep apnoea

Dyslipidaemia

Cardiovascular disease

- Hypertension
- Congestive heart failure
- Coronary artery disease
- Pulmonary embolism
- Stroke

Gallbladder disease

Type 2 diabetes

Cancer (various)

Osteoarthritis

Cardiovascular disease (CVD) is the leading cause of death in people with obesity⁹

40% of cancers diagnosed in the US are associated with overweight and obesity¹⁰

Physiological responses to weight loss favour weight regain¹⁴⁻¹⁹



Weight loss alters the body's homeostatic system, which controls appetite, energy intake, and energy expenditure, causing the body to increase hunger and lower the metabolic rate.¹⁹



Weight loss of 5% or more in patients with obesity brings health benefits including:²⁰⁻²⁵



Reductions:



the risk of type 2 diabetes²⁰



cardiovascular risk factors²⁴

Improvements:



blood lipid profile²⁴



blood pressure²⁴



health-related quality of life²⁵



osteoarthritic pain²³



severity of obstructive sleep apnoea^{21,22}

Introducing Saxenda®



Indication¹

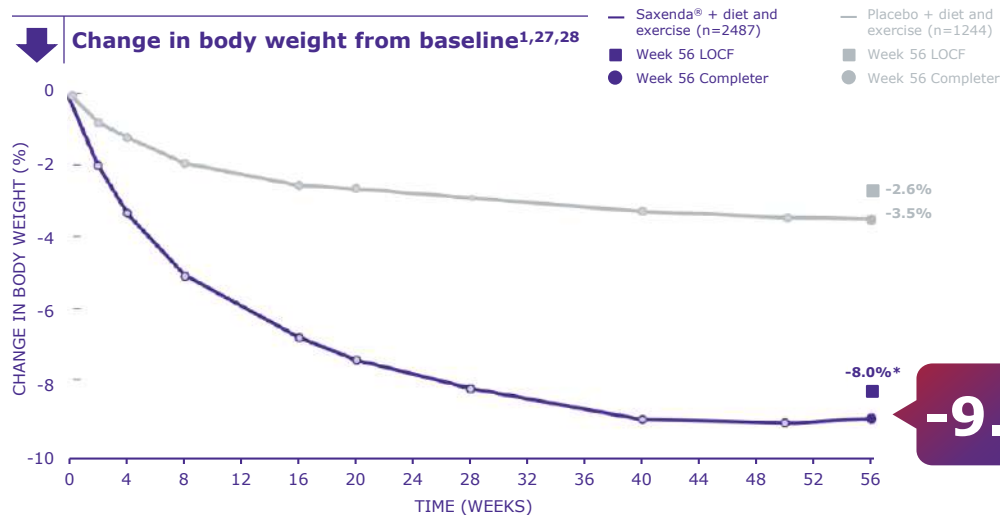
Saxenda® is the only GLP-1 analogue that is EMA and FDA approved for weight management as an adjunct to diet and exercise^{1,26}

Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial BMI of

- ≥ 30 kg/m² (obesity), or
- ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least 1 weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, or obstructive sleep apnoea



Patients taking Saxenda® lost weight and kept it off in a 1-year trial¹



“It is really hard and frustrating to lose weight and keep it off. That’s why I am so excited about Saxenda®.”



Patient portrayal.

72% of patients randomised to Saxenda® (1789 of 2487) completed the trial vs 64% with placebo (801 of 1244).²⁷

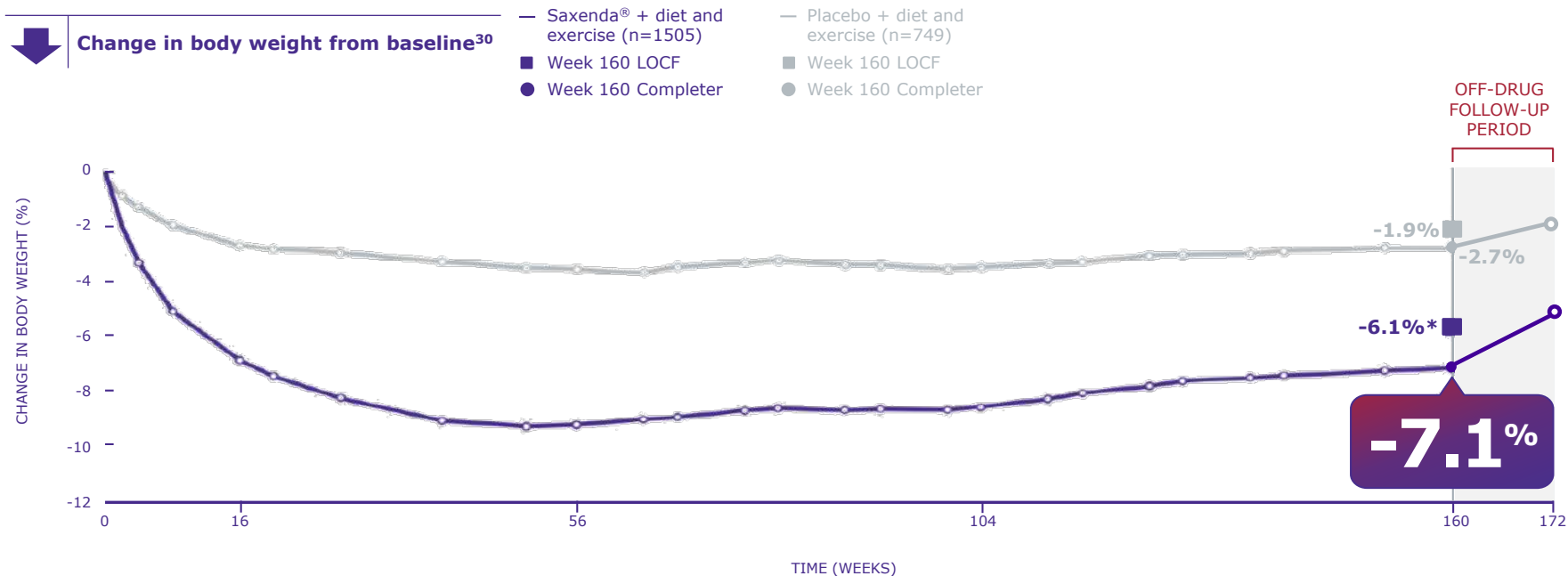


Patients treated with Saxenda® experienced an observed mean waist circumference **reduction of 8.2 cm** vs 3.9 cm with placebo ($P < 0.001$).²⁷

Data are observed means.
 LOCF=last observation carried forward.
 * $P < 0.001$ vs placebo.^{1,28}

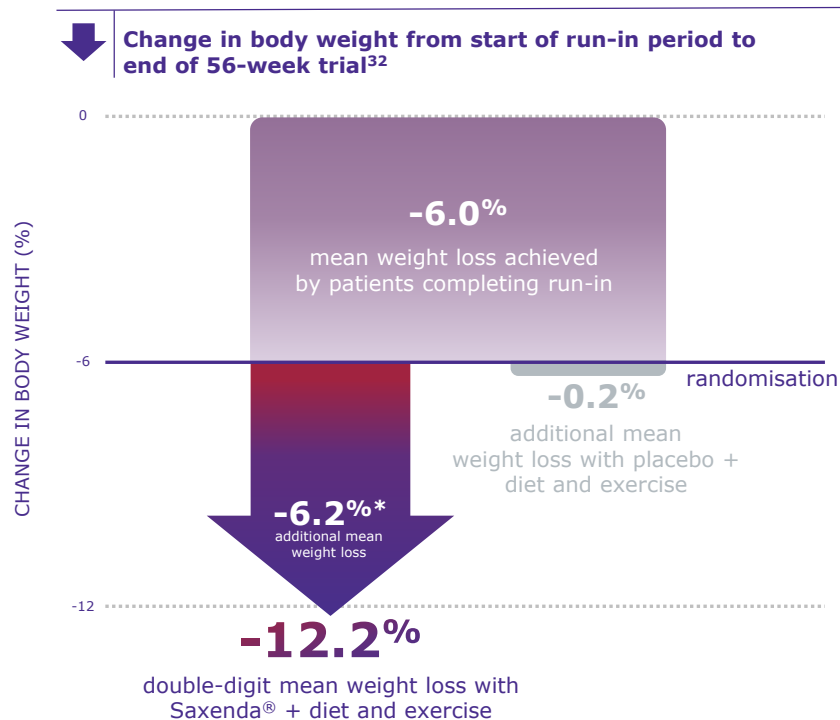
SARAH | Age: 43 | BMI: 37
Complications: Hypertension, osteoarthritis

Patients treated with Saxenda® lost weight and sustained their weight loss for 3 years¹



Line graphs are observed means.
 LOCF=last observation carried forward.
 * $P < 0.0001$.³⁰

Patients on Saxenda® kept losing weight vs patients on placebo in a weight-loss maintenance trial³²



- Run-in period patients (N=422). During 12-week run-in period, patients had to lose $\geq 5\%$ of initial body weight through a low-calorie diet (LCD) (1200 to 1400 kcal/day) and increased exercise
- Saxenda® + 500-kcal/day-deficit diet and exercise for a year (n=207)
- Placebo + 500-kcal/day-deficit diet and exercise for a year (n=206)

81% of patients randomised to Saxenda® + diet and exercise maintained a $\geq 5\%$ weight loss vs 49% of patients on placebo + diet and exercise.³²

Benefits beyond weight loss



**Lowered blood glucose
levels and risk of
diabetes^{1,27}**



**Improved
blood pressure^{1,27}**



**Cardiovascular
benefits^{1*}**

*The LEADER trial included 9340 patients with type 2 diabetes who were either at high risk for CVD or who had CVD, receiving up to a 1.8 mg dose.²
LEADER=Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results.

With Saxenda[®], many patients with pre-diabetes returned to normal glycaemic status after 1 year¹

69^{0%} returned to
normal
glycaemic status¹

"Finding out I had high blood glucose levels along with my weight issues... that was a call to action."



LINDA | Age: 40 | BMI: 36
Complications: Hypertension, pre-diabetes

Patient portrayal.

Saxenda® significantly reduced the risk of type 2 diabetes after 3 years³⁰



"I am reducing my diabetes risk and improving my overall health. That's what I think when I take Saxenda®."

LINDA | Age: 40 | BMI: 36
Complications: Hypertension, pre-diabetes

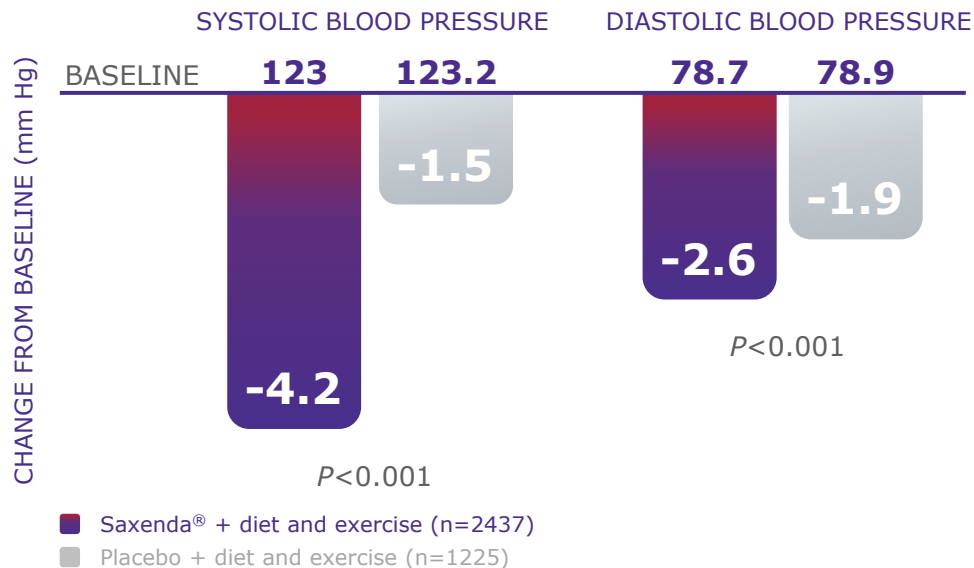
~80%

Risk reduction for development of type 2 diabetes relative to placebo³⁰

Patient portrayal.

Primary end point from this trial was the proportion of patients with type 2 diabetes at 160 weeks, evaluated as the time to onset of diabetes. In patients treated with Saxenda®, time to onset of type 2 diabetes was 2.7 times longer vs placebo (95% CI, 1.9 to 3.9, $P < 0.0001$).^{1,30}
Hazard ratio of 0.2 for risk of developing type 2 diabetes vs placebo.³⁰
Hazard ratio derived from the primary Weibull analysis.³⁰

Saxenda® provided significant reductions in blood pressure vs placebo²⁷



“ My weight made my family history of heart disease even more frightening. It feels good to be doing something so positive. ”

ROBERTO | Age: 48 | BMI: 39
Complications: Hypertension, dyslipidaemia, sleep apnoea

Patient portrayal.

Liraglutide provided a significant life-saving CV benefit²

The LEADER trial included 9340 patients with type 2 diabetes who were either at high risk for CVD or who had CVD, receiving up to a 1.8 mg dose²

13% overall relative risk reduction
vs placebo in major adverse CV events,
on top of standard of care treatment.^{1*}

22%



Risk reduction in CV deaths²⁺

CV disease is the **leading cause of death** in people with obesity⁹

The primary end point was the time from randomisation to a composite outcome consisting of the first occurrence of CV death, nonfatal myocardial infarction (MI) or nonfatal stroke.¹

*Hazard ratio of 0.87 (95% CI, 0.78 to 0.97, $P < 0.001$ for noninferiority, $P = 0.01$ for superiority). Composite primary end point absolute reduction was 1.9%. The primary composite outcome occurred in fewer patients in the liraglutide group (608 of 4668 patients [13%]) than in the placebo group (694 of 4672 patients [14.9%]), both in addition to standard of care.²

*Hazard ratio of 0.78 (95% CI, 0.66 to 0.93 $P = 0.007$). Death from CV causes absolute reduction was 1.3%. Death from CV causes occurred in fewer patients in the liraglutide group (219 patients [4.7%]) than in the placebo group (278 patients [6.0%]), both in addition to standard of care.²

Similar to natural GLP-1, Saxenda® works in the brain* to decrease appetite and thereby reduce food intake¹

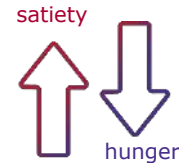
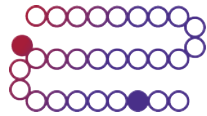
GLP-1 is a natural occurring hormone that is released in response to food intake and acts as a physiological regulator of appetite^{1,36}

Saxenda® is 97% similar to natural GLP-1[†]

Saxenda® works in the hypothalamus where it interacts with specific neurons involved in the regulation of appetite and food intake^{37*}

Saxenda® increases feelings of satiety and decreases hunger¹

As a result of its mechanism of action (MoA) patients taking Saxenda® feel satisfied and eat less food, leading to weight loss¹



MoA video

*Shown in animal models.

The exact MoA is unknown.

†Saxenda® is the result of 2 structural modifications to natural GLP-1 that prolong its half-life from less than 2 minutes to approximately 13 hours, when injected subcutaneously, allowing for once-daily dosing.^{38,39}

The long-term efficacy and safety profile of Saxenda[®] has been well established



4 SCALE clinical trials include
5358 patients¹



3-year data validated
The long-term efficacy and safety
profile of Saxenda^{®30}



Long-term CV safety profile of liraglutide (1.8 mg)
was confirmed by the LEADER trial of
9340 patients¹
With type 2 diabetes^{2,41}



The most common adverse events
were gastrointestinal (GI) disorders.¹
**Most episodes were mild to moderate
and transient.¹**

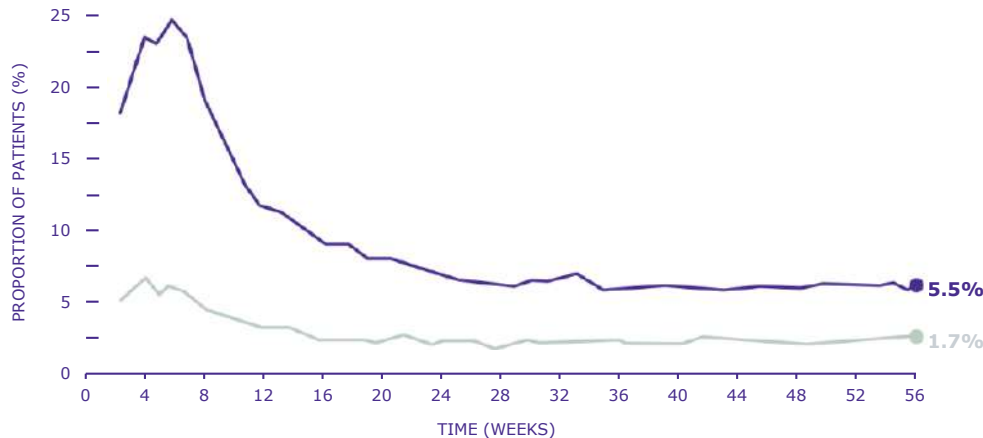
**Saxenda[®] is the only treatment
indicated for weight management along with diet and exercise to include CV benefits in its label¹**

Most common adverse events were GI disorders^{1,27}

- The 4-week dose-escalation schedule was designed to minimise GI symptoms¹
- Some patients withdrew due to adverse events (9.9% with Saxenda[®] vs 3.8% with placebo), but overall, more patients completed the trial with Saxenda[®] than with placebo (72% vs 64%, respectively)²⁷



Prevalence of nausea in a 56-week trial with 3731 patients^{27,28}



● Saxenda[®] + diet and exercise (n=2481)

● Placebo + diet and exercise (n=1242)

Proportion of patients reporting nausea at:

- **Week 4:** 24.7% (Saxenda[®]) vs 5.4% (placebo)
- **Week 8:** 14.7% (Saxenda[®]) vs 3.2% (placebo)

Most GI disorders were mild to moderate and transient.¹

Dose escalation improves tolerability¹

0.6 mg



WEEK 1

1.2 mg



WEEK 2

1.8 mg



WEEK 3

2.4 mg



WEEK 4

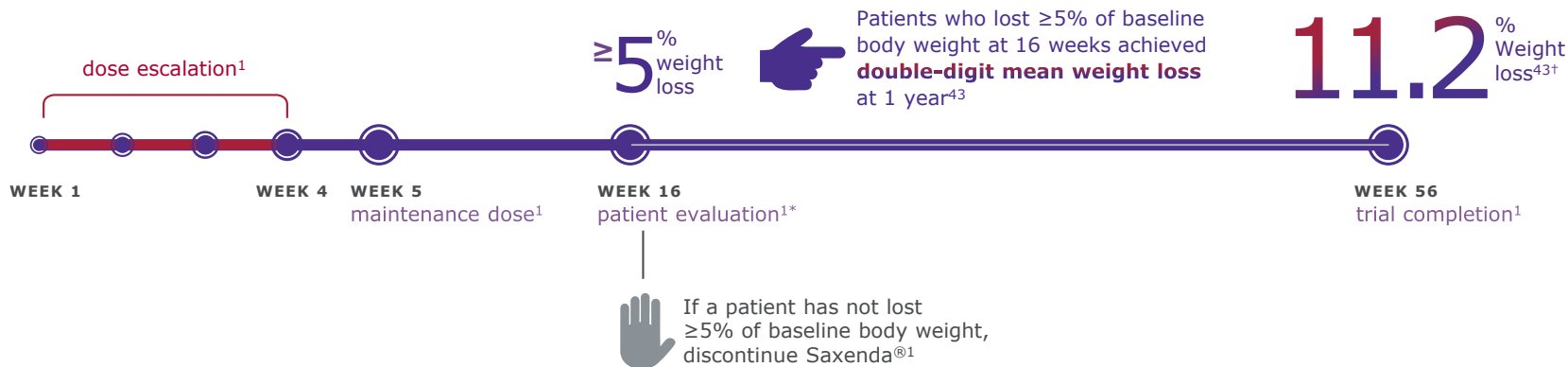
MAINTENANCE DOSE
3.0 mg



WEEK 5



Evaluate your patients' progress with Saxenda® at 16 weeks



65% of week 16 completers achieved ≥5% weight loss.⁴³

*After 12 weeks on the 3.0 mg maintenance dose, assess for ≥5% weight loss.⁴³

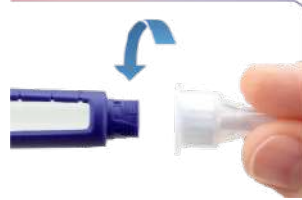
†Achieved by early responders at 56 weeks.⁴³

Injection instructions¹

1 check pen



2 attach needle



3 check flow



4 select dose



5 inject dose



6 remove needle



Once-daily Saxenda[®] can be taken **any time of day**, independent of meals¹

The Saxenda[®] pen is designed to be used with used with needles up to a length of 8 mm and as thin as 32G, such as the NovoFine[®] or NovoTwist[®] needles.

See Instructions For Use for dosing and administration.

[Dosing video](#)

Summary

Saxenda® overview



Patient profiles



Similar to natural GLP-1, Saxenda® works to decrease appetite and thereby reduce food intake¹




Patients achieved significant and sustained weight loss throughout 1-year and 3-year trials^{1,30}



Patients also experienced significant improvements in cardiometabolic risk factors and complications¹



The long-term safety profile of Saxenda® has been well established^{1,30}



There's a lot
to learn
about me

Meet NovoFine® Plus:

The 32G 4 mm pen needle that makes
injections a little friendlier

Novo Nordisk needle innovation

Improving the injection experience for over 25 years

Novo Nordisk launched the world's first pen needle back in 1985 and, since then, has strived to improve the injection experience for patients by developing smaller and thinner needles.



NovoFine® Plus 32G 4 mm

Comfort is key

NovoFine[®] Plus is more comfortable because of its benefits:

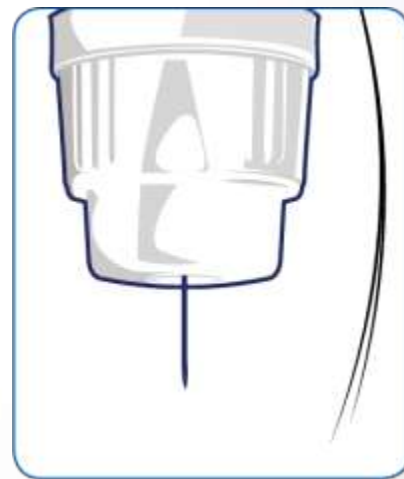
- Less pain to help improve comfort and adherence^{5,6}
- Reduces injection time and force
- The ergonomic design for ease of use



Understanding needle gauge

**The higher the gauge (G),
the thinner the needle**

- 32G=0.2350 mm
- 31G=0.2604 mm—that's 11% thicker than a 32G needle

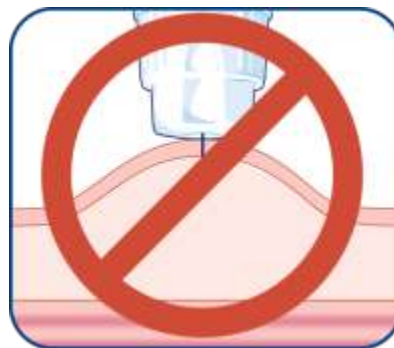


**NovoFine® Plus is as thin
as just two human hairs.¹¹**

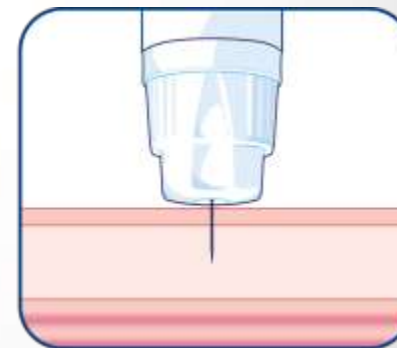


Injection technique with shorter needles

- Injection should be targeted at the subcutaneous skin layer to get predictable and reproducible absorption of therapy
- 4 mm needle can be inserted at a 90° angle without a skin fold in children and adolescents
 - The FIT Forum recommendations for best practices in injection technique advise that a skin lift may not be required when using a 4 mm needle¹⁸



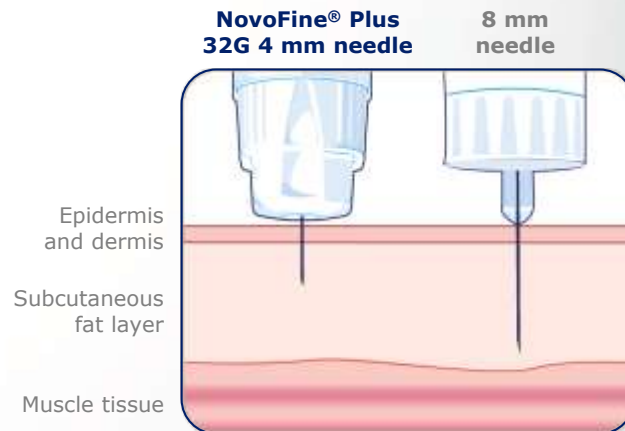
No need to use skin fold



90° angle straight into the skin

NovoFine® Plus works for patients across the BMI spectrum¹⁰

- 4 mm needle is long enough to safely and effectively deliver insulin to patients regardless of BMI
 - Since the thickness of the skin (epidermis and dermis) only varies between 1.9 mm and 2.4 mm around the body, a 4 mm needle can be used to effectively deliver insulin with minimal risk of intramuscular injection and without increasing the amount of back-flow of insulin to the skin surface⁷



NovoFine® Plus is designed with unique SuperFlow™ technology

- SuperFlow™ technology (ETW):
 - Increases the width of the internal bore without increasing the outer diameter of the needle
 - Increases the flow rate and reduces the resistance and force needed to push the insulin through the needle^{8,9}
 - This may be of clinical importance for patients with limited manual dexterity or reduced hand strength, such as pediatric patients or the elderly

Better flow, faster injections^{8,9}



NovoFine® Plus with SuperFlow™ technology



Regular Needle

ETW=extra thin wall.

NovoFine® Plus works with all major pen devices⁹

- ✓ NovoPen Echo®
- ✓ InnoLet®
- ✓ FlexPro®
- ✓ Victoza® pen
- ✓ FlexPen®
- ✓ FlexTouch®
- ✓ NovoPen® 3
- ✓ NovoPen® 4
- ✓ NovoPen® 5
- ✓ NordiFlex®
- ✓ NordiPen®
- ✓ KwikPen®
- ✓ SoloStar®
- ✓ ClickStar®
- ✓ Byetta® Pen
- ✓ Autopen® Classic
- ✓ Autopen® 24
- ✓ Omnican® Pen 31
- ✓ Ypsopen®
- ✓ BerliPen® Areo 2
- ✓ BerliPen® 302
- ✓ HumaPen® Luxura™
- ✓ HumaPen® Luxura™ HD
- ✓ TactiPen®



Novo Nordisk®, the Apis bull logo, NovoFine®, FlexPen®, FlexTouch®, NovoPen® 3, NovoPen® 4, NovoPen® 5, NovoPen Echo®, InnoLet®, NovoPen® Junior, and Victoza® are trademarks of Novo Nordisk A/S. All other brands are trademarks of their respective owners.

NovoFine® Plus

NovoFine® Plus needles have a unique design

- NovoFine® Plus needles are designed with a unique glue tower that provides added strength to reduce needle bending or breakage¹⁹
- The design also ensures:
 - Enhanced skin contact for better injection technique



NovoFine® Plus key messages

Primary messages

- **Ultra-short and ultra-thin:** 32G 4 mm needle associated with less pain⁵ and less risk of intramuscular injection⁷
- **Better flow, faster injections:** Designed with SuperFlow™ technology, reducing injection time and force⁸
- **Universal compatibility:** Compatible with all pen devices to simplify use⁹

Secondary messages

- **Ultra-strong:** Designed to reduce the risk of bending or breakage
- **For all patients:** 4 mm length is suitable for all patients, regardless of BMI¹⁰



Questions

