

Soliqua 100 units/mL + 33 micrograms/mL solution for injection in a pre-filled pen (30-60). INSTRUCTIONS FOR USE

Read the Package Leaflet and these Instructions for Use first

Soliqua (30-60) pen contains insulin glargine and lisinsinapril.
The combination of medicinal products in this pen is for the daily injection of 30 to 60 dose steps Soliqua.

Never reuse needles. If you do you might not get your full dose (under dosing) or get too much (over dosing) as the needle could block.

Never use a syringe to remove medicine product from the pen. If you do, you may not get the correct amount of medicine.

Keep these Instructions for Use handy for future reference.

Learn to inject:

- Talk with your healthcare provider about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your hands or fingers.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little medicine.

Need help?

If you have any questions about how to inject, before using your pen, ask your doctor, pharmacist or nurse. They will be able to help you. This number is given at the end of the Package Leaflet (see other side).

Extra items you will need:

- a new sterile needle (see STEP 2).
- needles and pens for used needles and pens (see **Throwing your pen away**).

Places to inject

Upper arms
Stomach
Thighs

Get to know your pen

Pen cap
Cartridge holder
Plunger*
Dose window
Dose selector
Injection button
Rubber seal
Scale
Product name

*You will not see the plunger until you have injected a few doses.

STEP 1: Check your pen

Take a new pen out of the refrigerator at least 1 hour before you inject. Injecting cold medicine is more painful.

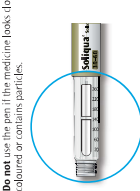
- A. Check the name and expiry date on the label of your pen.**
- Make sure you have the correct medicine. This pen is often coloured with a brown injection button.
 - Do not use this pen if you need a daily dose less than 30 dose steps or if you need more than 60 dose steps.** Reproduct with your doctor which pen is suitable for you.
 - Do not use your pen after the expiry date.**



- B. Pull off the pen cap.**



- C. Check that the medicine is clear.**
- Do not use the pen if the medicine looks cloudy, coloured or contains particles.



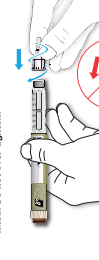
STEP 2: Attach a new needle

- Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blood-borne viruses.
- Always use needles that are compatible for use with Soliqua pen.

- A. Take a new needle and peel off the protective seal.**



- B. Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.**



- C. Pull off the outer needle cap. Keep this for later.**



- D. Pull off the inner needle cap and throw away.**



Handling needles

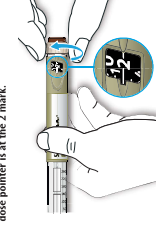
- Take care when handling needles to prevent needle injury and cross-infection.

STEP 3: Do a safety test

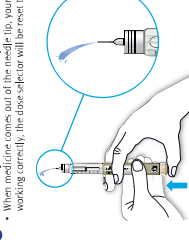
Always do a safety test before each injection to:

- Check your pen and the needle to make sure they are working correctly.
- Make sure that you get the correct dose.

- A. Select 2 dose steps by turning the dose selector until the dose pointer is at the 2 mark.**



- B. Press the injection button all the way in.**
- When medicine comes out of the needle tip, your pen is working correctly. The dose selector will be reset to '0'.



If no liquid appears:

- Repeat this step up to 3 times before seeing medicine.
- If no medicine comes out after the third time, the needle may be blocked. If this happens:
 - Do not use the pen.
 - Then repeat the safety test (STEP 3).
- Do not use your pen if there is still no medicine coming out of the needle tip.** Use a new pen.
- Do not use a syringe to remove medicine from your pen.**

If you see air bubbles:

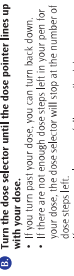
- You may see air bubbles in the medicine. This is normal, they will not harm you.

STEP 4: Select the dose

- Only use this pen to inject single daily doses from 30 to 60 dose steps.**
- Do not use the dose or press the injection button without a needle attached. This may damage your pen.



- A. Make sure a needle is attached and the dose is set to '0'.**



- B. Turn the dose selector until the dose pointer lines up with your dose.**
- If you turn your pen your dose, you can turn back down.
 - If there are 30 dose steps left in the pen for your dose, the dose selector will stop at the number of dose steps left.
 - If you cannot select your full prescribed dose, use a new pen to complete your dose. Only in this case, it is okay to inject a partial dose of less than 30 dose steps. Always use another Soliqua (30-60) pen to complete your dose and no other pen.

How to read the dose window

- Do not use the pen if your single daily dose is less than 30 dose steps.
- Do not use the pen if the dose window shows white numbers on a black background.



Units of medicine in your pen

- Your pen contains a total of 300 dose steps. You can select your dose in steps of 1 dose step.
- Do not use the pen if your single daily dose that is less than 30 dose steps, or more than 60 dose steps.**
- Each pen contains more than 1 dose.

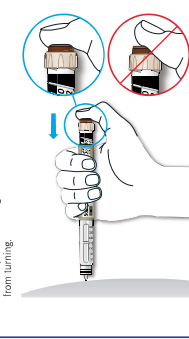
STEP 5: Inject the dose

- If you find it hard to press the injection button in, do not force it as this may break your pen.
- Push the needle into your skin as shown by your healthcare provider.**
- Do not press at an angle.** Your thumb could block the dose selector from turning.

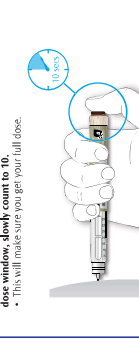
- A. Choose a place to inject as shown in the picture above.**
- B. Push the needle into your skin as shown by your healthcare provider.**
- Do not touch the injection button yet.



- C. Place your thumb on the injection button. Then press all the way in.**
- Do not press at an angle.
 - Do not touch the injection button yet.



- D. Keep the injection button held in and when you see '0' in the dose window, release the button.**
- This will make sure you get your full dose.



- E. After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.**



STEP 6: Remove the needle

- Take care when handling needles to prevent needle injury and cross-infection.
- Do not put the inner needle cap back on.**
- If you still find it hard to press in, get a new pen.
- Do not use a syringe to remove medicine from your pen.

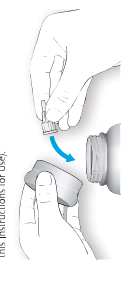
- A. Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap.**
- Do not touch the needle tip.
 - The needle cap puncture the cap if it is equipped at an angle.



- B. Grip and squeeze the widest part of the outer needle cap.**
- Do not touch the needle tip.
 - Do not touch the needle cap.
 - Try again if the needle does not come off the first time.



- C. Throw away the used needle in a puncture resistant container (see 'Throwing your pen away' at the end of this Instructions for Use).**



- D. Put your pen cap back on.**
- Do not put the pen back in the refrigerator.



How to store your pen

Before first use

- Keep new pens in the refrigerator between 2 °C to 8 °C.
- Do not freeze.

After first use

- Keep your pen at room temperature, below 25 °C.
- Do not** put your pen back in the refrigerator.
- Do not use the pen if the medicine looks cloudy, coloured or contains particles.
- Store the pen with your pen cap on.
- Only use your pen for up to 28 days after its first use.

How to care for your pen

Handle your pen with care

- If you think that your pen may be damaged, do not try to fix it. Use a new one.

Throwing your pen away

- Remove the needle before throwing your pen away.
- You can clean the outside of your pen with a damp cloth (water only).
- Do not soak, wash or lubricate the pen. This may damage it.

Project your pen from dust and dirt

- You can clean the outside of your pen with a damp cloth (water only).
- Do not soak, wash or lubricate the pen. This may damage it.

Disetujui oleh BPOM 1 April 2026

SAP/ID number	: PPL SOLIQUA /
Country	: Indonesia
Version number	: 2
Date	: 27.06.2023
Manufacturer	: PLS of gmp
Prepared by	: Rahmat Halid
Min. point size of text	: 10 pt
Type of text	: Ocean Sans Pro Family
Dimensions	: 995 x 420 mm
Type of proof	: 2x Vertical & 3x Horizontal
Dimension after folded	: 148.75 x 52.5 mm (± 2 mm)

Printing Colour	: Cyan
	: Magenta
	: Yellow
	: Black
Technical Information	: Outline

EREG10002212500296

glargine as basal insulin and 95.0% received at least 1 concomitant OAD. At week 30, Soliqua provided statistically significant improvement in HbA1c compared with insulin glargine plus a sulfonylurea in the overall population. See table and figure below for the other populations in the study.

Results at 30 weeks - Add-on to metformin clinical study (mITT population)			
Number of subjects (nITT)	Soliqua	Insulin glargine	Lisinsinide
HbA1c (%)	468	466	233
Baseline (mean)	8.1	8.1	8.1
End of study (mean)	6.5	6.9	7.3
LS change from baseline (mean)	-1.6	-0.8	-0.9
95% confidence interval (p-value)	[-0.4, -2.2]	[-0.4, -2.2]	[-0.4, -2.2]
Difference versus insulin glargine (p-value)	-0.8	-0.8	-0.8
Difference versus lisinsinide (p-value)	-0.8	-0.8	-0.8
Number of Patients (% reaching HbA1c < 7.0%)	345 (74%)	277 (59%)	77 (33%)
Fasting plasma glucose (mmol/L)			
Baseline (mean)	9.88	9.75	9.79
End of study (mean)	6.32	6.53	8.27
LS change from baseline (mean)	-3.46	-3.22	-1.50
95% confidence interval (p-value)	[-3.6, -3.3]	[-3.6, -3.3]	[-3.6, -3.3]
Difference versus insulin glargine (p-value)	-0.24	-0.24	-0.24
Difference versus lisinsinide (p-value)	-0.24	-0.24	-0.24
Mean body weight (kg)			
Baseline (mean)	87.1	87.1	87.1
End of study (mean)	87.1	87.1	87.1
LS change from baseline (mean)	0.0	0.0	0.0
95% confidence interval (p-value)	[-0.1, 0.1]	[-0.1, 0.1]	[-0.1, 0.1]
Difference versus insulin glargine (p-value)	0.0	0.0	0.0
Difference versus lisinsinide (p-value)	0.0	0.0	0.0

Results at 26 weeks - Type 2 Diabetes Uncontrolled on Basal Insulin mITT Population			
Number of subjects (nITT)	Soliqua	Insulin glargine	Lisinsinide
HbA1c (%)	468	466	233
Baseline (mean)	8.1	8.1	8.1
End of study (mean)	6.5	6.9	7.3
LS change from baseline (mean)	-1.6	-0.8	-0.9
95% confidence interval (p-value)	[-0.4, -2.2]	[-0.4, -2.2]	[-0.4, -2.2]
Difference versus insulin glargine (p-value)	-0.8	-0.8	-0.8
Difference versus lisinsinide (p-value)	-0.8	-0.8	-0.8
Number of Patients (% reaching HbA1c < 7.0%)	345 (74%)	277 (59%)	77 (33%)
Fasting plasma glucose (mmol/L)			
Baseline (mean)	9.88	9.75	9.79
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LS change from baseline (mean)	-3.46	-3.22	-1.50
95% confidence interval (p-value)	[-3.6, -3.3]	[-3.6, -3.3]	[-3.6, -3.3]
Difference versus insulin glargine (p-value)	-0.24	-0.24	-0.24
Difference versus lisinsinide (p-value)	-0.24	-0.24	-0.24
Mean body weight (kg)			
Baseline (mean)	87.1	87.1	87.1
End of study (mean)	87.1	87.1	87.1
LS change from baseline (mean)	0.0	0.0	0.0
95% confidence interval (p-value)	[-0.1, 0.1]	[-0.1, 0.1]	[-0.1, 0.1]
Difference versus insulin glargine (p-value)	0.0	0.0	0.0
Difference versus lisinsinide (p-value)	0.0	0.0	0.0

See table and figure below for the other populations in the study.

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