

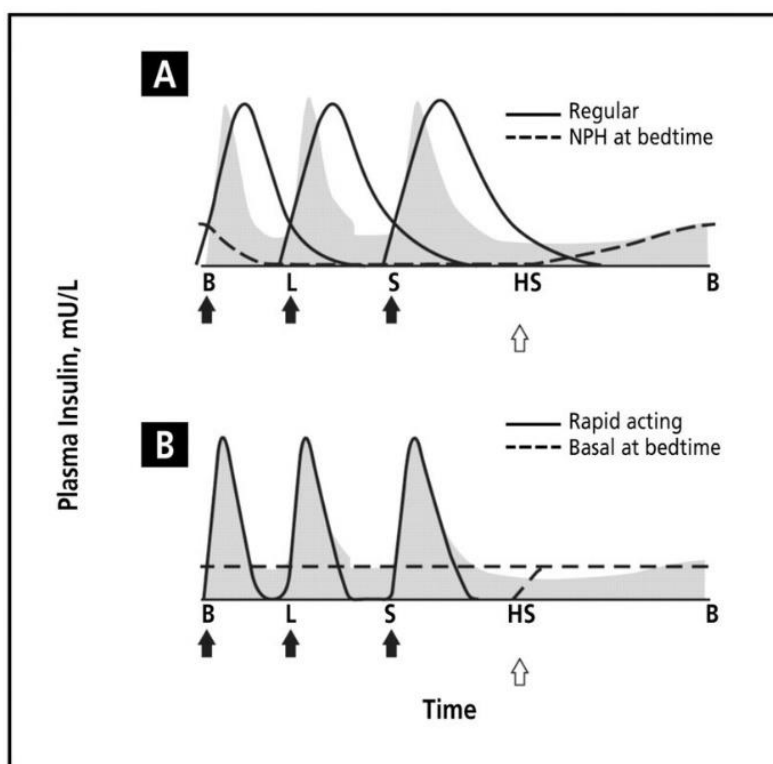
# Guide for switching children and youth with Type 1 diabetes FROM Humulin NPH & Regular or Premixed TO biosimilar insulin glargine (Basaglar) & insulin lispro (Humalog)



## Introduction

Biosimilar insulin glargine (brand name Basaglar) is a long-acting “basal” insulin analog, with duration of action up to 24 hours. Because it has virtually no peak, there is potentially less risk for hypoglycaemia when food is not available, and overnight. As glargine (Basaglar) predominantly covers the effect of hepatically- (liver-) produced glucose, a rapid acting “bolus” insulin such as lispro (Humalog) needs to be given before each meal. This regimen allows for more flexible mealtimes and meal sizes.

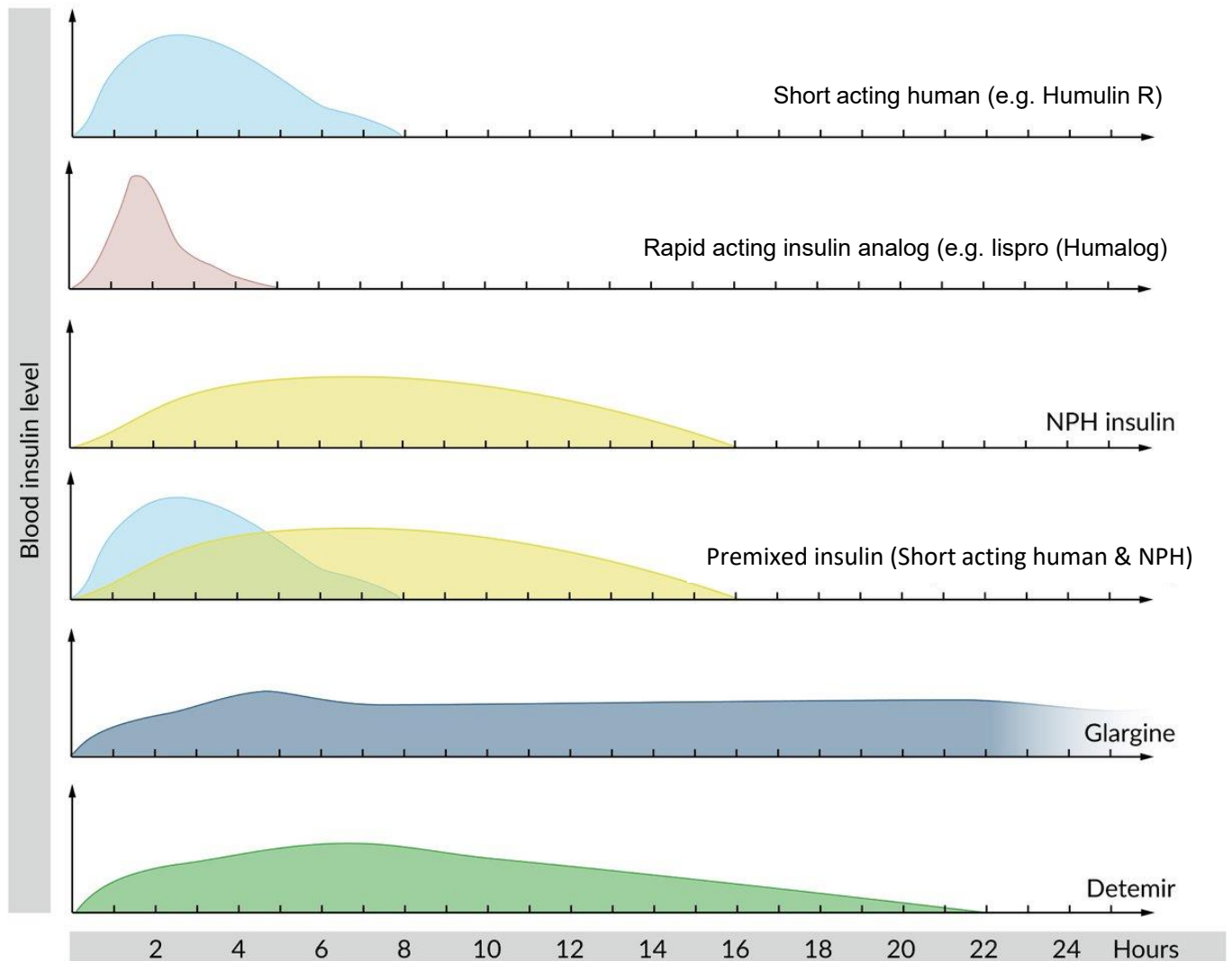
Figure 1 - Comparison of human (A) and analog (B) basal-bolus insulin regimens.



The shaded areas shows the physiological insulin secretion (in people without diabetes), and the lines indicate the relationship of each insulin therapy to physiologic conditions. Abbreviations: B - breakfast; HS - bedtime; L - lunch; NPH - Neutral Protamine Hagedorn; S - supper. Source: Edelman SV, Morello CM. Strategies for insulin therapy in type 2 diabetes. South Med J. 2005; 98:363-371. Copyright Southern Medical Association; Permission received from SV Edelman, Oct 2025

## Insulin Profiles

### Insulin action profiles



Insulin name	Insulin type	Formulation	Onset of action	Peak action	Duration of action	Mixing with other insulin	Number of injections per day
<b>Glargine (Basaglar), Lantus)</b>	Basal long-acting analog insulin	Clear- no mixing needed	2-4 hours	8-12 hours	22-24 hours (can be shorter in some individuals)	<b>Should not be mixed</b> with any other insulin	Usually 1  Sometimes 2**
<b>NPH (Humulin NPH)</b>	Basal intermediate-acting human insulin	Cloudy- needs to be mixed before each use	2-4 hours	4-12 hours	12-24 hours	Can be mixed with short acting insulin	Usually 2
<b>Regular insulin (e.g. Humulin R, Actrapid)</b>	Soluble/ short-acting insulin	Clear	30-60 min	2-4 hours	6-8 hours	Can be mixed with NPH	Multiple times given before each meal
<b>Lispro (Humalog)</b>	Rapid acting insulin	Clear	15-30 min	1-2 hours	≤5hours	Can be mixed with NPH insulin	Multiple times given before each meal
<b>Premixed insulin (e.g. Humulin 30/70)</b>	30% short-acting and 70% intermediate-acting human insulin	Cloudy- needs to be mixed before each use	30 min	4-12 hours	8-24 hours	<b>Cannot be mixed</b> with any other insulin	Usually 2

\*\* very young children using small doses may take 2 equal doses morning and evening. Injecting 2 doses a day can make dose titration (adjustment) easier.

Source: ISPAD 2018<sup>1</sup> & 2024<sup>2</sup> Clinical Practice Consensus Guidelines (Insulin treatment in children and adolescents with diabetes)

### **Note:**

The following switching options and clinical tips may be most useful for health care professionals with no prior experience in the use of insulin glargine. We recognize that many centers are already transitioning children and young people, have a process for doing this and should feel free to use their own clinical expertise, judgment and experience in transitioning.

**Important:** Switching calculations in the above tables **are used to determine initial doses**. Then **adjust** according on the resulting blood glucose levels – for more details see under the heading ‘*Initiation and Titration of New Regimen (page 5)*’

## Switching to glargine (Basaglar) and lispro (Humalog) insulin regimen

### Options and calculations

#### Option 1

**if currently on Humulin NPH (intermediate acting) and Regular (short acting) human insulin**

**Step 1:** Calculate current total daily doses (TDD) i.e. **add all NPH and all doses for meals (Regular) and corrections administered on a usual day**

**Step 2:** **Reduce TDD by 20% = New TDD** (use this to calculate glargine (Basaglar) starting dose)

**Step 3:** **Divide NEW TDD into 40% as glargine (Basaglar) and 60% as lispro (Humalog)**

**Note:** For children **less than 3 years of age**, use 30% of the NEW TDD as glargine (Basaglar) dose, 70% as lispro (lispro (Humalog)) insulin for meals.

**Note:** More lispro (lispro (Humalog)) insulin may be needed for breakfast due to morning insulin resistance.

If only 2 doses of Regular insulin were used previously (breakfast and dinner), a third dose of lispro (Humalog) will be needed for lunch, since glargine (Basaglar) has no peak action around lunchtime.

Dosage should be calculated based on the amount of carbs eaten with each meal. However, if no meal is eaten, no short acting insulin is needed.

Use pre-formulated Excel calculation sheet **Option 1** developed by Dr Ragnar Hanas for a quicker calculation method.

Example - Option 1		
Current daily doses	Calculations	New daily doses
Humulin NPH - 16 units morning, 8 units evening  Regular- 6 units morning and 4 units evening	<p><math>TDD (16+8+6+4) = 34</math></p> <p>Reduce TDD dose by 20% = 80% of 34 units <math>(0.8 \times 34) = 27 \text{ units}</math> (rounded down)</p> <p>Divide 27 units (NEW TDD) into:  <b>40% glargine (Basaglar) (Basaglar)</b> <math>(0.4 \times 27) = 11 \text{ units}</math> (rounded up)  and  <b>60% lispro (Humalog) (Humalog)</b> <math>(0.6 \times 27) = 16 \text{ units}</math> (rounded down)</p>	<p><b>glargine (Basaglar) (Basaglar) = 11 units</b> as one evening dose</p> <p><b>lispro (Humalog) = 16 units</b> divided into meal doses (depending on amounts of carbs eaten for each meal)</p> <p><b>Note:</b> A lispro (Humalog) dose is needed before lunch to cover the carbohydrate food in that meal, previously covered by the NPH peak. (for more details see under the heading 'Dividing lispro (Humalog) insulin into meal doses')</p>

**Option 2**  
**If currently on Premixed (Humulin 30/70) insulin**

**Step 1:** Calculate current total daily doses (TDD) i.e. add up all Humulin 30/70 and any additional Regular insulin doses (e.g. a lunchtime dose of short acting Regular insulin)

**Step 2:** Reduce the TDD by 20% = NEW TDD

**Step 3:** Divide NEW TDD into 40% as glargine (Basaglar) and 60% as lispro (Humalog)

**Note:** For children **less than 3 years of age**, use 30% of the NEW TDD as glargine (Basaglar) dose, 70% as lispro (Humalog) insulin for meals.

**Note:** More lispro (Humalog) insulin may be needed for breakfast due to morning insulin resistance.

If only 2 doses of Regular insulin were used previously (breakfast and dinner), a third dose of lispro (Humalog) insulin will be needed for lunch, since glargine (Basaglar) has no peak action around lunchtime.

Dosage should be calculated based on the amount of carbs eaten with each meal. However, if no meal is eaten, no short acting insulin is needed.

Use pre-formulated Excel calculation sheet **Option 2** developed by Dr Ragnar Hanas for a quicker calculation method.

Example – Option 2		
Current daily doses	Calculations	New daily doses
Humulin 30/70: 25 units morning dose; 12 units evening dose	<p><math>TDD = 25 + 12 = 37 \text{ units}</math></p> <p>Reduce TDD by 20% =  <math>80\% \text{ of } 37 \text{ units} = 0.8 \times 37 = 30 \text{ units (rounded up)}</math></p> <p>Divide 30 units (NEW TDD) into:  <b>40% glargine (Basaglar)</b>  <math>(0.4 \times 30) =</math>  <b>12 units</b>  and  <b>60% lispro (Humalog)</b> <math>(0.6 \times 30) =</math> <b>18 units</b></p>	<p>glargine (Basaglar) -12 units as one evening dose</p> <p>lispro (Humalog) -18 units divide into meal doses</p> <p><b>Note:</b> A lispro (Humalog) dose is needed before lunch to cover the carbs in that meal, previously covered by the NPH peak. (for more details see under the heading 'Dividing lispro (Humalog) insulin into meal doses')</p>

### Option 3

#### Use weight and pubertal status

#### for calculating glargine (Basaglar) and lispro (Humalog) insulin doses

This is especially helpful for new onset type 1 diabetes (T1D) in children and youth, but can be used for anyone

1. Measure weight
2. Determine pubertal status
3. Use weight and pubertal status to calculate total daily dose (TDD) as follows:
  - children under 3 years of age: 0.25 – 0.5 units/kg/day<sup>1</sup>
  - over 3-year prepubertal dosing: usually 0.5 – 1.0 units/kg/day for children with new onset T1D; and 0.7-1.0 units/kg/day<sup>1</sup> when switching to glargine (Basaglar)
  - pubertal dosing: may need 1.0 – 2.0 units/kg/day<sup>1</sup> (begin with 1.0-1.5 in newly diagnosed)
  - post pubertal dosing: 0.4 – 1.0 units/kg/day<sup>2</sup>

**Note:** For children/youth **newly diagnosed with T1D**, start on lower end of dosage and increase until normoglycemia is reached. Doses often need to be lowered considerably (< 0.5U/kg/day) during the **partial remission (honeymoon)** phase (for more information **see Appendix A**).

If transitioning from NPH&R or Premixed insulin, and if in doubt, also start on the lower end of dosage range. **Be aware** that the dose will probably require further adjustment, so a **close follow up of blood glucose levels is required**.

4. Divide TDD into 40% as glargine (Basaglar) and 60% as lispro (Humalog)  
**Note:** For children **less than 3 years of age**, use 30% of the NEW TDD as glargine (Basaglar) dose, 70% as lispro (Humalog) insulin for meals.
5. Divide the lispro (Humalog) dose between the meals the child/young adult consumes in a day (for more details see under the heading 'Dividing lispro (Humalog) insulin into meal doses')

#### Example

Young person	Calculations	New daily doses
12-year-old girl, in puberty, weight 40 kg. She has new onset T1D and did not present with Diabetic Ketoacidosis (DKA)	<p><i>New TDD will be 1.0 units/kg/day</i></p> <p><i>1.0 x 40 kg = 40 units (NEW TDD)</i></p> <p><i>Divide 40 units (NEW TDD) into:</i></p> <p><b>40% glargine (Basaglar)</b></p> <p><b>(0.4 x 40 = 16 units</b></p> <p><b>and</b></p> <p><b>60% lispro (Humalog) (0.6 x 40) = 24 units</b></p>	<p><b>glargine (Basaglar) - 16 units</b> as one evening dose</p> <p><b>lispro (Humalog) - 24 units</b> divide into meal doses</p> <p>e.g. if eating 3 meals per day = 10 units for breakfast, 6 units for lunch, 8 units for dinner (more details under the heading 'Dividing lispro (Humalog) insulin into meal doses' below)</p>

Use pre-formulated Excel calculation sheet **Option 1** developed by Dr Ragnar Hanas for a quicker calculation method.



## Dividing lispro (Humalog) rapid acting insulin into meal doses

- Obtain diet history and approximate amount of carbohydrate (carbs) eaten with each meal and snack.
- Determine proportion of total daily carbohydrate consumed at each meal\*\* and the total bolus insulin (lispro (Humalog)) will be divided in the same way that carbs are divided throughout the day.

Example: **Total daily lispro (Humalog) insulin is 16 units.**

25% of carbs before breakfast:  $0.25 \times 16 = 4$  **units** lispro (Humalog) before breakfast

40% of carbs before midday meal:  $0.4 \times 16 = 6.4$  rounded to **6 units** lispro (Humalog) before midday meal

35% of carbs before evening meal:  $0.35 \times 16 = 5.6$  rounded to **6 units** lispro (Humalog) before evening meal

- Plan for food insecurity: If the next meal is only going to be 30% of the usual intake, take only 30% of usual lispro (Humalog) insulin; if the next meal is only going to be 60% of the usual intake, take 60% of the usual lispro (Humalog) insulin, etc. (see also LFAC bulletin on:

Example: If the child/young adult usually takes 9 units lispro (Humalog) with breakfast, but breakfast will only be 30% of usual portion, she/he takes  $9 \times 0.3 = 2.7$  rounded to 3 units of lispro (Humalog) with the reduced meal



\*\*Using the child/young adult's hand is one way of measuring carbohydrate portion sizes. Use it to have them describe how much carbohydrate they have at each meal.

If available use local carb counting books or smart phone apps to determine carbohydrate amounts in various foods or refer to a dietitian.

- **Optional:** If possible, count the carbohydrate amounts in the meals eaten and use the Insulin to carbohydrate ratio (ICR). **The ICR indicates how much carbohydrate (in grams) is covered by one unit of lispro (lispro (Humalog)) insulin.** The initial ICR can be calculated by using the **500 rule** i.e. 500 divided by the TDD (see attached Excel calculation sheet by Ragnar Hanas).

Example: The child/young adult is going to eat 45 grams of carbohydrate with his evening meal. His TDD is 36 units, therefore his ICR is:  $500 \div 36 = 14$  (rounded) this means 1 unit of lispro (Humalog) insulin will cover 14 grams of carbohydrate food. He is eating 45 grams of carbohydrate ( $45 \div 14 = 3.2$  units; therefore, he needs 3 units of lispro (Humalog) insulin to cover the 45 grams of carbohydrate.

## Tips for lispro (Humalog) insulin

- Take lispro (Humalog) insulin 10-15 minutes before the meal unless the Blood Glucose Level (BGL) is under 100 mg/dL (5.6 mmol/L) - then take insulin right before eating
- The child/young adult should NOT have a small carbohydrate snack in between meals as is the case with Regular insulin. Note that since lispro (Humalog) insulin has its peak action between 1-2 hours, there is NOT an increased risk of hypoglycaemia in between meals.
- Keep lispro (Humalog) doses at least 2 hours apart to avoid “stacking” of insulin

## Initiation and Titration of New Regimen

**On the day** of switching from NPH or Premixed to glargine (Basaglar):

- The child/young adult should take the usual morning doses of insulin and eat as usual. This should be the last dose of NPH or Premixed.
- Give the lunch-time lispro (lispro (Humalog) dose if already on such regimen.
- Start the new regimen with the evening meal.
- The lispro (Humalog) dose should be given before the evening meal according to the new calculations.
- Start the first dose of glargine (Basaglar) preferably before the evening meal (easiest to remember) but it can be given at any time during the evening; whatever time that is most convenient and easiest to remember for the child/family/young adult.
- This schedule can be changed for young children who may take glargine (Basaglar) before the morning meal.

**After starting** the new glargine (Basaglar) and lispro (Humalog) regimen:

- **Check Blood Glucose Levels (BGL)** at a minimum: before each meal, at bedtime, and once at 3-4am for the first two weeks. If possible, more daily checks including before and 2-3 hours after every meal, at bedtime and at least 2-3 checks at 2-3 am is recommended for the first two weeks after initiation.
- **The BGL 2-3 hours after a meal** is used to adjust the lispro (Humalog) dose with that meal.
- **The BGL before a meal** indicates the effect of the basal insulin, i.e. glargine (Basaglar)
- **A follow up** phone call or clinic visit every 2-3 days in the first week after initiation of the new glargine (Basaglar)/lispro (Humalog) insulin should be made to ensure the child/young adult is coping with the new pen and regimen and to adjust insulin doses as needed.
- If available, Ketone testing would be beneficial at least in the first two weeks following the new regimen.

## Adjusting glargine (Basaglar) long-acting insulin dose

- **Use fasting blood glucose level to adjust glargine (Basaglar) dose.** Aim for a target of 70 -126 mg/dL (4.0 - 7.0 mmol/L); see 'Blood Glucose Level (BGL) Targets in Table 1' below.
- If fasting BGL is above target for 3 days or more after starting glargine (Basaglar), increase glargine (Basaglar) dose by 5-10%.
- If fasting BGL is below target for 1-2 days, decrease glargine (Basaglar) by 5-10%
- If fasting BGL is below 70 mg/dL (4 mmol/L) on any day in the first week after transition, decrease the glargine (Basaglar) dose by 5-10% the following day.
- If BGL rises before meals, try increasing glargine (Basaglar) slightly unless there is a tendency to nighttime hypoglycaemia. If so, you may be better off dividing glargine (Basaglar) into 2 daily doses.
- For tip on finetuning basal glargine (Basaglar) doses see Appendix B

Example 1: Child takes 24 units glargine (Basaglar) at the evening meal. Bedtime BGL levels are usually in the 120-180 mg/dL range (7-10 mmol/L), 2am BGL readings are around 140 mg/dL (8 mmol/L), and 7am fasting BGL readings are consistently over 240 mg/dL (13 mmol/L).

- 5% of 24 units = 1.2 units, rounded down to 1 unit
- 10% of 24 units = 2.4 units, rounded down to 2 units

In this case, either a 1 or 2 unit increase in glargine (Basaglar) is reasonable, i.e., 25-26 units total glargine (Basaglar)

Example 2: Child takes 13 units glargine (Basaglar) in the evening. Bedtime BGL readings are usually in the 120 - 180 (7 - 10 mmol/L) range, 2am BGL readings are usually 110-140 mg/dL (6 - 8 mmol/L), and 7am readings have been below 70 mg/dL (4 mmol/L) for 2 days out of the last week.

- 5% of 13 units = 0.65 units, rounded down to 0.5 units
- 10% of 13 units = 1.3 units, rounded down to 1 unit

In this case, either a 0.5 unit or 1 unit reduction in glargine (Basaglar) is reasonable, i.e., 12 - 12.5 units glargine (Basaglar) total. Since hypoglycaemia can be dangerous, the 10% reduction may be best.

**Table 1. Blood Glucose Level (BGL) Targets**

Before meal	4.0 - 7.0 mmol/L (70 - 126 mg/dL)
After meals	5.0 - 10.0 mmol/L (90 - 180 mg/dL)
At bedtime	6.0 – 10.0 mmol/L (108 - 180 mg/dL)
At 3 am	5.0 - 8.0 mmol/L (90 - 144 mg/dL)

Source: <sup>4</sup>[LFAC/ISPAD/IDF Pocket book guidelines, 2017](#)

## Clinical tips for transitioning to glargine (Basaglar) insulin

- If a child/young adult is known to have persistently high blood glucose levels with rare hypoglycaemia and is known to take all their injections, then there may not be a need to reduce the NPH or TDD by 20% when switching.
- If TDD is significantly greater than 1 unit/kg/day, consider not using the young adult's current dose of insulin as a guide (adolescent may be skipping doses) and recalculate the total dose, using weight and pubertal status (see Option 3). This dose can then be divided as 40% basal / 60% bolus and adjusted according to SMBGs.
- The dose of glargine (Basaglar) is usually given at the time of the evening meal and should be given at the same time every day as it lasts for up to 24 hours.
- For small children, it is acceptable to give glargine (Basaglar) in the morning, since insulin needs before awakening may be very low.
- Some children will benefit from splitting the glargine (Basaglar) dose into 2 equal doses, 12 hours apart. These are children who are on very small doses of glargine (Basaglar) (less than approximately 15 units a day) and those in whom glargine (Basaglar) appears to run out before the next dose is due. Injecting 2 doses a day can make dose titration (adjustment) easier.
- Splitting into 2 doses may also be advisable if BGL rises before meals, and then an increase in glargine (Basaglar) reduces the nighttime BGL too much. You can then adjust each dose: the evening glargine (Basaglar) according to the morning BGL; and the morning glargine (Basaglar) according to the premeal BGLs.
- Glargine (Basaglar) doses can be reduced on days when the child/young adult is more active or plays sport:
  - a) If on one daily dose of glargine (Basaglar): reduce the evening dose the day before the activity. This will decrease the risk of hypoglycaemia during the activity.
  - b) If on one daily dose of glargine (Basaglar): reduce the evening dose after the activity to decrease the risk of overnight hypoglycaemia.
  - c) If on 2 daily doses of glargine (Basaglar): reduce morning dose on the day of the activity and the evening dose after the activity.

A reduction of 20-30% is often advisable.

If insulin doses are not reduced for extra activity or sport, more carbohydrate food may be needed – always carry sugary food or drink when exercising or playing sport.

- Glargine (Basaglar) should not be mixed with other insulins.
- Some children report a burning sensation on injection of glargine (Basaglar) due to the acid pH. Sometimes, injecting with cold insulin taken directly from the refrigerator may reduce stinging.

- Glargine (Basaglar) should be injected subcutaneously and injections rotated – please refer to LFAC bulletin: [Why is correct insulin injection technique important?](#)
- Instructions for the reusable insulin pen, the 'HumaPen Ergo 2' are available in Appendix D.

### What to do if a dose of glargine (Basaglar) is missed?

- **If the next dose of glargine (Basaglar) is due in less than 6 hours**, do not give the missed dose at all. Check for ketones and advise to use lispro (Humalog) insulin to “correct” for high blood glucose levels that may result from missing the glargine (Basaglar) dose (to calculate extra doses use Insulin Sensitivity Factor – for more details see Appendix C – you can also use the calculation Excel sheet by Ragnar Hanas). A correction dose is best given before a meal and added to the usual lispro (Humalog) pre-meal dose.
- **If the child/young adult forgets the evening glargine (Basaglar) dose and remembers the next morning. Advise to give half the dose of glargine (Basaglar) in the morning and give the next evening dose as usual.** Check for ketones and advise to “correct” for high BGL that will have resulted from missing glargine (Basaglar) the evening before; this can be done by adding extra lispro (Humalog) insulin (calculated by using the Insulin Sensitivity Factor - see Appendix C) to the usual morning lispro (Humalog) breakfast dose.
- **Check BGLs more often for a couple of days after missing a dose of glargine (Basaglar).**

Example: Glargine (Basaglar) dose of 20 units at 7pm evening meal is missed. She/he remembers the dose the next morning at 7am. Advise the child to give half the usual 20 units glargine (Basaglar) now at 7am, i.e. 10 units. Then give the next dose as usual in the evening.

## Appendix A: Honeymoon (Remission) phase

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It is likely that large doses of insulin are needed when diabetes is first diagnosed. This is because the body will not be as sensitive to insulin as it should be, due to high blood glucose levels during the weeks immediately before diagnosis. Once treatment with insulin is started, the body is likely to regain its sensitivity to insulin very fast, within a week or so. The amount of insulin will need to be decreased, and sometimes no insulin is needed for a period of time.

When blood glucose levels have stabilized for some time, the beta cells usually start to produce some insulin again, and this makes it possible to decrease insulin doses further. Often this natural insulin production will continue to rise. If the insulin doses can be lowered to 0.5 U/kg body weight or less, and the HbA1c level is close to that of individuals without diabetes, < 53 mmol/mol (7.0%), this is described as the remission phase (also called honeymoon phase).

The advantage of endogenous (bodies own) insulin is that it is secreted in relation to the blood glucose level, which makes it easier to manage blood glucose levels.

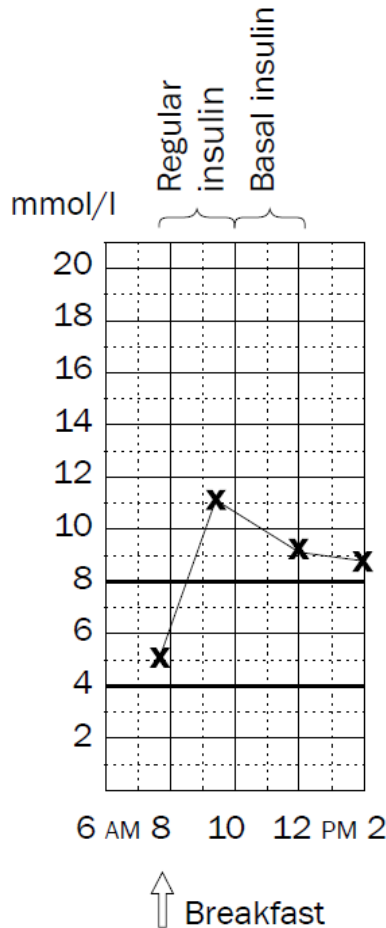
The duration of this remission phase varies widely among individuals but will often last 3-6 months, sometimes even longer, and some may never go into a remission phase. Insulin requirements are usually at their lowest between 1 and 4 months after the onset of type 1 diabetes. However, this varies from person to person.

It is crucial to educate families and young people that they have not been cured and that they will have to take insulin for the rest of their lives to stay alive. As the remaining beta cell are destroyed gradually (autoimmune process), insulin production then usually disappears completely.

After 2-4 years of insulin treatment in young people with type 1 diabetes, it is very unusual to be producing any endogenous insulin at all.

## Appendix B: Finetuning Basal and Bolus insulin doses

Major insulin effect:



When adjusting pre-meal **bolus** doses of lispro (Humalog) insulin, it is best to check blood glucose levels (BGLs) before and 2-3 hours after the meal.

In the above graph, BGLs are still high 2 hours after breakfast. Therefore, the breakfast dose of lispro (Humalog) insulin can be increased by 1-2 units or the insulin to carbohydrate ratio can be adjusted to a smaller number (if counting carbohydrates – see page 8). The dose of glargine (Basaglar) insulin seems to be correct since the BGLs don't change much more until lunchtime (although they remain high as a result of taking insufficient lispro (Humalog) insulin to cover the amount of carbohydrate food eaten for breakfast).

To adjust the **basal glargine** (Basaglar) dose, look at the changes in blood glucose levels during the night. If blood glucose levels increase after the dinner peak and remain high until breakfast ( $> 146 \text{ mg/dL}$  /  $> 8 \text{ mmol/L}$ ), then an increase in the basal dose (glargine) is recommended (increase by 1-2 units). If glucose decreases significantly during the night or if experiencing overnight or morning hypoglycemia ( $< 70 \text{ mg/dL}$  /  $< 4 \text{ mmol/L}$ ), a decrease in the glargine (Basaglar) dose is recommended (1-2 units).

For more advanced insulin dose adjustment see Chapter 14 (from page 147) in the book by Dr Ragnar Hanas 'Type 1 Diabetes in Children, Adolescents and Young Adults: How to become an expert on your own diabetes' <sup>3</sup> available [here](#) on the Life for a Child website.

## Appendix C: Calculating and Using Insulin Sensitivity Factor (ISF)

The Insulin Sensitivity Factor (ISF) also called Correction Factor (CF) indicates how “sensitive” a child/young adult is to insulin.

**The ISF indicates approximately how much 1 unit of lispro (Humalog) insulin will lower the child/young adult’s blood glucose level. The ISF is used to correct high blood glucose levels.**

To determine the child/young adult’s ISF, divide **1800 by TDD** (when using mg/dL) or **100 by TDD** (when using mmol/L). This will tell you how much 1 unit of **lispro (Humalog) (rapid acting) insulin** will lower her/his blood glucose level.

If **Regular short acting insulin** is used, the 1500/83 rule instead, that is divide 1500 by TDD (when using mg/dL) or 83 by TDD (when using mmol/L)

Daytime Correction Factor Rule for <b>mmol/L</b>	$100 \div \text{TDD}$
Daytime Correction Factor Rule for <b>mg/dL</b>	$1800 \div \text{TDD}$

**NOTE:** To reduce the risk of hypoglycemia, a higher correction factor/a lower correction dose may be needed in the evening and overnight (see attached Excel calculation sheet by Dr Ragnar Hanas)

Example: A child is taking 30 units of insulin a day (TDD). One morning, the BGL is 280 mg/dL (16 mmol/L), and you want to lower that BGL from 280 mg/dL to the target level of 100 mg/dL (16 to 6 mmol/L). The usual morning lispro (Humalog) insulin dose is 5 units.

### For mg/dL

**Step 1:** use the 1800 rule to calculate the **ISF** i.e.  $1800 \div 30 \text{ units (TDD)} = 60$

**60 is the ISF** which means 1 unit of lispro (Humalog) insulin reduces BGL by 60 mg/dL  
BGL is 280 mg/dL with a target of 100mg/dL.  $280 - 100 = 180$ ; this BGL is 180 mg/dL over the target, hence we want to lower the BGL by 180 mg/dL.

**Step 2:** Take the 180mg/dL and divide by the **ISF of 60**;  $180 \div 60 = 3 \text{ units}$ . She/he should take an additional 3 units lispro (Humalog) to bring BGL down to the target level of 100 mg/dL.

**Step 3:** Add 3 units to the Usual 5 units lispro (Humalog) = **8 units lispro (Humalog) this morning only.**

### For mmol/L

Follow Step 1-3 with the 100 Rule:

**Step 1:** Use the 100 rule to calculate the **ISF**:  $100 \div 30 \text{ (TDD)} = 3.3$

**3.3 is the ISF** which means 1 unit of lispro (Humalog) insulin reduces BGL by 3.3 mmol/L



BGL is 16 mmol/L with target of 6 mmol/L (rounded);  $16 - 6 = 10$ ; this BGL is 10mmol/L over the target, hence we want to lower the BGL by 10 mmol/L

**Step 2:** Take the 10mmol/L and divide by the **ISF of 3.3**;  $10 \div 3.3 = 3$  units.

**Step 3:** Add 3 units to the Usual 5 units lispro (Humalog) = **8 units lispro (Humalog) this morning only.**

The Insulin Sensitivity Factor can be used:

- Before a meal if the pre-meal BGL is above target (the correction dose needs to be added to the usual pre-meal dose as shown in Example above)
- Randomly, to correct a high BGLs especially during sick days or when symptomatic (polydipsia, polyuria); but **wait at least 2 hours after the last lispro (lispro (Humalog)) dose was given** (as it is still active and can lead to insulin stacking and hypoglycaemia).

**Note:** At bedtime, at night, or before exercise, the ISF is usually increased, as a more conservative (higher) correction factor can help prevent overnight or post exercise hypoglycaemia.

**Important:** The **lower** the Insulin Sensitivity Factor – the **more insulin** will be given for a correction

### Important Points:

- ◆ **Do not use basal insulin (i.e. glargine) for correction doses!** Only use ultra-rapid, rapid or Regular insulin when applying the ISF.
- ◆ Do not give more than 0.1 Unit/kg (or 10% of TDD) for correction of a high blood glucose.
- ◆ **Wait at least 2-3 hours before taking another dose, if needed** (to avoid insulin stacking)!
- ◆ **Correction factors offer a temporary solution to high BGL.** Always look for trends in BGL to decide when to make a permanent change to insulin doses.
- ◆ For more details on how to adjust lispro (Humalog) insulin refer to LFAC bulletin: [Insulin dose adjustment – basic rules and unexpected circumstances](#)

## Appendix D: Instructions for use of HumaPen Ergo II

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### **IMPORTANT:**

Life for a Child is currently supplying 2 identical HumaPen Ergo II insulin pens, one for the use of (Basaglar), and one for the use of Humulin R. Please **label the outside of each pen** to ensure the children, parents and young adults don't mix up the basal and bolus insulins. It can be dangerous if the wrong insulin is injected at the wrong time.

**NOTE:** Life for a Child will be providing a red Savvio reusable pen which can be used for lispro (Humalog) insulin. This will prevent mixing up the basal and bolus insulin as the pens look very different.

Video instructions for **Humapen Ergo**:

English: <https://www.youtube.com/watch?v=pqll2kOdZBo>

English spoken with French captions: <https://www.youtube.com/watch?v=NPYP8Klr-eE>

English spoken with Spanish captions: <https://www.youtube.com/watch?v=ivCVNI5lQSg>

Each new pen container contains an instruction leaflet (see copy below):

Video instructions for **Savvio pen**:

English: <https://www.youtube.com/watch?v=-gXKETYM8Fo>

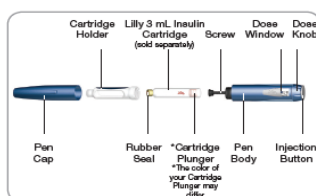
# HumaPen Ergo™ II

INSULIN DELIVERY DEVICE  
INSTRUCTIONS FOR USE

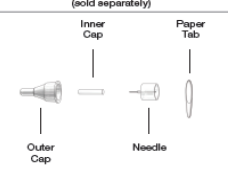
For use only with Lilly 3 mL insulin cartridges (100 IU/mL). Do not use other brands of insulin cartridges.  
The color of your HumaPen Ergo™ II is Two-Tone Blue.



## HumaPen Ergo™ II Pen Parts



## Pen Needle (sold separately)



HumaPen Ergo II is designed for ease of use. You can give yourself multiple doses from one Lilly 3 mL Insulin Cartridge (100 IU/mL). You can inject from 1 to 60 units of insulin from a Lilly 3 mL insulin cartridge in each injection. You can dial your dose one unit at a time. If you dial the wrong dose, you can correct the dose without wasting any insulin.

Read these instructions completely and follow the directions carefully before using the pen. Failure to follow the instructions may result in the wrong insulin dose being delivered.

**DO NOT SHARE YOUR PEN OR NEEDLES AS THIS MAY RISK TRANSMISSION OF INFECTIOUS AGENTS.**

If any of the parts of your Pen appear broken or damaged, **DO NOT USE**. Contact your healthcare professional for a replacement pen.

HumaPen Ergo II is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it.

Always carry a spare insulin pen in case your pen is lost or damaged.

## 1 INSERT THE INSULIN CARTRIDGE

### Important Notes

- Your healthcare professional has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.
- HumaPen Ergo II is for use only with Lilly 3 mL insulin cartridges.
- Do not use other brands of insulin cartridges.
- Read and follow the instructions provided in your Lilly 3 mL insulin cartridge package insert.
- Before each injection, read the cartridge label and be sure the pen contains the correct Lilly 3 mL insulin cartridge.
- The color of the pen is not intended to indicate insulin type.
- The numbers on the cartridge holder give an estimate of the amount of insulin remaining in the cartridge. Do not use these numbers for measuring an insulin dose.
- For more information on HumaPen Ergo II and Lilly insulin, please contact your healthcare professional.

### Frequently Asked Questions about Inserting the Insulin Cartridge

#### 1. Why doesn't the screw move out when there is no cartridge in the pen?

The screw may not move out when you push the injection button unless there is a cartridge in the pen. This feature of the pen allows you to easily push the screw into the pen body when replacing a cartridge. Once a cartridge is inserted, the screw will move out when the injection button is pushed.

#### 2. What should I do if I can't attach the cartridge holder to the pen body?

Check that the insulin cartridge is fully inserted into the cartridge holder. Then carefully line up the cartridge holder with the pen body and screw together until secure.

## 3 INJECT THE DOSE

### Important Notes

- You must **PUSH** the injection button straight down for the dose to be delivered.
- You will **NOT** receive your insulin by turning the dose knob.
- Do not attempt to change the dose while injecting.

### Frequently Asked Questions about Injecting

#### 1. Why is it difficult to push the injection button when I try to inject?

- Your needle may be clogged. Try attaching a new needle, and then prime the pen.
- Pushing the injection button down quickly may make the button harder to push. Pushing the button more slowly may make it easier.
- Using a larger diameter needle will make it easier to push the injection button during injection. Ask your healthcare professional which needle is best for you.
- Your injection button may become harder to push if the inside of your pen gets dirty with insulin, food, drink or other materials. Following the CARE AND STORAGE instructions below should help prevent this.

If none of the above steps resolves the problem, your pen may need to be replaced.

#### 2. Why doesn't the dose knob go to zero when I inject my dose?

This can happen if the insulin cartridge does not have enough insulin left in it for your entire dose. The number in the dose window is the amount you did **NOT** receive. To get the rest of your dose, remove the needle, change the insulin cartridge, attach a new needle, and prime the pen. Then complete your dose by dialing the amount that you did **NOT** receive and inject only this amount.

## 2 PRIME THE PEN (BEFORE EVERY INJECTION)

### Important Notes

- HumaPen Ergo II is suitable for use with Becton, Dickinson and Company pen needles.
- The directions regarding needle handling are not intended to replace local, healthcare professional, or institutional policies.
- Use a new needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce needle clogs.

### Frequently Asked Questions about Priming

#### 1. Why is it important to prime before every injection?

If you do **NOT** prime, you may get the wrong insulin dose. Priming helps to ensure that the pen and needle are working properly. Once the pen is properly primed, insulin will flow from the needle. You may need to prime several times before you see insulin at the tip of the needle.

#### 2. Why can it take several attempts to prime when a new cartridge is inserted?

There may be a gap between the screw and the cartridge plunger. Repeating the priming steps will move the screw out to touch the cartridge plunger. Once the end of the screw pushes the cartridge plunger out, insulin will flow from the needle.



- Repeat the priming steps until insulin is seen at the needle tip.
- If you are still unable to see insulin flow from the needle, go to Question 3.

#### 3. Why should I prime until I see insulin at the tip of the needle?

- Priming moves the screw into contact with the cartridge plunger and gets the air out of the cartridge.
- You may see insulin on the tip of the needle when you first attach it. This only shows that the needle is attached and not clogged. You must still prime the pen.
- You may also see no insulin at all when you are priming the pen. This may be because the screw is moving forward to close a gap between the screw and the cartridge plunger.
- Insulin will flow only when the pen is properly primed.
- If the injection button is hard to push, the needle may be clogged. Attach a new needle. Repeat the priming steps until insulin is seen at the tip of the needle.

If you are still unable to see insulin flow from the needle, **do NOT** use the pen. Contact your healthcare professional for assistance or to obtain a replacement.

#### 4. What should I do if I have an air bubble in the cartridge?

Priming your pen will remove air. Point the pen up, and tap the cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until insulin is seen at the tip of the needle. A small air bubble may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, this small air bubble will not affect your insulin dose.

## CARE AND STORAGE

- Remove the needle after every use. Do not store the pen with the needle attached.
- Keep your HumaPen Ergo II, Lilly 3 mL insulin cartridges, and needles out of the reach and sight of children.
- Keep the pen away from moisture, dust, extreme hot or cold temperatures, and direct sunlight.
- Do not store the pen in a refrigerator.
- Wipe the pen cap, pen body, and case with a damp cloth to clean them.
- Do not use alcohol, hydrogen peroxide, or bleach on the pen body or dose window.
- Also, do not cover in liquid or apply lubrication such as oil, as this could damage the pen.
- Refer to the insulin cartridge package insert for complete insulin storage instructions.

## REPLACEMENT

Do not use your pen for more than 3 years after the first use or past the expiration date on the carton. Contact your healthcare professional if a prescription is necessary, or go directly to a pharmacy when you need a new HumaPen Ergo II.

Record the date your Pen was first used here:

DAY MONTH YEAR

If you have any questions or problems with your HumaPen Ergo II, contact your healthcare professional for assistance.


### Getting Ready

Wash your hands and make sure you have the following items before beginning:

- HumaPen Ergo™ II
- Lilly 3 mL Insulin Cartridge
- New Pen Needle
- Alcohol Swab

## HumaPen Ergo™ II

INSULIN DELIVERY DEVICE

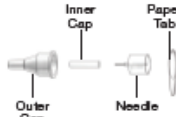


Pen Cap   Cartridge Holder   Rubber Seal   \*Cartridge Plunger (The color of your Cartridge Plunger may differ)   Screw   Dose Window   Dose Knob   Injection Button   Pen Body

Lilly 3 mL Insulin Cartridge (sold separately)

HumaPen Ergo™ II Pen Parts


### Pen Needle (sold separately)




Inner Cap   Paper Tab   Outer Cap   Needle

### 1 INSERT THE INSULIN CARTRIDGE

#### A Pull Off Pen Cap




#### B Insert Cartridge



Insert small end of Lilly 3 mL insulin cartridge into the cartridge holder.

**Note:** Check the insulin cartridge to make sure it is not cracked or broken and your insulin is not expired before inserting the insulin cartridge.

#### C Push Screw Back




The screw may be in or out when you get the pen.

If the screw is out, use the cartridge plunger to push the screw back.

**Note:** If you push the injection button without a cartridge in the cartridge holder the screw will not move forward.


#### D Attach Cartridge Holder



Push the cartridge holder and pen body straight together. Screw the pen body onto the cartridge holder until it is secure.

**Caution:** If the cartridge holder is not completely attached, the screw may not move and you may not get your full dose.

#### E Inspect Insulin




Be sure to check your insulin for:

- Type
- Appearance

Wipe the small rubber seal on the end of the cartridge with an alcohol swab.

#### F For Cloudy Insulin Only




Roll the pen gently 10 times.

and invert the pen 10 times. The insulin should look evenly mixed.

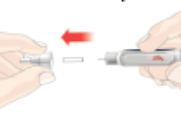
### 2 PRIME THE PEN (BEFORE EVERY INJECTION)

**Caution:** If you do NOT prime, you may get the wrong insulin dose.

#### A Remove Paper Tab




#### B Attach Needle



Screw needle straight onto the cartridge holder.


#### C Remove Needle Cap



Pull off the outer cap. Save the outer cap to remove the needle after your injection.

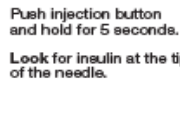
Pull off the inner cap and throw it away.

#### D Dial 2 Units



Tap Cartridge Point pen up. Tap cartridge to collect air at the top for removal.

#### E Prime The Pen




Push injection button and hold for 5 seconds.

Look for insulin at the tip of the needle.

**Caution:** Several prime attempts may be needed the first time a cartridge is used. If no insulin flows after several attempts the needle may be clogged.

#### F If No Insulin Is Seen, Repeat Priming




Dial 2 units.

Tap cartridge.

Push injection button and look for insulin at the needle tip.

### 3 INJECT THE DOSE

#### A Dial Your Dose




Turn dose knob to your desired dose.

**Example:** 15 units shown in the drawing above.

If you dial too many units, you can correct the dose by dialing backwards.

The dose knob clicks as you turn it. **DO NOT** dial your dose by counting clicks because you may dial the wrong dose.

#### B Inject Your Dose



Insert the needle as directed by your healthcare professional.

Place your thumb on the injection button then slowly and firmly push the button until it stops moving.

Continue to hold the button for 5 seconds, then remove the needle from your skin.


Check to make sure you see a 0 in the dose window to confirm you received the complete dose.

**Note:** It is possible to set a dose larger than the amount of insulin left in the cartridge.

At the end of an injection, the number in the dose window should be 0. If it is not, this is the amount of insulin you did NOT receive. Remember this number. Remove the needle and the empty cartridge. Insert a new cartridge as shown in (1), attach a new needle, and prime the pen as shown in (2). Complete your dose by injecting only the amount you did not receive.

If you do not think you received your full dose, do not take another dose. Call Lilly or your healthcare professional for assistance.


#### C Replace Needle Outer Cap



Carefully replace the outer cap as instructed by your healthcare professional.


**Note:** To prevent air from entering the cartridge, do not store the pen with a needle attached.

#### D Remove The Needle



- Remove the capped needle by twisting it off.
- Put used needles in a sharps container or a hard plastic container with a secure lid. Do not throw Needles directly into your household trash.
- Do not recycle the filled sharps container.
- Ask your healthcare provider about options to dispose of the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare provider or institutional policies.

**Replace Pen Cap**



If you have any questions or problems with your HumaPen Ergo II, contact your healthcare professional for assistance.

Lilly and Company Pharmaceutical Delivery Systems   Packaged by: Lilly S.A. Avenida Industria 30   28108 Alcobendas, Madrid, Spain   Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ UTRECHT The Netherlands

HumaPen Ergo II meets the dose accuracy and functional requirements of ISO 11608-1 with Lilly 3 mL cartridges.

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**Lilly**   PA 0235/PX/502



# HumaPen SAVVIO® INSULIN DELIVERY MEDICAL DEVICE INSTRUCTIONS FOR USE

PA02052020

## INTRODUCTION

**Intended Use:** HumaPen SAVVIO® is a reusable insulin pen intended for the self-injection of insulin available in Lilly 3 ml cartridges using disposable pen needles (sold separately).

**Intended Users:** The intended users of HumaPen Savvio are those prescribed Lilly 3 ml insulin cartridges, including adults, adolescents and children who are capable of self-injection, or adult caregivers who administer insulin to others.

**Contraindications:** There are no known contraindications for HumaPen Savvio. HumaPen SAVVIO® Pen is designed for ease of use. You can give yourself multiple doses from one Lilly 3 ml insulin cartridge (100 IU/ml or units/ml). You can inject from 1 to 60 units of insulin in each injection. You can dial your dose one unit at a time. If you dial the wrong dose, you can correct the dose without wasting any insulin.

**For more information on HumaPen SAVVIO Pens and Lilly insulin, please visit our website at [www.lilly.co.uk](http://www.lilly.co.uk) and [www.lilly.ie](http://www.lilly.ie)**

**Read these instructions completely and follow the directions carefully before using the pen. Failure to follow the instructions may result in the wrong insulin dose being delivered.**  
**Do not share your pen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give an infection to them or get an infection from them.**  
**If any of the parts of your Pen appear broken or damaged, DO NOT USE. Contact your local Lilly affiliate office (see end of leaflet for contact details) or your healthcare professional for a replacement Pen.**  
**HumaPen SAVVIO is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it. Always carry a spare insulin pen in case your pen is lost or damaged.**

## IMPORTANT NOTES

Your healthcare professional has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.

- HumaPen SAVVIO is for use only with Lilly 3 ml insulin cartridges. Do not use other brands of insulin cartridges.
- Before each injection, read the cartridge label and be sure the pen contains the correct Lilly 3 ml insulin cartridge.

The colour of the pen is not intended to indicate insulin type.

## INSERT THE CARTRIDGE

- Read and follow the instructions provided in your Lilly 3 ml insulin cartridge information for the Patient (package leaflet).
- Check to make sure the insulin cartridge is not cracked or broken and your insulin is not expired before inserting the insulin cartridge into your pen.
- Check the cartridge label for the type of insulin and appearance before each injection.

## ATTACH NEEDLE

- HumaPen SAVVIO is suitable for use with BD (Becton, Dickinson and Company) Pen needles.
- Use a new needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce needle clogs.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.

## PRIME THE PEN

- Prime every time. The pen must be primed until you see insulin at the needle tip before each injection to make sure the pen is ready to dose.
- If you do not prime, you may get the wrong dose.

## INJECT THE DOSE

- HumaPen SAVVIO will not allow you to dial more than the number of units left in the cartridge.
- Do not push down on the injection button while dialling your dose.

- Do not attempt to inject your insulin by turning the dose knob. You will NOT receive your insulin by turning the dose knob. You must PUSH the injection button straight in for the dose to be delivered.
- Do not attempt to change the dose while injecting.

- You may see a drop of insulin at the needle tip. This is normal and it does not affect the dose you just received.

## CARE AND STORAGE

- Remove the needle after every use. Do not store the pen with the needle attached.
- Keep your HumaPen SAVVIO, Lilly 3 ml insulin cartridges, and needles out of the reach and sight of children.
- Keep the pen away from dust.
- Store pen between -40°C and 70°C without the insulin cartridge.
- Wipe the pen cap, pen body and case with a damp cloth to clean them.
- Do not use alcohol, hydrogen peroxide or bleach on the pen body or dose window. Also, do not cover in liquid, as this could damage the pen.
- Do not apply lubrication such as oil, as this could damage the pen.
- Keep the pen away from extreme hot or cold temperature, after the Lilly 3 ml insulin cartridge is inserted.
- Refer to the insulin cartridge information for the Patient (package leaflet) for complete insulin storage instructions.

## REPLACEMENT AND DISPOSAL OF PEN

Do not use your pen for more than 6 years after the first use or past the use-by date on the carton.

The expired pen may be discarded in your household waste after you have removed the needle. Ask your healthcare professional about options to dispose of the pen properly.

Contact your healthcare professional if a prescription is necessary, or go directly to a pharmacy when you need a new HumaPen SAVVIO.

If you have any questions or problems with your HumaPen SAVVIO Pen, contact your local Lilly affiliate office or your healthcare professional for assistance.

Record the date your Pen was first used here: \_\_\_ / \_\_\_ / \_\_\_.

Record the Use-by date from your carton here: \_\_\_ / \_\_\_ / \_\_\_.

## FREQUENTLY ASKED QUESTIONS

### QUESTIONS ABOUT INSERTING THE CARTRIDGE

#### 1. Why doesn't the screw move out when there is no cartridge in the pen?

The Screw may not move out when you push the injection button unless there is a cartridge in the pen. Once a cartridge is inserted, then the screw will move out when the injection button is pushed.

#### 2. What should I do if I can't attach the cartridge holder to the pen body?

Check that the Lilly 3 ml insulin cartridge is correctly inserted into the cartridge holder. Then carefully line up the cartridge holder with the pen body and twist together until secure.

### QUESTIONS ABOUT PRIMING THE PEN

#### 1. Why is it important to prime before every injection?

- Priming helps to ensure that the pen and needle are working properly.
- Priming removes air that may collect in the needle or insulin cartridge during normal use.

If you do NOT prime, you may get the wrong insulin dose.

Priming helps to ensure that the pen and needle are working properly. Once the pen is properly primed, insulin will flow from the needle. You may need to prime several times before you see insulin at the tip of the needle.

#### 2. Why can it take several attempts to prime when a new cartridge is inserted?

There may be a gap between the screw and the cartridge plunger. Repeating the priming steps will move the screw out to touch the cartridge plunger. Once the end of the screw pushes the cartridge plunger out, insulin will flow from the needle.

#### 3. Why should I prime until I see insulin at the tip of the needle?

Priming moves the screw into contact with the cartridge plunger and gets the air out of the cartridge.

- You may see insulin on the tip of the needle when you first attach it. This only shows that the needle is attached and not clogged. You must still prime the pen.

- You may also see no insulin at all when you are priming pen. This may be because the screw is moving forward to close a gap between the screw and the cartridge plunger.

- Insulin will flow only when the pen is properly primed.
- If the injection button is hard to push, the needle may be clogged. Attach a new needle. Repeat the priming steps until insulin is seen at the needle tip.

If you are still unable to see insulin flow from the needle, do NOT use the pen. Contact your healthcare professional for assistance or to obtain a replacement.

#### 4. What should I do if I have an air bubble in the cartridge?

Priming your pen will remove air. Point the pen up, and tap the cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until insulin is seen at the tip of the needle. A small air bubble may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, this small air bubble will not affect your insulin dose.

### QUESTIONS ABOUT INJECTING

#### 1. What should I do if I dial a wrong dose (too high or too low)?

Turn the dose knob backward or forward to correct the dose before injecting.

#### 2. What should I do if my full dose cannot be dialled?

If your dose is greater than the number of units left in the cartridge, you may either inject the amount remaining in your current cartridge, and then use a new cartridge to complete your dose, OR inject the full dose with a new cartridge.

For example, if you need 31 units and only 25 units remain in the cartridge you will not be able to dial past 25. In this instance you will need an additional 6 units. Do not attempt to dial past this point. You may either:

- Inject the partial dose and then inject the remaining dose using a new cartridge. OR
- Inject the full dose with a new cartridge.

#### 3. Why is it difficult to push the injection button when I try to inject?

- Your needle may be clogged. Try attaching a new needle, and then prime the pen.

- Place your thumb directly on top of the injection button so the dose knob can turn freely.

- Pushing the injection button down quickly may make the button harder to push. Pushing the button more slowly may make it easier.

- Using a larger diameter needle will make it easier to push the injection button during injection. Ask your healthcare professional which needle is best for you.

If none of the above steps resolves the problem, your pen may need to be replaced.

Your Injection Button may become harder to push if the inside of your pen gets dirty with insulin, food, drink or other materials. Following the CARE AND STORAGE instructions should prevent this.

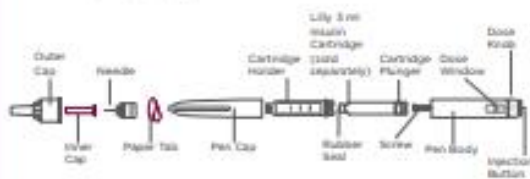
If you have any questions or problems with your HumaPen SAVVIO Pen, contact your local Lilly affiliate office or your healthcare professional for assistance.

## MAKE SURE YOU HAVE ALL YOUR PEN COMPONENTS.

Wash your hands before each injection.

**PEN NEEDLE (sold separately)**

**HUMAPEN SAVVIO PEN PARTS**



Be sure to check your insulin cartridge for:

- Type of insulin
- Expiry Date
- Appearance
- Cracks or leakage

## 1. INSERT THE CARTRIDGE

Put off pen cap and set aside.



Twist cartridge holder to detach.



Insert small end of Lilly 3 ml insulin cartridge into the cartridge holder.



If the screen is out, use the cartridge plunger to push it back.



Push the cartridge holder and pen body straight together. Twist the cartridge holder onto the pen body until you feel a click and it is secure.



Wipe the small rubber seal on the end of the cartridge with an alcohol swab.



## FOR CLOUDY MIXTURE INSULIN ONLY

Follow these instructions before each injection.

Roll the pen gently 10 times.

Insert the pen gently 10 times.

The insulin should look evenly mixed.

Insert the pen gently 10 times.

The insulin should look evenly mixed.

Insert the pen gently 10 times.

The insulin should look evenly mixed.

Insert the pen gently 10 times.

The insulin should look evenly mixed.

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Insert the pen gently 10 times.

The insulin should look evenly mixed.

Insert the pen gently 10 times.

The insulin should look evenly mixed.

## 2. ATTACH NEEDLE

Remove the paper tab and discard.

Insert needle straight into the cartridge holder until secure.

Put off outer needle cap.

Save the outer needle cap to remove the needle after your injection.

Put off inner needle cap and throw it away.

Keep Discard

Put off outer needle cap.

Save the outer needle cap to remove the needle after your injection.

Put off inner needle cap and throw it away.

Keep Discard

Put off outer needle cap.

Save the outer needle cap to remove the needle after your injection.

Put off inner needle cap and throw it away.

Keep Discard

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Keep Discard

Put off outer needle cap.

Save the outer needle cap to remove the needle after your injection.

Put off inner needle cap and throw it away.

Keep Discard

Put off outer needle cap.

Save the outer needle cap to remove the needle after your injection.

Put off inner needle cap and throw it away.

Keep Discard

## 4. INJECT THE DOSE

Turn dose knob to your desired dose. Example: 28 units is shown in the diagram below.



⚠️ If you dial too many units, you can correct the dose by dialing backwards.

⚠️ The Pen will not allow you to dial more than the number of units left in the cartridge.

⚠️ The dose knob clicks as you turn it. **DO NOT** dial your dose by counting clicks. Because you may dial the wrong dose.

Insert needle into skin using the injection technique recommended by your healthcare professional.

⚠️ Place your thumb on the injection button and then slowly and firmly push the injection button until it stops moving.

Continue to hold the button for 5 seconds then remove the needle from your skin.

⚠️ After removal check to make sure you see 0 in the dose window to confirm you received the complete dose. If you are not sure you injected your full dose, **do not inject another dose.** Call your local Lilly affiliate office or your healthcare provider.



## 5. STORE YOUR PEN

⚠️ Carefully replace the outer needle cap as instructed by your healthcare professional.

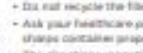
While grasping cartridge holder, uncap the capped needle.

⚠️ Put used needles in a sharps container or a hand plastic container with a secure lid. Do not throw needles directly into your household waste.

⚠️ Do not recycle the filled sharps container.

⚠️ Ask your healthcare provider about options to dispose of the sharps container properly.

⚠️ The directions regarding needle handling are not intended to replace local, healthcare provider or institutional policies.



⚠️ If you have any questions or problems with your Humapen SAVVIO Pen, contact your local Lilly affiliate office (see below) or your healthcare professional for assistance.

Report all MEDICAL DEVICE COMPLAINTS or UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to local Lilly affiliate office (see below). You are also encouraged to report all UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS to:

United Kingdom: Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland: HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie)

Australia: [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)

New Zealand: [nzphvc.otago.ac.nz/reporting/](http://nzphvc.otago.ac.nz/reporting/)

South Africa: [www.sahpra.org.za/health-products-vigilance/](http://www.sahpra.org.za/health-products-vigilance/)

Local Lilly affiliate contact details:

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The Netherlands

Importer  
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Avenida Industrial 30  
28058 Alcobendas  
Madrid, Spain

Humapen SAVVIO meets the dose accuracy and functional requirements of ISO 7808-1 with Lilly 3 ml cartridges.

Non-Sterilized/Single-Use

OR Patient information website

MD Medical device

SI Single patient - multiple use

⚠️ Caution: include non-hazardous symbols used in the labeling.

⚠️ Symbol used on the carton.

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## Disclaimer:

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