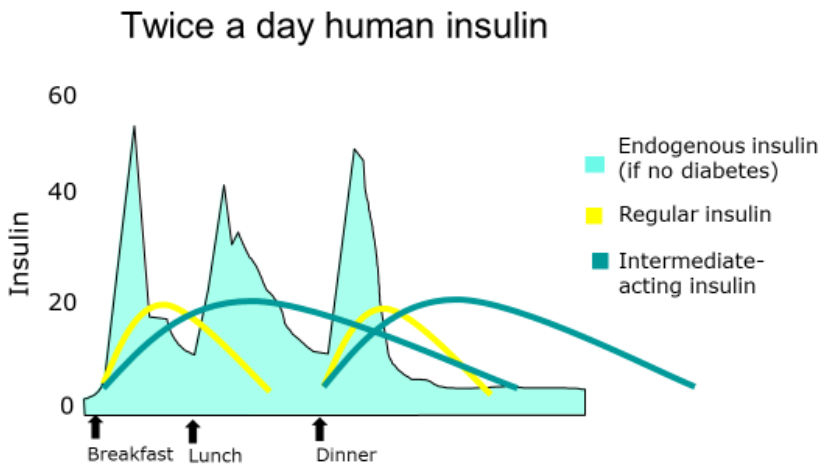
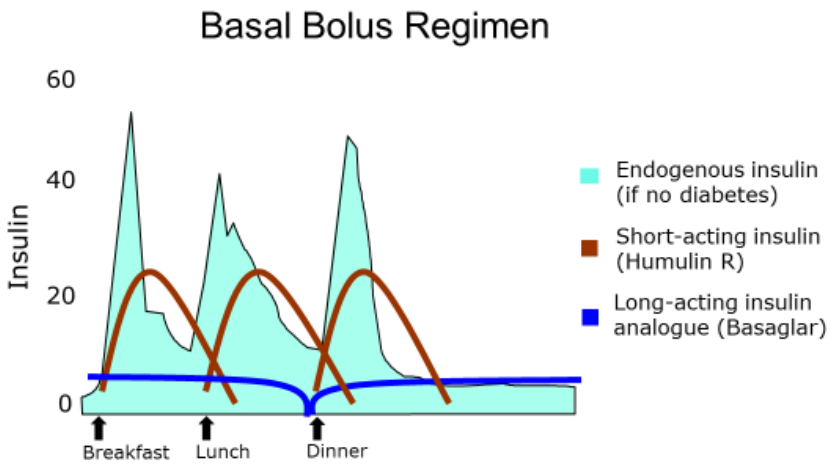
Guide for switching children and youth with Type 1 diabetes from Humulin NPH & Regular or Pre-mixed to Basaglar & Regular Insulins

Introduction

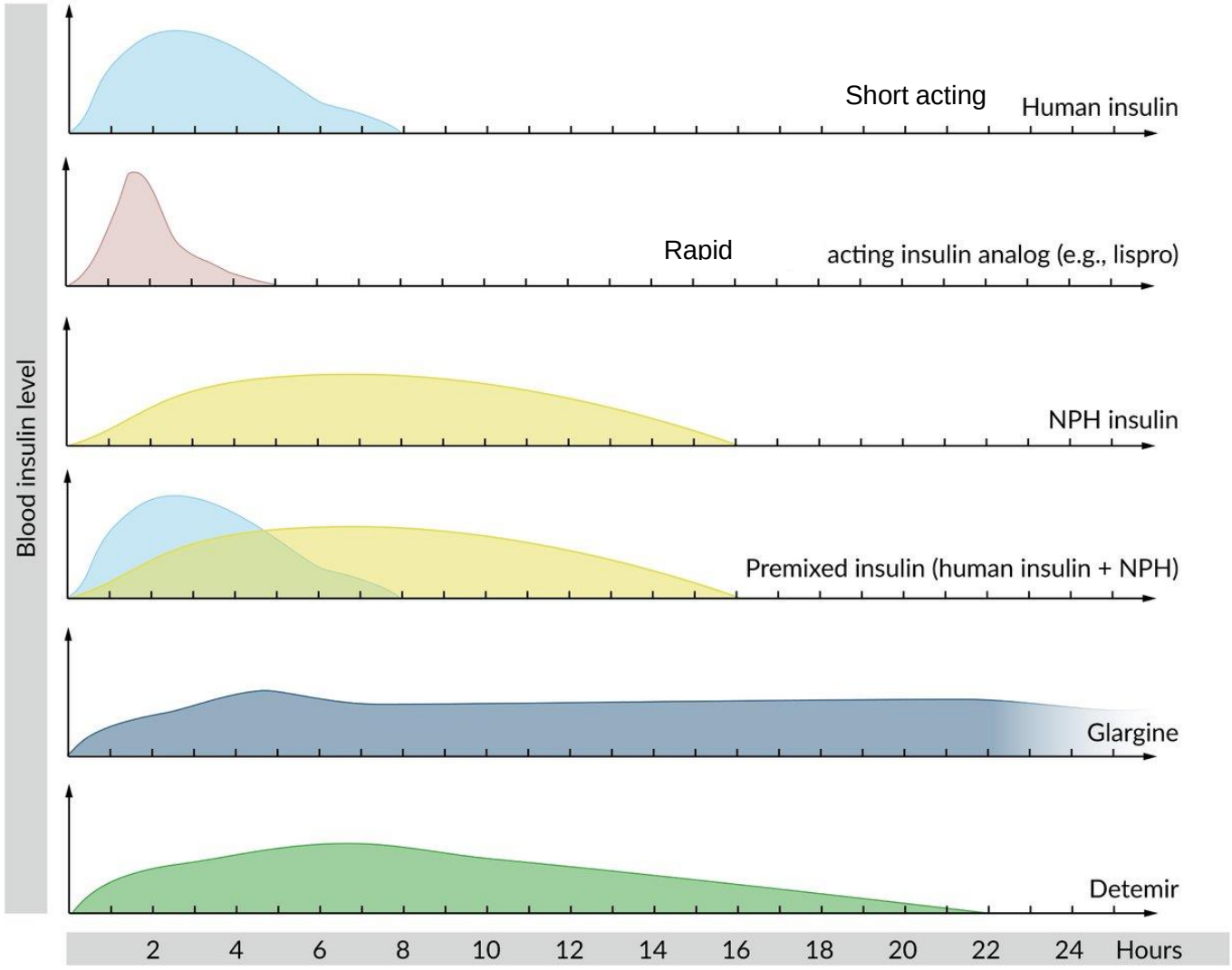
Basaglar (insulin glargine) is a long-acting “basal” insulin analog, with duration of action up to 24 hours. Because it has virtually no peak, there is potentially less risk for hypoglycaemia when food is not available, and overnight. As Basaglar predominantly covers the effect of hepatically- (liver-)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





Insulin Profiles

Insulin action profiles



Insulin name	Insulin type	Formu-lation	Onset of action	Peak action	Duration of action	Mixing with other insulin	Number of injections per day
Basaglar (insulin glargine)	Basal long-acting analog insulin	Clear- no mixing needed	2-4 hours	8-12 hours	22-24 hours (can be shorter in some individuals)	**Should not be mixed** with any other insulin	Usually 1 Sometimes 2**
Humulin R (Regular)	Soluble/ short-acting insulin	Clear	30-60 min	2-4 hours	5-8 hours	can be mixed	Multiple- given before each meal
Humulin NPH	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
Pre-mixed insulin Humulin 30/70	30% short-acting and 70% intermediate-acting human insulin	Cloudy- needs to be mixed before each use	30 min	4-12 hours	8-24hours	**Cannot be mixed** 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 Clinical Practice Consensus Guidelines

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 a Basaglar (long-acting analog) and Regular (short acting) 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 Basaglar starting dose)

Step 3: **Divide NEW TDD into 40% as Basaglar and 60% as Regular**

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

Note: More Regular 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 will be needed for lunch, since 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	*TDD (16+8+6+4) = 34* *Reduce TDD dose by 20% = 80% of 34 units (0.8 x 34) =* ***27 units*** *(rounded down)* *Divide 27 units (NEW TDD) into:* ***40% Basaglar*** *(0.4 x 27) = 11 units (rounded up)* *and* ***60% Regular*** *(0.6 x 27) = 16 units (rounded down)*	Basaglar = **11** units as one evening dose Regular = **16** units divide into meal doses (depending on amounts of carbs eaten for each meal) **Note:** A Regular 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 Regular insulin into meal doses')

Option 2
If currently on Pre-mixed (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 Basaglar and 60% as Regular**

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

Note: More Regular 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 will be needed for lunch, since 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	*TDD = 25 + 12 = 37 units* *Reduce TDD by 20% = 80% of 37 units = 0.8 x 37 = 30 units (rounded up)* *Divide 30 units (NEW TDD) into:* ***40% Basaglar** (0.4 x 30) = **12 units*** *and* ***60% Regular** (0.6 x 30) = **18 units***	Basaglar -12 units as one evening dose Regular -18 units divide into meal doses **Note:** A Regular 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 Regular insulin into meal doses')

Option 3

Use weight and pubertal status

for calculating Basaglar (long-acting analog) and Regular (short acting human 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[1]
   - 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[1] when switching to Basaglar
   - pubertal dosing: may need 1.0 – 2.0 units/kg/day[1] (begin with 1.0-1.5 in newly diagnosed)
   - post pubertal dosing: 0.4 – 1.0 units/kg/day[2]

   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 pre-mixed 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 Basaglar and 60% as Regular
   Note: For children **less than 3 years of age**, use 30% of the NEW TDD as Basaglar dose, 70% as Regular insulin for meals.
5. Divide the Regular dose between the meals the child/young adult consumes in a day (for more details see under the heading 'Dividing Regular 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**)**	*New TDD will be 1.0 units/kg/day* *1.0 x 40 kg = 40 units (NEW TDD)* *Divide 40 units (NEW TDD) into:* ***40% Basaglar (0.4 x 40 = 16 units*** *and* ***60% Regular (0.6 x 40) = 24 units***	**Basaglar - 16 units** as one evening dose **Regular - 24** units divide into meal doses 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 Regular insulin into meal doses' below)

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

Dividing Regular 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 (Regular) will be divided in the same way that carbs are divided throughout the day.

  Example**: Total daily Regular insulin is 16 units**.

  25% of carbs before breakfast: 0.25 x 16 = **4 units** Regular before breakfast

  40% of carbs before midday meal: 0.4 x 16 = 6.4 rounded to **6 units** Regular before midday meal

  35% of carbs before evening meal: 0.35 x 16 = 5.6 rounded to **6 units** Regular 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 Regular insulin; if the next meal is only going to be 60% of the usual intake, take 60% of the usual Regular insulin, etc. (see also LFAC bulletin on: Insulin dose adjustment – basic rules and unexpected circumstances)

  Example: If the child/young adult usually takes 9 units Regular with breakfast, but breakfast will only be 30% of usual portion, she/he takes 9 x 0.3 = 2.7 rounded to 3 units of Regular 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 Regular 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÷36=14 (rounded) this means 1 unit of Regular insulin will cover 14 grams of carbohydrate food. He is eating 45 grams of carbohydrate (45÷14) = 3.2 units; therefore, he needs 3 units of Regular insulin to cover the 45 grams of carbohydrate.

Tips for Regular insulin

- Take Regular insulin 20-30 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 have a small carbohydrate snack (less than or equal to 15 grams) in between meals if there is more than 5 hours between meals. Note that since Regular insulin lasts at least 5 and up to 8 hours, there is a risk of hypoglycaemia.
- Keep Regular doses at least 3-4 hours apart to avoid “stacking” of insulin

Initiation and Titration of New Regimen

On the day of switching from NPH or pre-mixed to 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 pre-mixed.
- Give the lunch-time Regular dose if already on such regimen.
- Start the new regimen with the evening meal.
- The Regular dose should be given before the evening meal according to the new calculations.
- Start the first dose of 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 Basaglar before the morning meal.

After starting the new Basaglar and Regular 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 3-4am is recommended for the first two weeks after initiation.
- **The BGL 2-3 hours after a meal** is used to adjust the Regular dose with that meal.
- **The BGL before a meal** indicates the effect of the basal insulin, i.e. Basaglar
- **A follow up** phone call or clinic visit every 2-3 days in the first week after initiation of the new Basaglar/Regular 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 Basaglar Dose

- **Use fasting blood glucose level to adjust Basaglar dose**. Aim for a target of 70 -130 mg/dL (4.0 - 7.0 mmol/L); see 'Blood Glucose Level Targets in Table 1' below.
- If fasting BGL is above target for 3 days or more after starting Basaglar, increase Basaglar dose by 5-10%.
- If fasting BGL is below target for 1-2 days, decrease 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 Basaglar dose by 5-10% the following day.
- If BGL rises before meals, try increasing Basaglar slightly unless there is a tendency to nighttime hypoglycaemia. If so, you may be better off dividing Basaglar into 2 daily doses.
- For tip on finetuning basal (Basaglar) doses see Appendix B

Example 1: Child takes 24 units 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 Basaglar is reasonable, i.e., 25-26 units total Basaglar

Example 2: Child takes 13 units 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 Basaglar is reasonable, i.e., 12 - 12.5 units Basaglar total. Since hypoglycaemia can be dangerous, the 10% reduction may be best.

Table 1. Blood Glucose Level Targets

Pre-meals	4.0 - 7.0 mmol/l (70 - 126 mg/dL)
Post-meals	5.0 - 10.0 mmol/l (90 - 180 mg/dL)
Pre-bed	6.0 – 10.0 mmol/L (108 - 180 mg/dL)
At 3 am	**5.0 - 8.0 mmol/l (90 - 145 mg/dL)**

Source: ISPAD, IDF, LFAC pocketbook guidelines 2017

Clinical tips for transitioning to 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 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. In some children/young adults Basaglar may not last for 24 hours, but Regular insulin from the previous meal may still be in the circulation and provide coverage.
- For small children, it is acceptable to give Basaglar in the morning, since insulin needs before awakening may be very low.
- Some children will benefit from splitting the Basaglar dose into 2 equal doses, 12 hours apart. These are children who are on very small doses of Basaglar (less than approximately 15 units a day) and those in whom 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 Basaglar reduces the nighttime BGL too much. You can then adjust each dose: the evening Basaglar according to the morning BGL; and the morning Basaglar according to the premeal BGLs.
- 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 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 Basaglar: reduce the evening dose after the activity to decrease the risk of overnight hypoglycaemia.

c) If on 2 daily doses of 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.

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

- **If the next dose of Basaglar is due in less than 6 hours**, do not give the missed dose at all. Check for ketones and advise to use Regular insulin to "correct" for high blood glucose levels that may result from missing the 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 Regular pre-meal dose.
- **If the child/young adult forgets the evening Basaglar dose and remembers the next morning. Advise to give half the dose of 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 Basaglar the evening before; this can be done by adding extra Regular insulin (calculated by using the Insulin Sensitivity Factor - see Appendix C) to the usual morning Regular breakfast dose.
- **Check BGLs more often for a couple of days after missing a dose of Basaglar.**

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

Appendix A: Honeymoon (Remission) phase

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 been 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).

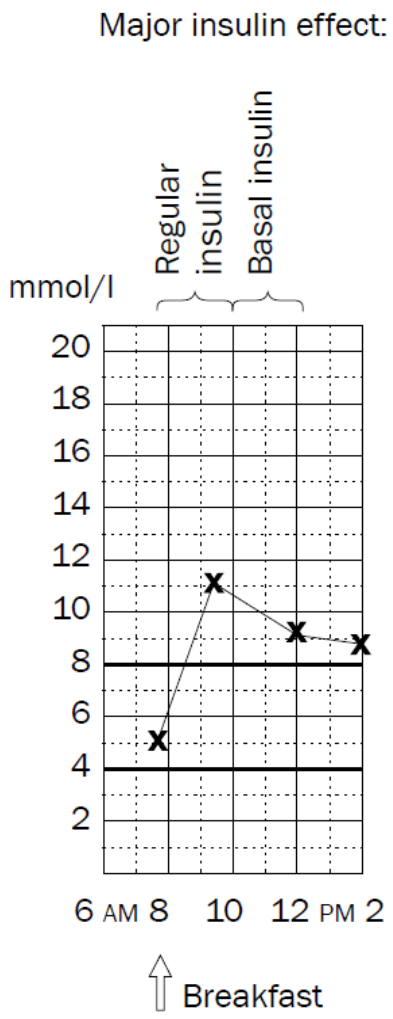
The advantage of endogenous (bodies own) insulin is that it is secreted in relation to the blood glucose level, which makes it easier to manage blood glucose levels.

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



When adjusting pre-meal **bolus** doses of Regular 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 Regular 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 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 Regular insulin to cover the amount of carbohydrate food eaten for breakfast).

To adjust the **basal** 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 mg/dL/ >8mmol/L), then an increase in the basal dose (Basaglar) is recommended (increase by 1-2 units). If glucose decreases significantly during the night or if experiencing overnight or morning hypoglycemia (< 70mg/dL/< 4 mmol/L), a decrease in the 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' [3] 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 Regular 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 **1500 by TDD** (when using mg/dL) or **83 by TDD** (when using mmol/L). This will tell you how much 1 unit of **Regular (short acting) insulin** will lower her/his blood glucose level.

For **rapid acting analog insulin** use the 1800/100 rule instead, that is divide 1800 by TDD (when using mg/dL) or 100 by TDD (when using mmol/L)

Daytime Correction Factor Rule for **mmol/L**	83 ÷TDD
Daytime Correction Factor Rule for **mg/dL**	1500 ÷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 Regular insulin dose is 5 units.

For mg/dL

Step 1: use the 1500 rule to calculate the **ISF** i.e. 1500 ÷ 30 units (TDD) = **50**
50 is the ISF which means 1 unit of Regular insulin reduces BGL by 50 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 50;** 180 ÷ 50 = **3.6 rounded to 4 units.** She/he should take an additional 4 units Regular to bring BGL down to the target level of 100 mg/dL.
Step 3: Add 4 units to the Usual 5 units Regular = **9 units Regular this morning only.**

For mmol/L

Follow Step 1-3 with the 83 Rule:
Step 1: Use the 83 rule to calculate the **ISF**: 83 ÷ 30 (TDD) = 2.7
2.7 is the ISF which means 1 unit of Regular insulin reduces BGL by 2.7 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 10mmol/L

Step 2: Take the 10mmol/L and divide by the **ISF of 2.7;** 10 ÷ 2.7 = **3.7 units (rounded to 4)**
Step 3: Add 4 units to the Usual 5 units Regular = **9 units Regular 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 3-4 hours after the last Regular 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 long-acting insulin (Basaglar) 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 3-4 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 Regular insulin refer to LFAC bulletin: Insulin dose adjustment – basic rules and unexpected circumstances

Appendix D: Instructions for use of HumaPen Ergo ll

IMPORTANT:

Life for a Child is currently supplying 2 identical HumaPen Ergo ll 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.

Video instructions:

English: **https://www.youtube.com/watch?v=pgll2kOdZBo**

English spoken with French captions: **https://www.youtube.com/watch?v=NPYP8KIr-eE**

English spoken with Spanish captions: **https://www.youtube.com/watch?v=ivCVNl5IQSg**

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

CDL22FEB2019 PA023SPXS02

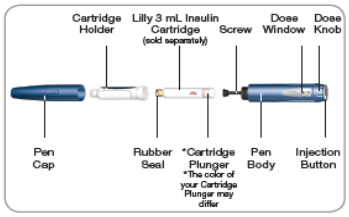
HumaPen Ergo™ II

INSULIN DELIVERY DEVICE INSTRUCTIONS FOR USE

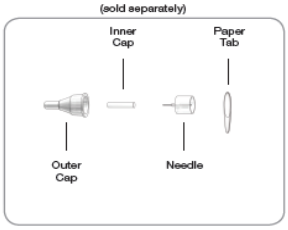
For use only with Lilly 3 mL insulin cartridges (100 IU/mL). Do not use other brands of insulin cartridges.
The color of your HumaPen Ergo™ II is Two-Tone Blue.

Lilly

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.

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.

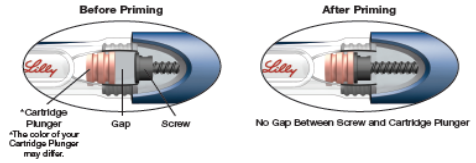
Frequently Asked Questions about Priming

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.

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.

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.

HumaPen Ergo™ II

INSULIN DELIVERY DEVICE

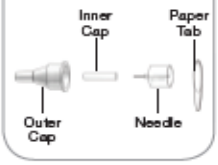
Getting Ready

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

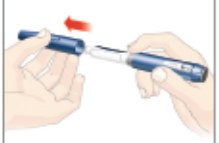
HumaPen Ergo™ II Pen Parts

Pen Needle (sold separately)



1 INSERT THE INSULIN CARTRIDGE

Pull Off Pen Cap



Unscrew Cartridge Holder

A

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.

B

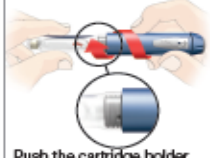
Push Screw Back

- 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.

C

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.

D

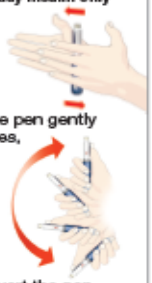
Inspect Insulin

Be sure to check your insulin for:
- Type
- Appearance

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

E

For Cloudy Insulin Only



Roll the pen gently 10 times,

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

F

2 PRIME THE PEN (BEFORE EVERY INJECTION)

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

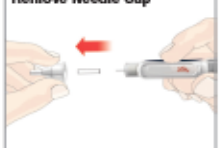
Remove Paper Tab

Attach Needle

Screw needle **straight** onto the cartridge holder.

A

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.

B

Dial 2 Units

Tap Cartridge

Point pen up.

Tap cartridge to collect air at the top for removal.

C

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.

D

If No Insulin Is Seen, Repeat Priming

Dial 2 units.

Tap cartridge.

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

E

3 INJECT THE DOSE

Dial Your Dose

Turn dose knob to your desired dose.

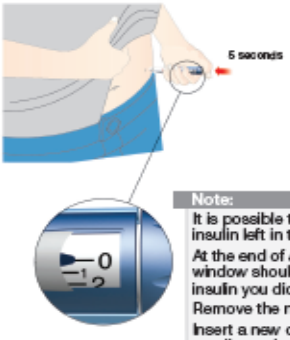
Example: 15 units shown in the drawing above.

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.

A

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.

B

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.

C

Remove The Needle

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

Replace Pen Cap

D

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

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Lilly Corporate Center Indianapolis, IN 46285 USA

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28108 Alcobendas, Madrid, Spain

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

CE 0344

Revision date: June 2019

Lilly PA 023SPX S02

References:

1. Eda Cengiz, Thomas Danne, Tariq Ahmad, Ahila Ayyavoo, David Beran, Ethel Codner, Sarah Ehtisham, Przemyslawa Jarosz-Chobot, Lucy N. W. Mungai, Sze May Ng, Megan Paterson, Leena Priyambada. ISPAD Clinical Practice Consensus Guidelines 2024: Insulin and adjunctive treatments in children and adolescents with diabetes. Hormone Research in Pediatrics. 2024. Available here

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3. Ragnar Hanas. Type 1 Diabetes in Children, Adolescents and Young Adults: How to become an expert on your own diabetes. Seventh edition, Class Health, UK. Available here

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Disclaimer:

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