RAPILIN INSULIN ASPART 100U/ML SOLUTION FOR INJECTION

Insulin Aspart (100 U/mL)

What is in this leaflet

1. What is Rapilin used for
2. How Rapilin works
3. Before you use Rapilin
4. How to use Rapilin
5. While you are using it
6. Side Effects
7. Storage and Disposal of Rapilin
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What Rapilin is used for

Rapilin is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of your blood sugar.

How Rapilin works

Rapilin is a rapid-acting modern insulin (insulin analogue). Modern insulin products are improved versions of human insulin. Rapilin will start to lower your blood sugar 10–20 minutes after you take it, a maximum effect occurs between 1 and 3 hours and the effect lasts for 3–5 hours. Due to this short action, Rapilin should normally be used in combination with intermediate-acting or long-acting insulin preparations.

Before you use Rapilin

- *When you must not use it*

- If you are allergic (hypersensitive) to insulin aspart or any of the other ingredients in Rapilin.
- If you suspect hypoglycaemia (low blood sugar) is starting.
- If the cartridge or the device containing the cartridge is dropped, damaged or crushed.
- If it has not been stored correctly or if it has been frozen.
- If the insulin does not appear clear and colourless.

- *Before you start to use it*

- Check the label to make sure it is right type of insulin.
- Always check the cartridge, including the rubber stopper. Do not use it if any damage is seen. Take it back to your supplier. See your delivery system manual for further instructions.
- Always use a new needle for each injection to prevent contamination
- Needles and GanleePen must not be shared.

- *Taking other medicines*

Some medicines affect the way glucose works in your body and this may influence your insulin dose. The most common medicines which may affect your insulin treatment are listed below. Tell your doctor, nurse or pharmacist if you take or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you use any medicine listed below that may affect your blood sugar level.

If you take any of the following medicines, your blood sugar level may fall (hypoglycaemia):

Oral antidiabetic medicinal products, monoamine oxidase inhibitors (MAOI), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.

If you take any of the following medicines, your blood sugar level may rise (hyperglycaemia):

Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Octreotide and lanreotide may either increase or decrease your blood sugar level.

Beta-blockers may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

Thiazolidinediones (class of oral antidiabetic medicines used for treatment of type 2 diabetes mellitus)

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

How to use Rapilin

- *How much to use it*

Talk about your insulin dose with your doctor and nurse. Make sure you use Rapilin as your doctor and nurse have told you and follow their advice carefully. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor. Do not change your insulin unless your doctor tells you to.

Use in children

Rapilin can be used in children instead of soluble human insulin when a rapid onset effect is preferred. For example, when it is difficult to dose the child in relation to meals.

Use in special populations

If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

- *When to use it*

Rapilin is generally given immediately before a meal. When necessary, Rapilin can be given soon after a meal.

RAPILIN INSULIN ASPART 100U/ML SOLUTION FOR INJECTION

Insulin Aspart (100 U/mL)

- *How to use it*

Rapilin is for injection under the skin (subcutaneously). Never inject your insulin directly into a muscle (intramuscularly).

Always vary the sites you inject within the same region to reduce the risk of developing lumps or skin pitting. The best places to give yourself an injection are: the front of your waist (abdomen); the upper arm or the front of your thighs. The insulin will work more quickly if you inject into the waist (abdomen). You should measure your blood sugar regularly.

How to inject this insulin

- Inject the insulin under the skin. Use the injection technique advised by your doctor or nurse and as described in your delivery system manual.
- Keep the needle under your skin for at least 6 seconds. Keep the push-button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.
- After each injection be sure to remove and discard the needle and store Rapilin without the needle attached. Otherwise, the liquid may leak out which can cause inaccurate dosing.

Do not refill the cartridge.

Rapilin cartridge is designed to be used with GanleePen delivery systems and compatible needles. If you are treated with Rapilin and another insulin, you should use two insulin delivery systems, one for each type of insulin.

As precautionary measure, always carry a spare insulin delivery system in case your *GanleePen* is lost or damaged.

- *How long to use it*

Continue taking Rapilin for as long as your doctor recommends. Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycemia and diabetic ketoacidosis.

- *If you forget to use it*

If you forget to take your insulin, your blood sugar may get too high (this is called hyperglyceaemia).

Hyperglycaemia may also happen:

- If you repeatedly take less insulin than you need.
- If you get an infection or a fever.
- If you eat more than usual.
- If you exercise less than usual.

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath. These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death. If you get any of the signs mentioned above, test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.

- *If you stop taking it*

This could lead to severe hyperglycaemia and ketoacidosis. Do not stop taking your insulin without speaking to a doctor, who will tell you what needs to be done.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- *If you use too much (overdose)*

If you take too much insulin, your blood sugar gets too low (this is called hypoglycaemia).

Hypoglycaemia may also happen:

- If you eat too little or miss a meal.
- If you exercise more than usual.

The warning signs of a hypoglycaemia may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

If you feel a hypoglycaemic episode coming on, take a high sugar snack and then measure your blood sugar

If your blood sugar is too low, eat glucose tablets or another high sugar snack (sweets, biscuits, fruit juice), then rest.

When the symptoms of hypoglycaemia have disappeared or when your blood sugar level is stabilised, continue insulin treatment.

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon, you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or an emergency ward after an injection of glucagon; you need to find the reason for your hypoglycaemia to avoid getting more.

- If prolonged severe hypoglycaemia is not treated, it can cause brain damage (temporary or permanent) and even death.

RAPILIN INSULIN ASPART 100U/ML SOLUTION FOR INJECTION

Insulin Aspart (100 U/mL)

- If you have a hypoglycaemia that makes you pass out, or a lot of hypoglycaemias, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Rapilin has a rapid effect. Therefore, if hypoglycaemia occurs, you may experience it earlier after an injection when compared to soluble human insulin.

While you are using it

- *Things you must do*

  Eat a meal or snack containing carbohydrates within 10 minutes of the injection to avoid hypoglycaemia.

- *Things you must not do*

  Do not take any insulin if you feel a hypoglycaemic episode coming on. Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

  Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (becoming unconscious) due to a hypoglycaemia.

  Tell relevant people that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink. It could choke you.

- *Things to be careful of*

- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- If you exercise more than usual or if you want to change your usual diet, as this may affect your blood sugar level.
- If you are ill: carry on taking your insulin and consult your doctor.
- If you are going abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling.
- If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Driving and using machines

If your blood sugar is low or high, your concentration and ability to react might be affected and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car or operate a machine:

- If you have frequent hypoglycaemia.
- If you find it hard to recognize hypoglycaemia.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant, planning a pregnancy or breast-feeding, please contact your doctor for advice. Rapilin can be used during pregnancy and breast-feeding. Your insulin dosage may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Side effects

Like all medicines, Rapilin can cause side effects, although not everybody gets them.

Very common side effects (affects more than 1 user in 10)

Low blood sugar (hypoglycaemia). See the advice in 'If you use too much (overdose)'.

Uncommon side effects (affects 1 to 10 users in 1,000)

Vision problems. When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Skin changes at the injection site. If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (affects 1 to 10 users in 1,000). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Signs of allergy. Reactions (pain, redness, hives, inflammation, swelling and itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Seek medical advice immediately:

- If signs of allergy spread to other parts of your body.
- If you suddenly feel unwell and you start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.

RAPILIN INSULIN ASPART 100U/ML SOLUTION FOR INJECTION

Insulin Aspart (100 U/mL)

Diabetic retinopathy (an eye disease related to diabetes which can lead to loss of vision). If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

Swollen joints. When you start taking insulin, water retention may cause swelling around your ankles and other joints. Normally this soon disappears.

Rare side effects (affects 1 to 10 users in 10,000)
Painful neuropathy (pain due to nerve damage). If your blood sugar level improves very fast, you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

Very rare side effects (affects less than 1 user in 10,000)
Serious allergic reaction to Rapilin or one of its ingredients (called a systemic allergic reaction).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Rapilin
- *Storage*

Unopened cartridges
Store in a refrigerator (2°C - 8°C). Do not freeze. Keep away from the cooling element. Keep the cartridge in the outer carton in order to protect from light.

In-use cartridges
Do not refrigerate. Store below 30°C. Use within 4 weeks. Do not freeze. Do not expose from excessive heat or direct light.
Keep out of reach of children.

- *Disposal*

Consult your doctor or pharmacist how to dispose the medicine of which no longer required or has expired.

Product Description
- *What it looks like*

A clear, colourless and aqueous solution for injection in cartridge.

- *Ingredients*

Active ingredient:
- Insulin aspart

Inactive ingredients:
- *m*-Cresol
- Glycerin
- Phenol
- Zinc chloride
- Sodium phosphate dibasic anhydrous
- Sodium chloride
- Water for injection
- Hydrochloric acid
- Sodium hydroxide

- *MAL Number*

MAL25056008AZ

Manufacturer
Gan & Lee Pharmaceuticals
No. 8 Nanfeng West First Road, Tongzhou District, Huoxian Town, Beijing, 101109, China.

Product Registration Holder
GoodScience Sdn. Bhd.
No.7, Jalan KPK 4/3,
Kawasan Perindustrian Kundang,
Kundang Jaya, 48020 Rawang,
Selangor, Malaysia.

Date of revision
08/01/2026

Serial number
NPRA (R3) 25/77