

# RAPILIN 30 Insulin Aspart Mix 30/70

## 100 U/mL Suspension for Injection

Insulin Aspart Mix 30/70 (100 U/mL)

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- If the resuspended insulin does not appear uniformly white and cloudy
- If after re-suspension clumps of material are present or if solid white particles stick to the bottom or the wall of the cartridge.

### Before you start to use it

- Check the label to make sure it is right type of insulin
- 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 your blood sugar works in your body and this may influence your insulin dose. Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines than Rapilin 30, including medicines obtained without a prescription. Listed below are the most common medicines which may affect your insulin treatment.

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

- Other medicines for the treatment of diabetes.
- Monoamine oxidase inhibitors (MAOI) (used to treat depression).
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure).
- Salicylates (used to relieve pain and lower fever).
- Anabolic steroids (such as testosterone).
- Sulfonamides (used to treat infection)

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

- Oral contraceptives (birth control pills).

- Thiazides (used to treat high blood pressure or excessive fluid retention).
- Glucocorticoids (such as 'cortisone' used to treat inflammation).
- Thyroid hormones (used to treat thyroid gland disorders).
- Sympathomimetics (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma).
- Growth hormone (medicines for stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes).
- Danazol (medicines acting on ovulation).

Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) 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)**

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 30**

#### How much to use it

Talk about your insulin dose with your doctor and nurse. Always use Rapilin 30 as prescribed by your

### What Rapilin 30 is used for

Rapilin 30 is used to treat patients with diabetes mellitus (diabetes) requiring insulin. Diabetes is a disease where your body does not produce enough insulin to control the level of your blood sugar.

### How Rapilin 30 works

Rapilin 30 is a modern insulin (insulin analogue) with both a rapid-acting and an intermediate-acting effect, in the ratio 30/70. Modern insulin products are improved versions of human insulin. Rapilin 30 will start to lower your blood sugar 10-20 minutes after you take it, a maximum effect occurs between 1 and 4 hours after the injection and the effect will last for up to 24 hours. In treatment of type 2 diabetes mellitus, Rapilin 30 may be used in combination with tablets for diabetes and/or with injectable antidiabetic products.

### Before you use Rapilin 30

#### When you must not use it

- If you are allergic (hypersensitive) to insulin aspart or any of the other ingredients in Rapilin 30.
- If you suspect hypoglycaemia (low blood sugar) is starting.
- In insulin infusion pumps
- If GanleePen is dropped, damaged or crushed.
- If it has not been stored correctly or if it has been frozen.

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doctor and follow the doctor's 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 30 can be used in children and adolescents aged 10 years and above when premixed insulin is preferred. Limited clinical data exists for children aged 6-9 years. No data are available for Rapilin 30 in children below 6 years of age.

### 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 30 is generally given immediately before a meal. When necessary, Rapilin 30 can be given soon after a meal.

When Rapilin 30 is used in combination with tablets for diabetes and/or with injectable antidiabetic products your dose may have to be adjusted by your doctor.

Rapilin 30 is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein (intravenously) or muscle (intramuscularly). With each injection, change the injection site within the particular area of skin that you use. This reduces the risk of developing lumps or skin pitting. The best places to give yourself an injection are: the front of your waist (abdomen); your buttocks; the front of your thighs or upper arms. The insulin will work more quickly if you inject around the waist. You

should always measure your blood sugar regularly.

### - How long to use it

#### **If you stop taking your insulin**

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 forget to use it

If you forget to take your insulin, your blood sugar may get too high (this is called hyperglycaemia). This may also happen:

- If have not injected enough insulin.
- If you repeatedly take less insulin than you need or stop taking insulin
- 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 use too much (overdose)

If you take too much insulin, your blood sugar gets too low (this is

called hypoglycaemia). This may also happen:

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

The warning signs of a hypo 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 hypo 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. Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

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

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.

- If prolonged severe hypoglycaemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have such low blood sugar that you pass out, if you have had need for an injection of glucagon, or if you have experienced many incidents of hypoglycaemia, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

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### 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.

Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (become unconscious) due to a hypo. Tell relevant people that if you pass out (become unconscious), they must turn you on your side and get medical advice straight away. They must not give you any food or drink. It could choke you.

#### - Things you must not do

Do not take any insulin if you feel a hypo coming on.

#### - 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.

### Drinking alcohol and taking Rapilin 30

If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant or planning a pregnancy, please contact your doctor

for advice. There is limited clinical experience with insulin aspart in pregnancy. Your insulin dose 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.

There are no restrictions on treatment with Rapilin 30 during breast-feeding.

### 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.

### 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, shrunk 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 30 can cause side effects, although not everybody gets them.

Side effects may occur with certain frequencies, which are defined as follows:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000
- Not known: frequency cannot be estimated from the available data

### Very common side effects

#### Low blood sugar (hypoglycaemia).

See the advice in '*If you use too much (overdose)*'.

### Uncommon side effects

#### 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.

### 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

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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.

### Swollen joints

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

### 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.

### Rare side effects

#### 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

**Serious allergic reaction** to Rapilin 30 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 [npa.gov.my](http://npa.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of Rapilin 30

#### - 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

The suspension is cloudy, white and aqueous suspension for injection in cartridge

#### - Ingredients

Active ingredient:

- Insulin aspart

Inactive ingredients:

- Protamine sulphate
- Glycerin
- M-cresol
- Phenol
- Zinc chloride
- Sodium chloride
- Sodium phosphate dibasic anhydrous
- Hydrochloric acid
- Sodium hydroxide
- Water for injections

#### - MAL Number

MAL25036017AZ

### 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.

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