Apidra Solostar 100 Units/ml

Solution for Injection in a Pre-filled Pen

Insulin glulisine (100 Units/ml)

What is in this leaflet:

What Is Apidra Used For

Apidra is used in the treatment of adults, adolescents and children 6 years or older with diabetes mellitus, where treatment with insulin is required.

How Apidra Works

Apidra is an antidiabetic agent, used to reduce high blood sugar in patients with diabetes mellitus. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar.
It is made by biotechnology. It has a rapid onset within 10-20 minutes and a short duration, about 4 hours.

Insulin glulisine lowers blood glucose levels by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis (breakdown of fats) in the adipocyte (cells for the storage of fat), inhibits proteolysis (breakdown of proteins) and enhances protein synthesis.

Before you use Apidra

-When you must not use it

- If you are allergic (hypersensitive) to insulin glulisine or any of the other ingredients of Apidra.
- If your blood sugar is too low (hypoglycaemia), follow the guidance for hypoglycaemia (see HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet).

-Before you start to use it

Apidra in a pre-filled pen is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.

Take special care with Apidra

Follow closely the instructions for dose, monitoring (blood tests), diet and physical activity (physical work and exercise) as discussed with your doctor.

Special patient groups

If you have liver or kidney problems, speak to your doctor as you may need a lower dose.
There is insufficient clinical information on the use of Apidra in children younger than the age of 6 years.

Skin changes at the injection site

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see How to use Apidra). Contact your doctor if you are currently injecting into a lumpy area 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.

Travel

Before travelling consult your doctor. You may need to talk about
- the availability of your insulin in the country you are visiting,
- supplies of insulin, needles etc,
- correct storage of your insulin while travelling,
- timing of meals and insulin administration while travelling,
- the possible effects of changing to different time zones,
- possible new health risks in the countries to be visited,
- what you should do in emergency situations when you feel unwell or become ill.

Illnesses and injuries

In the following situations, the management of your diabetes may require extra care:
- If you are ill or have a major injury then your blood sugar level may increase (hyperglycaemia).
- If you are not eating enough your blood sugar level may become too low (hypoglycaemia).

In most cases you will need a doctor. **Make sure that you contact a doctor early.**

If you have type 1 diabetes (insulin dependent diabetes mellitus), do not stop your insulin and continue to get enough carbohydrates. Always tell people who are caring for you or treating you that you require insulin.

-Taking other medicines

Some medicines cause changes in the blood sugar level (decrease, increase or both depending on the situation). In each case, it may be necessary to adjust your insulin dose to avoid blood sugar levels that are either too low or too high. Be careful when you start or stop taking another medicine.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Before taking a medicine ask your doctor if it can affect your blood

sugar level and what action, if any, you need to take.

Medicines that may cause your blood sugar level to fall (hypoglycaemia) include:
- all other medicines to treat diabetes,
- angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure),
- disopyramide (used to treat certain heart conditions),
- fluoxetine (used to treat depression),
- fibrates (used to lower high levels of blood lipids),
- monoamine oxidase (MAO) inhibitors (used to treat depression),
- pentoxifylline, propoxyphene, salicylates (such as aspirin, used to relieve pain and lower fever),
- sulfonamide antibiotics.

Medicines that may cause your blood sugar level to rise (hyperglycaemia) include:
- corticosteroids (such as "cortisone" used to treat inflammation),
- danazol (medicine acting on ovulation),
- diazoxide (used to treat high blood pressure),
- diuretics(used to treat high blood pressure or excessive fluid retention),
- glucagon (pancreas hormone used to treat severe hypoglycaemia),
- isoniazid (used to treat tuberculosis),
- oestrogens and progestogens (such as in the contraceptive pill used for birth control),
- phenothiazine derivatives (used to treat psychiatric disorders),
- somatropin (growth hormone),
- sympathomimetic medicines (such as epinephrine [adrenaline] or salbutamol, terbutaline used to treat asthma),
- thyroid hormones (used to treat thyroid gland disorders),
- protease inhibitors (used to treat HIV),
- atypical antipsychotic medicines (such as olanzapine and clozapine).

Your blood sugar level may either rise or fall if you take:
- beta-blockers (used to treat high blood pressure),
- clonidine (used to treat high blood pressure),
- lithium salts (used to treat psychiatric disorders).

Pentamidine (used to treat some infections caused by parasites) may cause hypoglycaemia which may sometimes be followed by hyperglycaemia.

Beta-blockers like other sympatholytic medicines (such as clonidine, guanethidine, and reserpine) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

If you are not sure whether you are taking one of those medicines ask your doctor or pharmacist.

Using Apidra with food and drink
Your blood sugar levels may either rise or fall if you drink alcohol.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Inform your doctor if you are planning to become pregnant, or if you are already pregnant. Your insulin dose may need to be changed during pregnancy and after giving birth. Careful control of your diabetes, and prevention of hypoglycaemia, is important for the health of your baby.

There are no adequate data on the use of Apidra in pregnant women.

If you are breast-feeding consult your doctor as you may require adjustments in your insulin doses and your diet.

Important information about some of the ingredients of Apidra
This medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially 'sodium-free'.
Apidra contains metacresol, which may cause allergic reactions.

How to use Apidra
-How much to use
Based on your life-style and the results of your blood sugar (glucose) tests and your previous insulin usage, your doctor will determine how much Apidra you will need.

Always use Apidra exactly as your doctor has told you. You should check with your doctor if you are not sure.

Apidra is a short-acting insulin. Your doctor may tell you to use it in combination with an intermediate, long acting insulin, a basal insulin or with tablets used to treat high blood sugar levels.

If you switch from another insulin to insulin glulisine, your dosage may have to be adjusted by your doctor.

Many factors may influence your blood sugar level. You should know these factors so that you are able to react correctly to changes in your blood sugar level and to prevent it from becoming too high or too low. See HYPERGLYCAEMIA AND

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HYPOGLYCAEMIA at the end of this leaflet for further information.

-When to use it
Apidra should be taken shortly (0-15 minutes) before or soon after meals.

-How long touse it
Do not stop taking Apidra unless instructed by your doctor.

Method of administration
Apidra is injected under the skin (subcutaneously).
Your doctor will show you in which area of the skin you should inject Apidra. Apidra can be injected in the abdominal wall, the thigh or upper arm or by continuous infusion in the abdominal wall. The effect will be slightly quicker if the insulin is injected into your abdomen. As for all insulins, injection sites and infusion sites within an-injection area (abdomen, thigh or upper arm) must be rotated from one injection to the next.

Instructions for proper use
How to handle SoloStar
SoloStar is a pre-filled disposable pen containing insulin glulisine.
Apidra in a pre-filled pen is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.

Read carefully the "SoloStar Instructions for use". You must use the pen as described in these Instructions for use.

To prevent the possible transmission of disease, each pen must be used by one patient only.

Before use always attach a new needle, and perform a safety test. Only use needles that are compatible for use with SoloStar (see "SoloStar Instructions for use").

Look at the cartridge sealed in the disposable pen injector before you use it. Only use it if the solution is clear, colourless and has no visible particles in it. Do not shake or mix it before use.

Always use a new pen if you notice that your blood sugar control is unexpectedly getting worse. If you think you may have a problem with SoloStar, please consult your Health Care Professional.

-If you use more Apidra too much (overdose)
- If you **have injected too much Apidra**, your blood sugar level may become too low (hypoglycaemia).
Check your blood sugar frequently. In general, to prevent hypoglycaemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycaemia, see HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet.

-If you forget to use Apidra
- If you **have missed a dose of Apidra** or if you **have not injected enough insulin,** your blood sugar level may become too high (hyperglycaemia). Check your blood sugar frequently. For information on the treatment of hyperglycaemia, see HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Apidra
This could lead to severe hyperglycaemia (very high blood sugar) and ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). Do not stop Apidra 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.

While you are using Apidra

-Things you must do
Take Apidra according to your doctor's instructions.
Tell your doctor or pharmacist if any side effect become serious, or if you notice any side effects not listed in this leaflet.

-Things you must not do
Do not stop taking Apidra unless advised by your doctor.

-Things to be careful of
Driving and using machines
Your ability to concentrate or react may be reduced if:
- you have hypoglycaemia (low blood sugar levels),
- you have hyperglycaemia (high blood sugar levels).
Keep this possible problem in mind in all situations where you might put yourself and others at risk (such as driving a car or operating machines).

You should contact your doctor for advice on driving if:
- you have frequent episodes of hypoglycaemia,
- the first warning symptoms which help you to recognise hypoglycaemia are reduced or absent.

Insulin mix-ups
You must always check the insulin label before each injection to avoid medication mix-ups between Apidra and other insulins.

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-Side Effects

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

Hypoglycaemia (low blood sugar) can be very serious. If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, take actions to increase your blood sugar level **immediately.**

If you experience the following symptoms, contact your doctor immediately: large-scale skin reactions (rash and itching all over the body), severe swelling of skin or mucous membranes (angiooedema), shortness of breath, a fall in blood pressure with rapid heart beat and sweating. These could be symptoms of **generalised allergy to insulin, including anaphylactic reaction, which may be life-threatening.**

The frequency of possible side effects listed below is defined using the following convention:
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 reported side effects

- **Hypoglycaemia**

Hypoglycaemia (low blood sugars) means that there is not enough sugar in the blood.
See HYPERGLYCA AND HYPOGLYCAEMIA at the end of this leaflet for important further information about hypoglycaemia and its treatment.

Common reported side effects

- **Skin and allergic reactions**

Reactions at the injection site may occur (such as reddening, unusually intense pain on injection, itching, hives, swelling or inflammation). They can also spread around the injection site. Most minor reactions to insulins usually resolve in a few days to a few weeks.

Uncommon reported side effects

- **Systemic allergic reactions**

Generalised allergy to insulin. Associated symptoms may include large-scale skin reactions (rash and itching all over the body), severe swelling of skin or mucous membranes (angiooedema), shortness of breath, a fall in blood pressure with rapid heart beat and sweating. Severe cases of generalized reactions, including anaphylactic reaction, may be life-threatening.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

- **Skin changes at the injection site:**

If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy) (*may affect up to 1 in 1,000 people*). Lumps under the skin may also be caused by build-up of a protein called amyloid.
Frequency 'not known': Changes at the injection site (Cutaneous amyloidosis).
The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Other side effects (frequency not known) include:

- **Hyperglycaemia (high blood sugars) means there is too much sugar in the blood**

If your blood sugar level is too high, this tells you that you could have needed more insulin than you injected. See HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet for further information.

- **Eye reactions**

A marked change (improvement or worsening) in your blood sugar control can disturb your vision temporarily. If you have proliferative retinopathy (an eye disease related to diabetes) severe hypoglycaemic attacks may cause temporary loss of vision.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor 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 Apidra

-<u>*Storage*</u>

Keep out of the reach and sight of children.
Do not use Apidra after the expiry date, which is stated on the carton and on the label of the pen. The expiry date refers to the last day of that month.

<u>Not in-use pens</u>

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Store in a refrigerator (2°C-8°C). Do not freeze. Do not put SoloStar next to the freezer compartment or a freezer pack.
Keep the pre-filled pen in the outer carton in order to protect from light.

In-use pens
Pre-filled pens in use (or carried as a spare) may be stored for a maximum of 4 weeks below 25°C and away from direct heat or direct light. The pen in use must not be stored in a refrigerator.
Do not use it after this time period.

Do not use Apidra if it does not appear clear and colourless.

-Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

- Product Description
-What is looks like
Apidra SoloStar 100 Units/ml, solution for injection in a pre-filled pen is a clear, colourless, aqueous solution with no particles visible.
Each pen contains 3 ml solution, equivalent to 300 Units.

-Ingredients
-*Active ingredients*: Insulin glulisine. Each ml of the solution contains 100 Units of insulin glulisine (equivalent to 3.49 mg).
-Inactive ingredients: metacresol, sodium chloride, trometamol, polysorbate 20, concentrated hydrochloric acid, sodium hydroxide, water for injections

-MAL Number:
MAL20081842AZ

Manufacturer
Sanofi-Aventis Deutschland GmbH
D-65926 Frankfurt am Main, Germany

Product Registration Holder
Sanofi-aventis (Malaysia) Sdn. Bhd.
Unit TB-18-1, Level 18-1, Tower B,
Plaza 33, No.1 Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor Darul Ehsan,
Malaysia.

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HYPERGLYCAEMIA AND HYPOGLYCAEMIA

Always carry some sugar (at least 20 grams) with you.
Carry some information with you to show you are a person with diabetes.

HYPERGLYCAEMIA (high blood sugar levels)

If your blood sugar is too high (hyperglycaemia), you may not have injected enough insulin.

Why does hyperglycaemia occur?
Examples include:
- you have not injected your insulin or not injected enough, or if it has become less effective, for example through incorrect storage,
- you are doing less exercise than usual, you are under stress (emotional distress, excitement), or you have an injury, operation, infection or fever,
- you are taking or have taken certain other medicines (see *Taking other medicines*).

Warning symptoms of hyperglycaemia
Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heart beat and glucose and ketone bodies in urine. Stomach pain, fast and deep breathing, sleepiness or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

What should you do if you experience hyperglycaemia?
Test your blood sugar level and your urine for ketones as soon as any of the above symptoms occur. Severe hyperglycaemia or ketoacidosis must always be treated by a doctor, normally in a hospital.

HYPOGLYCAEMIA (low blood sugar levels)

If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. You normally should be able to recognise when your blood sugar is falling too much so that you can take the right actions.

Why does hypoglycaemia occurs?
Examples include:
- you inject too much insulin,
- you miss meals or delay them,
- you do not eat enough, or eat food containing less carbohydrate than normal (sugar and substances similar to sugar are called carbohydrates;

however, artificial sweeteners are NOT carbohydrates),
- you lose carbohydrates due to vomiting or diarrhoea,
- you drink alcohol, particularly if you are not eating much,
- you are doing more exercise than usual or a different type of physical activity,
- you are recovering from an injury or operation or other stress,
- you are recovering from an illness or from fever,
- you are taking or have stopped taking certain other medicines (see *Taking other medicines*).

Hypoglycaemia is also more likely to occur if:
- you have just begun insulin treatment or changed to another insulin preparation,
- your blood sugar levels are almost normal or are unstable,
- you change the area of skin where you inject insulin (for example from the thigh to the upper arm),
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning symptoms of hypoglycaemia
- In your body
Examples of symptoms that tell you that your blood sugar level is falling too much or too fast: sweating, clammy skin, anxiety, fast heart beat, high blood pressure, palpitations and irregular heartbeat. These symptoms often develop before the symptoms of a low sugar level in the brain.

- In your brain
Examples of symptoms that indicate a low sugar level in the brain: headaches, intense hunger, nausea, vomiting, tiredness, sleepiness, sleep disturbances, restlessness, aggressive behaviour, lapses in concentration, impaired reactions, depression, confusion, speech disturbances (sometimes total loss of speech), visual disorders, trembling, paralysis, tingling sensations (paraesthesia), numbness and tingling sensations in the area of the mouth, dizziness, loss of self-control, inability to look after yourself, convulsions and loss of consciousness.

The first symptoms which alert you to hypoglycaemia ("warning symptoms") may change, be weaker or may be missing altogether if:
- you are elderly,
- you have had diabetes for a long time,
- you suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently suffered hypoglycaemia (for example the day before) or if it develops slowly,
- you have almost normal or, at least, greatly improved blood sugar levels,
- you are taking or have taken certain other medicines (see *Taking other medicines*.)

In such a case, you may develop severe hypoglycaemia (and even faint) before you are aware of the problem. Be familiar with your warning symptoms. If necessary, more frequent blood sugar testing can help to identify mild hypoglycaemic episodes that may otherwise be overlooked. If you are not confident about recognising your warning symptoms, avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

What should you do if you experience hypoglycaemia?
1. Do not inject insulin. Immediately take about 10 to 20 g sugar, such as glucose, sugar cubes or a sugar-sweetened beverage. Caution: Artificial sweeteners and foods with artificial sweeteners (such as diet drinks) are of no help in treating hypoglycaemia.

2. Then eat something that has a long-acting effect in raising your blood sugar (such as bread or pasta). Your doctor or nurse should have discussed this with you previously.

3. If the hypoglycaemia comes back again take another 10 to 20 g sugar.

4. Speak to a doctor immediately if you are not able to control the hypoglycaemia or if it recurs.

Tell your relatives, friends and close colleagues the following:
If you are not able to swallow or if you are unconscious, you will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections are justified even if it is not certain that you have hypoglycaemia.

It is advisable to test your blood sugar immediately after taking glucose to check that you really have hypoglycaemia.