

Apidra® and Apidra SoloSTAR®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Apidra and Apidra SoloSTAR?

Apidra and Apidra SoloSTAR contain the active ingredient insulin glulisine. Apidra/Apidra SoloSTAR is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

For more information, see Section [1. Why am I using Apidra or Apidra SoloSTAR?](#) in the full CMI.

2. What should I know before I use Apidra or Apidra SoloSTAR?

Do not use if you have ever had an allergic reaction to Apidra or Apidra SoloSTAR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Apidra or Apidra SoloSTAR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Apidra or Apidra SoloSTAR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Apidra or Apidra SoloSTAR?

- Your doctor will tell you how much Apidra or Apidra SoloSTAR you need to use each day. Your doctor may increase or decrease the dose, depending on your blood sugar levels.

More instructions can be found in Section [4. How do I use Apidra or Apidra SoloSTAR?](#) in the full CMI.

5. What should I know while using Apidra or Apidra SoloSTAR?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Apidra or Apidra SoloSTARMeasure your blood sugar level regularly.Keep using Apidra or Apidra SoloSTAR even if you feel well.Tell your doctor if you often have hypoglycaemia or if you have ever become unconscious after using Apidra or Apidra SoloSTAR.Always carry some sugary food or drink with you.Tell your doctor, pharmacist or diabetes educator if you are travelling.
Things you should not do	<ul style="list-style-type: none">Do not stop using Apidra or Apidra SoloSTAR unless your doctor tells you to.Do not skip meals while using Apidra or Apidra SoloSTAR.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Apidra/Apidra SoloSTAR affects you. Be careful not to let your blood sugar levels fall too low.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.Alcohol may mask the symptoms of hypoglycaemia.
Looking after your medicine	<ul style="list-style-type: none">Keep Apidra vials and unopened cartridges and pens of Apidra in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

For more information, see Section [5. What should I know while using Apidra or Apidra SoloSTAR?](#) in the full CMI.

6. Are there any side effects?

The most common side effect when using insulin is low blood sugar levels (hypoglycaemia - a "hypo"). Serious side effects may include more severe symptoms of hypoglycaemia (disorientation, seizures, fits or convulsions, loss of consciousness) or a serious allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Apidra® and Apidra® SoloSTAR®

Active ingredient(s): *insulin glulisine* (in-sue-lin glue-lee-seen)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Apidra and Apidra SoloSTAR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Apidra or Apidra SoloSTAR.**

Where to find information in this leaflet:

1. [Why am I using Apidra or Apidra SoloSTAR?](#)
2. [What should I know before I use Apidra or Apidra SoloSTAR?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Apidra and Apidra SoloSTAR?](#)
5. [What should I know while using Apidra or Apidra SoloSTAR?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Apidra or Apidra SoloSTAR?

Apidra and Apidra SoloSTAR contain the active ingredient **insulin glulisine**. Apidra and Apidra SoloSTAR are antidiabetic agents used to reduce high blood sugar.

Apidra and Apidra SoloSTAR are used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

Apidra and Apidra SoloSTAR are modified insulins that are very similar to human insulin. It is a substitute for the insulin produced by the pancreas.

Apidra and Apidra SoloSTAR are short-acting insulins. Your doctor may tell you to use a long-acting insulin in combination with Apidra or Apidra SoloSTAR.

Apidra and Apidra SoloSTAR are not addictive.

Ask your doctor if you have any questions about why Apidra or Apidra SoloSTAR has been prescribed for you.

2. What should I know before I use Apidra or Apidra SoloSTAR?

Warnings

Do not use Apidra or Apidra SoloSTAR:

- you are allergic to insulin glulisine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- **If you are experiencing low blood sugar levels (hypoglycaemia - a "hypo").**
If you have a lot of hypos discuss appropriate treatment with your doctor.
- **After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**
If you use Apidra or Apidra SoloSTAR after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.
- **If the product appears cloudy, discoloured or contains particles, or if the injection pen, cartridge or vial appears damaged.**
If you are not sure whether you should start using this medicine, talk to your doctor.

Do not give Apidra or Apidra SoloSTAR to children less than 4 years of age.

- There is no experience with the use of Apidra or Apidra SoloSTAR in children less than 4 years.

Check with your doctor if you:

- have any other medical conditions such as kidney problems or liver problems.
- take any medicines for any other condition

Tell your doctor if:

- you have allergies to any other medicines, foods, preservatives or dyes
- you drink alcohol
- you do not eat regular meals
- you do a lot of exercise
- you are ill or feeling unwell

Alcohol, diet, exercise and your general health all affect the control of your diabetes.

If you have not told your doctor above any of the above, tell them before you start using Apidra or Apidra SoloSTAR.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Pregnancy may make managing your diabetes more difficult.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines that may increase the blood sugar lowering effect of Apidra/Apidra SoloSTAR include:

- oral antidiabetic medicines that are used to treat type 2 diabetes
- blood pressure, blood flow, cholesterol and heart medications
- medications for pain and inflammation
- some antidepressants
- sulfonamide antibiotics

Medicines that may reduce the blood sugar lowering effect of Apidra/Apidra SoloSTAR include:

- corticosteroids, glucagon and other hormonal therapies
- oral contraceptives and gynaecological medications
- fluid and glaucoma medications
- tuberculosis and HIV/AIDS treatments
- some psychiatric medications
- adrenaline (epinephrine) and asthma medications such as salbutamol, terbutaline

Certain heart medications, especially beta-blockers, may mask the symptoms of hypoglycaemia.

Your doctor and pharmacist have a full list of medicines with which you must be careful or avoid while using Apidra or Apidra SoloSTAR. Please check with your doctor or pharmacist before starting any new medicines or over the counter products.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Apidra/Apidra SoloSTAR.

4. How do I use Apidra and Apidra SoloSTAR?

Your doctor, pharmacist or diabetes educator will have shown you how to use Apidra or Apidra SoloSTAR.

Carefully follow all the directions.

Do not inject Apidra or Apidra SoloSTAR into a vein.

Apidra and Apidra SoloSTAR are intended for injection under the skin.

Any change in this medicine should be made cautiously and only under medical supervision.

If you do not understand the instructions, ask your doctor, pharmacist or diabetes educator for help.

How much to use

- Your doctor will tell you how much Apidra/Apidra SoloSTAR you need to use each day. Your doctor may increase or decrease the dose, depending on your blood sugar levels.
- It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.
- Follow the instructions provided and use Apidra/Apidra SoloSTAR until your doctor tells you to stop.

When to use Apidra/Apidra SoloSTAR

- Your doctor will tell you when to use Apidra/Apidra SoloSTAR.
- Apidra and Apidra SoloSTAR should be used within 15 minutes before or immediately after a meal.

How to use Apidra and Apidra SoloSTAR

ALWAYS CHECK YOUR APIDRA INJECTION PEN, CARTRIDGE OR VIAL.

Do not use Apidra or Apidra SoloSTAR if it is no longer clear and colourless or if it contains particles.

Make sure you are using the correct injection pen, cartridge or vial.

Always check the insulin label on the SoloSTAR pen, cartridge or vial before each injection to make sure you are using the right insulin.

Keep the injection pen, cartridge or vial at room temperature for 1 or 2 hours before use. Cold insulin is more painful to inject.

Apidra pre-filled pens or cartridges

PREPARING A DOSE FOR INJECTION

Always do a safety test before use.

The safety test may highlight a problem with your injection pen. The safety test also removes any air bubbles and helps indicate whether or not a needle is bent or broken.

Becton Dickinson (BD Micro-Fine™+) needles should be used with injection pens.

Reusable pens for Apidra cartridges

We recommend that Apidra cartridges only be used with the AllStar, AllStar Pro or JuniorStar reusable pens.

Carefully follow the instructions provided with the pen, for loading a cartridge, attaching a needle, performing a safety test and administering the insulin injection.

If the reusable injection pen does not work properly, Apidra may be withdrawn from the cartridge into a syringe. Ask your doctor, pharmacist or diabetes educator for help.

Apidra SoloSTAR pre-filled disposable pens

Apidra SoloSTAR disposable pens are pre-filled and ready for use. Once all the insulin is used, you cannot replace the cartridge.

Carefully follow the instructions provided with the Apidra SoloSTAR pen for attaching a needle, performing a safety test and administering the insulin injection.

Never use an injection pen if it is damaged or if you are not sure that it is working properly. Use a new pen.

INJECTING A DOSE

Apidra and Apidra SoloSTAR should be injected under the skin, being careful not to inject it into a muscle or vein.

Choose a site for injection.

Inject Apidra/Apidra SoloSTAR into the abdomen, thighs or upper arms.

1. With one hand, stabilise the skin by spreading it or pinching up a large area, as recommended by your healthcare professional.
2. Insert the needle into the skin as recommended by your healthcare professional.
3. Inject the full dose of Apidra or Apidra SoloSTAR by pushing the plunger as far as it will go.
4. Slowly count to 10 before removing the needle from the skin.

Change the place within the area you inject each day. This will reduce the risk of skin shrinking or thickening or lumps at the site (see "Side effects").

Do not use the exact same spot for each injection

Do not inject where the skin has pits, is thickened, or has lumps

Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin

If you develop 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.

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.

AFTER INJECTING

Using the outer needle cap, unscrew the needle and dispose of it safely into a sharps container.

Do not share needles, cartridges or injection devices. Do not reuse needles.

Leave the cartridge in the pen until it needs to be replaced.

Do not attempt to replace the cartridge in a pre-filled disposable pen.

Empty disposable pens must never be reused and must be properly discarded.

Apidra Vials

PREPARING A DOSE FOR INJECTION

Using one insulin type (Apidra)

1. Wash your hands.
2. Draw air into a U100 insulin syringe equal to the dose of Apidra to be injected.
3. Push the needle through the rubber top of the vial and inject the air into the vial.
4. Leave the needle in the vial. Hold the vial and syringe firmly in one hand, with the vial above the syringe.
5. Make sure the tip of the needle is in the insulin and withdraw the correct dose into the syringe.
6. Before removing the needle from the vial, check the syringe for air bubbles. If bubbles are present, hold the syringe vertically (needle pointed upwards) and tap firmly until the bubbles float to the top. Push the bubbles out with the plunger and then withdraw the correct dose. Remove the needle from the vial.
7. If you need to put the syringe down, make sure the needle does not touch anything.

Mixing Apidra with NPH (isophane) insulin

Only mix Apidra with another insulin if your doctor has instructed you to do so.

Do not mix Apidra with insulins other than NPH (Neutral Protamine Hagedorn) insulin.

Draw Apidra into the syringe first, then NPH insulin.

1. Wash your hands
2. Just before use, roll the vial of cloudy (longer acting) NPH insulin between your hands until the liquid is white and uniformly cloudy. Do not shake the vial.
3. Draw air into a U100 insulin syringe equal to the dose of cloudy NPH insulin you are using. Put the needle through the rubber top of the NPH insulin vial and inject air into the vial. Withdraw the needle without drawing up any insulin.

4. Draw air into the syringe equal to your dose of Apidra and inject it into the Apidra vial but do not withdraw the needle.
5. Leave the needle in the vial. Hold the vial and syringe firmly in one hand, with the vial above the syringe.
6. Make sure the tip of the needle is in the Apidra and withdraw the correct dose into the syringe.
7. Pull the needle out of the Apidra vial. Expel any air from the syringe and check that the dose is correct.
8. Insert the needle into the vial of cloudy NPH insulin.
9. Leave the needle in the vial. Hold the vial and syringe firmly in one hand, with the vial above the syringe.
10. Make sure the tip of the needle is in the insulin and withdraw your dose of cloudy NPH insulin.
11. Remove the needle from the vial.
12. If you need to put the syringe down for a brief moment, make sure the needle does not touch anything.

INJECTING A DOSE

Apidra should be injected under the skin, being careful not to inject it into a muscle or vein.

Choose a site for injection.

Inject Apidra into the abdomen, thighs, or upper arms.

Apidra mixed with NPH insulin should be injected immediately after mixing.

1. With one hand, stabilise the skin by spreading it or pinching up a large area, as recommended by your healthcare professional.
2. Insert the needle into the skin as recommended by your healthcare professional.
3. Inject the full dose of Apidra, or Apidra mixed with NPH insulin, by pushing the plunger as far as it will go.
4. Slowly count to 10 before removing the needle from the skin.

Change the place within the area you inject each day. This will reduce the risk of skin shrinking or thickening or lumps at the site (see "Side effects").

Do not use the exact same spot for each injection

Do not inject where the skin has pits, is thickened, or has lumps

Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin

If you develop 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.

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.

AFTER INJECTING

Dispose of your insulin syringes safely into a sharps container.

Do not share vials, needles or syringes. Do not reuse needles.

How long to use Apidra/Apidra SoloSTAR

Continue using Apidra or Apidra SoloSTAR for as long as your doctor recommends.

Make sure you keep enough Apidra or Apidra SoloSTAR to last over weekends and holidays.

If you forget to use Apidra or Apidra SoloSTAR - Hyperglycemia

Apidra/Apidra SoloSTAR should be used regularly at the same time each day. If you miss your dose at the usual time, check your blood sugar level as soon as possible. Your blood sugar level may become high (hyperglycaemia).

Do not take an extra dose at a later time just because you have missed a dose.

If you miss taking your dose at the regular scheduled time, taking a dose at another time can increase your risk of having a hypo. You should therefore plan in advance with your doctor or healthcare professional so that you know what to do in case you miss a dose.

If you have missed a dose and are not sure what to do, contact your doctor or healthcare professional for specific advice.

Do NOT use a double dose of your insulin.

If you double a dose, this may cause low blood sugar levels.

The risk of hyperglycaemia is increased if you:

- miss doses of Apidra/Apidra SoloSTAR or other insulins, or use less Apidra/Apidra SoloSTAR than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed
- take certain other medicines

High blood sugar levels over a period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is very high or you experience any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and, in extreme cases, death if untreated.

Discuss any worries you may have about this with your doctor, pharmacist or diabetes educator.

If you use too much Apidra or Apidra SoloSTAR - Hypoglycaemia, a "Hypo"

If you accidentally use too much Apidra or Apidra SoloSTAR your blood sugar level may become too low (hypoglycaemia) and you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

The risk of hypoglycaemia is increased if you:

- accidentally use too much Apidra/Apidra SoloSTAR
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypoglycaemia can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

Always carry some sugary food or drink with you.

If you experience any of these symptoms of hypoglycaemia, you need to raise your blood sugar urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of a sugar-containing soft drink (not a diet soft drink)
- 2-3 concentrated glucose tablets

Follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk, when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood sugar level.

If not treated quickly, the initial symptoms of hypoglycaemia may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and seizures.

If severe hypoglycaemia is not treated, it can cause brain damage and death.

Tell your relatives, friends, close workmates or carers that you have diabetes.

It is important that they recognise the signs and symptoms of a "hypo".

Make sure they know to turn you on your side and get medical help immediately if you lose consciousness.

Make sure they know not to give you anything to eat or drink if you are unconscious.

This is because you could choke.

Provide them with the telephone number for your doctor, the Poisons Information Centre (13 11 26) and Emergency services.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, have some sugary food or drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes educator, or the closest hospital.

If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you keep having "hypos", or if you have ever become unconscious after using Apidra or Apidra SoloSTAR.

Your dose of Apidra/Apidra SoloSTAR or other medicines may need to be changed.

If severe hypoglycaemia is not treated, it can cause brain damage and death.

5. What should I know while using Apidra or Apidra SoloSTAR?

Things you should do

Measure your blood sugar level regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

It is important to keep using Apidra or Apidra SoloSTAR even if you feel well.

Apidra/Apidra SoloSTAR helps to control your condition but does not cure it.

Tell your doctor if you often have hypoglycaemia or if you have ever become unconscious after using Apidra or Apidra SoloSTAR.

Your doctor may need to adjust your dose of Apidra/Apidra SoloSTAR or of other medicines you are taking.

Always carry some sugary food or drink with you.

If you experience any of the symptoms of hypoglycaemia, immediately eat some sugary food or have a drink, e.g. jelly beans, sugar, honey, sugar-containing soft drink, glucose tablets. Diet and low calorie soft drinks do NOT contain sugar and are unsuitable to take for hypoglycaemia.

Make sure that you tell every doctor, dentist, pharmacist or other healthcare professional who is treating you that you have diabetes and are using Apidra or Apidra SoloSTAR.

Tell your doctor, pharmacist or diabetes educator if you are travelling.

Ask your doctor for a letter explaining why you are taking injecting pens and needles with you.

Each country you visit will need to see this letter, so you should take several copies.

You may need to inject Apidra/Apidra SoloSTAR and eat your meals at different times because of time differences in and between countries.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, e.g. sugar sachets or jelly beans
- carry emergency food rations in case of a delay, e.g. dried fruit, biscuits or muesli bars
- keep Apidra/Apidra SoloSTAR readily available; take enough Apidra/Apidra SoloSTAR for your expected needs whilst travelling - you may not be able to get Apidra or Apidra SoloSTAR in the country you are visiting

Your doctor, pharmacist or diabetes educator can provide you with some helpful information.

Tell your doctor if you are having trouble or difficulty with your eyesight.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Things you should not do

Do not stop using Apidra/Apidra SoloSTAR unless your doctor tells you to.

Do not skip meals while using Apidra or Apidra SoloSTAR.

Do not use Apidra or Apidra SoloSTAR if you think it has been frozen or exposed to excessive heat (temperatures above 25°C).

Do not re-use empty cartridges.

Do not give Apidra or Apidra SoloSTAR to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Apidra/Apidra SoloSTAR affects you. Be careful not to let your blood sugar levels fall too low.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia.

Things to be careful of

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

If you become sick with a cold or flu, it is very important to continue using Apidra/Apidra SoloSTAR, even if you feel unable to eat your normal meal. If you have trouble eating solid foods, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for Apidra/Apidra SoloSTAR. Exercise may also speed up the effect of a dose of Apidra/Apidra SoloSTAR, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Storage

CARTRIDGES

Keep unopened cartridges of Apidra in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

When the cartridge has been inserted in the injection pen, the cartridge-pen combination should not be put in the refrigerator and should be kept below 25°C. Do not leave it near heat or in direct light. Discard the cartridge within 28 days of first use. Cartridges that are first carried as a spare for a while must also be discarded 28 days after being removed from the refrigerator.

PRE-FILLED DISPOSABLE PENS

Before use, keep unopened Apidra SoloSTAR pre-filled pens in a refrigerator where the temperature is between 2-8°C. Do not allow to freeze. Discard if frozen.

Before first use, store the pre-filled pen at room temperature for 1 to 2 hours. Once in use, the pre-filled pen should not be put in the refrigerator and it should be kept below 25°C. Do not leave it near heat or in direct light. Discard the pre-filled pen within 28 days of first use. Pre-filled pens that are first carried as a spare for a while must also be discarded 28 days after being removed from the refrigerator.

VIALS

Keep Apidra in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

Once opened, the vial should be refrigerated between 2-8°C, but may be kept unrefrigerated for up to 28 days as long as it is kept below 25°C. Do not leave it near heat or in direct light. Discard the vial within 28 days of first use. Vials that are first carried as a spare for a while must also be discarded 28 days after being removed from the refrigerator.

When and how to discard your medicine

Dispose of your needles and disposable injection devices safely into a sharps container.

If your doctor tells you to stop using Apidra or Apidra SoloSTAR or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor, pharmacist or diabetes educator as soon as possible if you do not feel well while you are using Apidra or Apidra SoloSTAR.

Apidra/Apidra SoloSTAR helps most people with diabetes, but it may have unwanted side effects in a few people. All

medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, pharmacist or diabetes educator to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (hypoglycaemia - a "hypo").

Less serious side effects

Less serious side effects	What to do
<p>General:</p> <ul style="list-style-type: none"> hypoglycaemia (mild to moderate) <p>Injection site-related:</p> <ul style="list-style-type: none"> redness, swelling or itching at the injection site; usually these symptoms disappear within a few weeks during continued use a depression or thickening of the skin around the injection site (lipodystrophy); this can often occur if you inject too often at the same injection site 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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). Lumps under the skin may also be caused by build-up of a protein called amyloid (localized 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.

Serious side effects

Serious side effects	What to do
<p>More severe symptoms of hypoglycaemia, including:</p> <ul style="list-style-type: none"> disorientation seizures, fits or convulsions loss of consciousness <p>Signs of a serious allergic reaction, including:</p> <ul style="list-style-type: none"> skin rashes over a large part of the body shortness of breath, wheezing swelling of the face, lips or tongue 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> fast pulse sweating 	

The above list includes some very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Apidra and Apidra SoloSTAR contain

Active ingredient (main ingredient)	insulin glulisine (100IU/mL)
Other ingredients (inactive ingredients)	meta-cresol trometamol sodium chloride polysorbate 20 hydrochloric acid sodium hydroxide water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Apidra and Apidra SoloSTAR look like

Apidra is a clear, colourless solution available in 3mL cartridges (AUST R 99146) and 10mL vials (AUST R 99145).

Apidra SoloSTAR is a pre-filled disposable pen containing a 3mL cartridge of Apidra (AUST R 132816).

Who distributes Apidra and Apidra SoloSTAR

Distributed by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

This leaflet was prepared in June 2024

Further information

You can get more information about diabetes and insulin from:

Diabetes Australia: Freecall helpline 1300 136 588

www.diabetesaustralia.com.au

apidra-ccds12-cmiv16-04jun24