



**Insulin Glargine Impact 100 units/ml,**  
solution for injection in a cartridge

**sonofi**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may further need to read it.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are not the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).

**What is in this leaflet**

1. What Insulin Glargine Impact is and what it is used for
2. What you need to know before you use Insulin Glargine Impact
3. How to use Insulin Glargine Impact
4. Possible side effects
5. How to store Insulin Glargine Impact
6. Contents of the pack and other information

**1. WHAT INSULIN GLARGINE IMPACT IS AND WHAT IT IS USED FOR**

Insulin Glargine Impact contains insulin glargine. This is a modified insulin, very similar to human insulin. Insulin glargine is used to treat diabetes mellitus in adults. Insulin glargine Impact is used to treat those whose diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar. Insulin glargine has a long and steady blood-sugar-lowering action.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE INSULIN GLARGINE IMPACT**

**Contraindications**  
Do not use Insulin Glargine Impact if you are allergic to insulin or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**  
Insulin glargine Impact is suitable for injecting just under the skin using a reusable pen (see also section 3). Speak to your doctor if you need to inject your insulin in another method. Talk to your doctor, pharmacist or nurse before using Insulin Glargine Impact.

Follow closely the instructions for dosology, monitoring blood and urine tests, diet and physical activity (physical work and exercise) as discussed with your doctor. (See also section 3).  
If your blood sugar is too low (hypoglycaemia), follow the guidance for hypoglycaemia (see box at the end of this leaflet).

**Start changes at the injection site**  
The injection site should be rotated to prevent skin changes such as lipoatrophy or lipohypertrophy. The injection site should be rotated into a lumpy area. See How to use Insulin Glargine Impact. 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 often, and to adjust your insulin or your other anti-diabetic 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.
- 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 a lot of care (for example, adjustment to insulin dose, blood and urine tests):

- If you are ill or have a major injury then your blood sugar level may increase (hypertglycaemia).
- If you are not eating enough your blood sugar level may become too low.

**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.

Insulin treatment can cause the body to produce antibodies to insulin (antibodies that act against insulin). However, only very rarely, this will cause a problem. Some patients with long-standing Type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone (oral anti-diabetic medicine used to treat type 2 diabetes mellitus) and insulin experienced the development of 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).

Children  
There is no experience with the use of Insulin Glargine Impact in children below the age of 2 years.  
**Other medicines and Insulin Glargine Impact**  
Insulin glargine Impact may interact with other medicines. An increase or a drop 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 or when you are taking, have recently taken or might take any other medicines. 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.
- beta-blockers (beta-1 and beta-2) inhibitors (used to treat certain heart conditions or high blood pressure)
- diuretics (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).
- penicillamine, propylthiouracil, salicylates (such as acetylsalicylic acid, used to relieve pain and lower fever).

**Medicines that may increase your blood sugar level to rise (hypertglycaemia) include:**

- corticosteroids (such as "cortisone" used to treat inflammation).
- danazol (medicines acting on ovulation).
- diazoxide (used to treat high blood pressure).
- glycolic acid (used to treat high blood pressure or excessive fluid retention).
- glucagon (pancreas hormone used to treat severe hypoglycaemia).
- growth hormone (used to treat growth problems).
- oestrogens and progestogens (such as in the contraceptive pill) used for birth control.
- sympathomimetic derivatives (used to treat psychiatric disorders).
- somatropin (growth hormone).
- sympathomimetic medicines (such as epinephrine (adrenaline), salbutamol, terbutaline used to treat asthma).
- thyroid hormones (used to treat thyroid gland disorders).
- topical anticholinergic medicines (such as clozapine, olanzapine, apical anticholinergics used to treat HIV).

**Always use your insulin carefully**  
Do not stop your insulin suddenly. This is because the insulin may worsen your diabetes. If you have any questions, ask your doctor or pharmacist. Insulin Glargine Impact is not created by your doctor or pharmacist.

**Special care before injection**  
Your injection remove any air bubbles (see instructions for using the pen).  
Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin.  
Do not re-fill and re-use empty cartridges. Do not add any other insulin to the cartridge. Do not mix Insulin Glargine Impact with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of Insulin Glargine Impact.

**Problems with the insulin pen**  
**Refer to the manufacturer's instructions for using the pen.**  
**If the insulin pen is damaged or not working properly, due to mechanical defects it has to be discarded, and a new insulin pen has to be used.**

**Insulin mix-ups**  
You must always check the insulin label before each injection to avoid mix-ups between Insulin Glargine Impact and other insulins.  
**If you use more insulin Glargine Impact than your insulin should**  
more food and monitor your blood sugar. For information on the treatment of hypoglycaemia, see box at the end of this leaflet.

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

**If you stop using Insulin Glargine Impact**  
This could lead to severe hypertglycaemia (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 Insulin Glargine Impact without consulting a doctor, who will tell you what needs to be done.  
If you are taking any other medicines on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.  
**If you notice signs of your blood sugar being too low (hypoglycaemia), take action at once.** If this happens, you should stop taking the medicine as soon as possible. Insulin treatment may affect your very sense and is very common with insulin treatment (more after more than 1 m. 10 people). Low blood sugar means that there is not enough sugar in your blood (hypoglycaemia). Serious hypoglycaemia may cause brain damage and may be life-threatening. For more information, see the box at the end of this leaflet.

**Severe allergic reactions** (rare, may affect up to 1 in 1,000 people) – the signs include: itchy, hives, swelling of the face and tongue (an allergic reaction), shortness of breath, a fall in blood pressure with rapid heart beat and sweating. Severe allergic reactions to insulins may

you to use it in combination with a short-acting insulin or with tablets used to treat high blood sugar levels.  
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. These factors are: the amount of insulin you use, your diet, your work, your stress, your illness, your physical activity, your emotions, your age, your sex, your weight, your pregnancy, your menstrual cycle, your alcohol or tobacco use.  
See the box at the end of this leaflet for further information.

**Use in children and adolescents**  
Insulin Glargine Impact is used in children, adolescents and children aged 2 years and above. Use this medicine exactly as your doctor has told you.

**Frequency of administration**  
You need one injection of Insulin Glargine Impact every day, at the same time of the day.

**Method of administration**  
Insulin Glargine Impact is injected under the skin. Do NOT inject Insulin Glargine Impact in a vein, since this will change its action and may cause hypoglycaemia.  
Your doctor will show you in which area of the skin you should inject Insulin Glargine Impact. With each injection, change the puncture site within the particular area of skin that you are using.

**How to handle the cartridges**  
Insulin Glargine Impact in cartridges is only suitable for injecting just under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method.  
Do not use the insulin in the Insulin Glargine Impact cartridge if you have the following:  
• JARDISTAR which delivers doses in steps of 0.5 units  
• CHISTAR, Tacipen, Autopen 24, AIDSTAR or AIDSTAR PRO which deliver doses in steps of 1 unit.

All of these pens may be marketed in your country.  
The pen should be used as recommended in the information provided by the device manufacturer.  
The manufacturer's instructions for using the pen must be followed when using any of the cartridges, attaching the needle, and administering the insulin into the skin.  
Look at the cartridge before use. It is only use if it the solution is clear, colourless and waterlike, and has no visible particles in it. Do not shake or mix it before use.

Always use a new cartridge if you notice that your blood sugar control is unexpectedly getting worse. This is because the insulin may worsen your diabetes. If you have any questions, ask your doctor or pharmacist. Insulin Glargine Impact is not created by your doctor or pharmacist.

**Special care before injection**  
Your injection remove any air bubbles (see instructions for using the pen).  
Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin.  
Do not re-fill and re-use empty cartridges. Do not add any other insulin to the cartridge. Do not mix Insulin Glargine Impact with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of Insulin Glargine Impact.

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**Refer to the manufacturer's instructions for using the pen.**  
**If the insulin pen is damaged or not working properly, due to mechanical defects it has to be discarded, and a new insulin pen has to be used.**

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more food and monitor your blood sugar. For information on the treatment of hypoglycaemia, see box at the end of this leaflet.

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If you have missed a dose of Insulin Glargine Impact or if you have not injected enough insulin, your blood sugar level may become too high (hypertglycaemia). Check your blood sugar frequently. For information on the treatment of hypertglycaemia, see box at the end of this leaflet.  
Do not take a double dose to make up for a forgotten dose.

**If you stop using Insulin Glargine Impact**  
This could lead to severe hypertglycaemia (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 Insulin Glargine Impact without consulting a doctor, who will tell you what needs to be done.  
If you are taking any other medicines on the use of this medicine, ask your doctor, pharmacist or nurse.

become life-threatening. Tell a doctor straight away if you notice signs of severe allergic reaction.

**Skin changes at the injection site:**  
If you inject insulin too often at the same place, the skin may either thicken (lipoatrophy) (may affect up to 1 in 100 people) or thicken (lipohypertrophy) (may affect up to 1 in 10 people). Lumps under the skin may also be caused by lipoatrophy or a problem called amyloid (amyloidosis) which may very rarely be injected into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

**Common reported side effects (may affect up to 1 in 10 people)**

- Skin and allergic reactions at the injection site. In rare cases, insulin treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.
- Very rare reported side-effects (may affect up to 1 in 10,000 people) include: hypokalaemia (low potassium levels), hypomagnesaemia (low magnesium levels), hypocalcaemia (low calcium levels) and myalgia (muscular pain) can occur.

**Use in children and adolescents**  
In general, the side effects in children and adolescents of 18 years of age or less are similar to those seen in adults.  
Complaints of injection site reactions (injection site pain, injection site reaction) and skin reactions (rash, urticaria) are reported relatively more frequently in children and adolescents of 18 years of age or less than in adults.

**Reporting of side effects**  
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

**Keep this medicine out of the sight and reach of children.**  
Do not use on the medicine after the expiry date which is stated on the carton and on the label after the expiry date which is "EXP". The expiry date refers to the last day of that month.

**Unopened cartridges**  
Store in a refrigerator (2°C-8°C). Do not freeze or place next to the freezer or a freezer pack. Keep the cartridge in the outer carton in order to protect from light.

**In-use cartridges**  
Cartridges may use (in the insulin pen) or carried as a spare as may be stored for a maximum of 4 weeks not above 30°C and away from direct heat or light. The cartridge must not be stored in a refrigerator. Do not use it after this time period.

**Do not use Insulin Glargine Impact if you notice particles in it. Only use Insulin Glargine Impact if the solution is clear, colourless and waterlike. Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.**

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Insulin Glargine Impact contains**  
The active substance is insulin glargine. Each ml of the solution contains 100 units of insulin glargine (equivalent to 3.64 mg).  
• The other ingredients are zinc chloride, metacresol, glycerol, sodium hydroxide (see section 2).  
• Important information about some of the ingredients of Insulin Glargine Impact: hydrochloric acid (for pH adjustment) and water for injection.

**What Insulin Glargine Impact looks like and contents of the pack**  
Insulin Glargine Impact 100 units/ml solution for injection in a cartridge is a clear and colourless solution.

Insulin Glargine Impact comes in a special cartridge to be used only in conjunction with the pens CHISTAR, Tacipen, Autopen 24, AIDSTAR, AIDSTAR PRO or JARDISTAR. Each cartridge contains 3 ml of solution for injection (see sections 3, 4, 5, 6, 8, 9 and 10 cartridges).

In very rare cases, hypokalaemia (low potassium levels) and myalgia (muscular pain) can occur.  
There is no experience in children under 2 years.

**Conditions of prescription and issuance: List II**  
**Marketing Authorisation Holder and Manufacturer**  
Sonofi-Aventis, Deutschland GmbH, D45526 Frankfurt am Main, Germany.

**This leaflet was last revised in August 2020**  
For updated Leaflet in your country language: <http://http://tq.impact-sonofi.com/garnc> or Scan QR Code a outer box.



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**HYPERTGLYCAEMIA AND HYPOLYCAEMIA**

**Always carry some sugar (at least 20 grams) with you.**  
**Get some information with you to show your doctor.**

You are taking or have stopped taking certain other medicines (see section 2). Other medicines and Insulin Glargine Impact.  
**Hypoglycaemia is also more likely to occur if:**

- you have just begun insulin treatment or changed to another insulin preparation (when changing from your previous basal insulin to Insulin Glargine Impact/hypoglycaemia, if it occurs, may be more likely to occur in the morning than at night).
- your blood sugar levels are almost normal or are unstable.
- you have had a major injury when 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**

Examples of symptoms that tell you that your blood sugar level is falling too much or too fast: sweating, dizziness, anxiety, fast heartbeat, high blood pressure, palpitations and irregular heartbeat. These symptoms often develop before the symptoms of a low sugar level in the brain.

**Low blood sugar**

Examples of symptoms that indicate a low sugar level in the brain: dizziness, intense hunger, nausea, vomiting, tiredness, sleepiness, sleep disturbances, irritability, depression, aggression, confusion, visual disturbances (sometimes, total loss of speech), visual disorders (troubling, 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, loss of consciousness.

The first symptoms which alert you to hypoglycaemia ("warning symptoms") may change, be weaker or may be missing altogether if you have had diabetes for a long time or if you suffer from a certain type of nervous disease (diabetic autonomic neuropathy).

You have recently suffered hypoglycaemia (for example the day before or the day before yesterday).

- you have almost normal or, at least, greatly improved blood sugar levels.
- you have recently changed from an animal insulin to a human insulin such as Insulin Glargine Impact.
- you are taking or have taken certain other medicines (see section 2).  
Other medicines and Insulin Glargine Impact.

In such a case, you may develop severe hypoglycaemia (see even first) before you are aware of the problem. Be familiar with your warning