

Package leaflet: Information for the user

ABASAGLAR 100 units/mL Tempo Pen solution for injection in a pre-filled pen insulin glargine

Read all of this leaflet carefully including the Instructions for Use of the ABASAGLAR Tempo pre-filled pen, before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What ABASAGLAR is and what it is used for

ABASAGLAR contains insulin glargine. This is a modified insulin, very similar to human insulin.

ABASAGLAR is used to treat diabetes mellitus in adults, adolescents and children aged 2 years and above.

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 ABASAGLAR

Do not use ABASAGLAR

If you are allergic to insulin glargine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using ABASAGLAR.

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

If your blood sugar is too low (hypoglycaemia), follow the guidance for hypoglycaemia (see box at the end of this leaflet).

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 well if you inject into a lumpy area (See How to use Abasaglar). Contact your doctor if you are currently injecting into a lumpy area before you start injecting into 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 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 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 (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.

Insulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). However, only very rarely, this will require a change to your insulin dose.

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone 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).

Insulin mix-ups

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

Tempo Pen

The Tempo Pen contains a magnet. If you have a medical device fitted, such as a heart pacemaker, this may not work correctly if the Tempo Pen is held too close. The magnetic field extends to approximately 1.5 cm.

Children

There is no experience with the use of ABASAGLAR in children below the age of 2 years.

Other medicines and ABASAGLAR

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, 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,
- 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),
- somatostatin analogues (such as octreotide, used to treat an uncommon condition in which you make too much growth hormone),
- sulphonamide 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], salbutamol, terbutaline used to treat asthma),
- thyroid hormones (used to treat thyroid gland disorders),
- atypical antipsychotic medicines (such as clozapine, olanzapine),
- protease inhibitors (used to treat HIV).

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.

ABASAGLAR with alcohol

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. Particularly careful control of your diabetes, and prevention of hypoglycaemia, is important for the health of your baby.

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

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),
- you have problems with your sight.

Keep this possible problem in mind in all situations where you might put yourself and others at risk (such as driving a car or using 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.

ABASAGLAR contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, which means it is essentially 'sodium-free'.

3. How to use ABASAGLAR

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Although ABASAGLAR contains the same active substance as Toujeo (insulin glargine 300 units/mL), these medicines are not interchangeable. The switch from one insulin therapy to another requires medical prescription, medical supervision and blood glucose monitoring. Please consult your doctor for further information.

Dose

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 ABASAGLAR per day you will need and at what time,
- tell you when to check your blood sugar level, and whether you need to carry out urine tests,
- tell you when you may need to inject a higher or lower dose of ABASAGLAR.

ABASAGLAR is a long-acting insulin. Your doctor may tell 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 and to prevent it from becoming too high or too low. See the box at the end of this leaflet for further information.

Use in children and adolescents

ABASAGLAR can be used in 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 ABASAGLAR every day, at the same time of the day.

Method of administration

ABASAGLAR is injected under the skin. Do NOT inject ABASAGLAR 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 ABASAGLAR. With each injection, change the puncture site within the particular area of skin that you are using.

How to handle ABASAGLAR Tempo Pen

ABASAGLAR Tempo Pen is a pre-filled disposable pen containing insulin glargine.

Read carefully the "ABASAGLAR Tempo Pen Instructions for Use" included with this package leaflet. You must use the pen as described in these Instructions for Use.

A new needle must be attached before each use. Only use needles that are compatible for use with ABASAGLAR Tempo Pen (see "ABASAGLAR Tempo Pen Instructions for Use").

A safety test must be performed before each injection.

Look at the cartridge before you use the pen. Do not use ABASAGLAR Tempo Pen if you notice particles in it. Only use ABASAGLAR Tempo Pen if the solution is clear, colourless and water-like. Do not shake or mix it before use.

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

Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin.

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 ABASAGLAR Tempo Pen, consult your doctor, pharmacist or nurse.

Empty pens must not be re-filled and must be properly discarded.

Do not use ABASAGLAR Tempo Pen if it is damaged or not working properly, it has to be discarded and a new Tempo Pen has to be used.

The Tempo Pen is designed to work with the Tempo Smart Button. The optional additional feature Tempo Smart Button is a product available for the Tempo Pen, which may be used for transmitting dose information to a mobile application. The Tempo Pen can be used with or without the Tempo Smart Button attached. See instructions provided with the Tempo Smart Button and the mobile application for further information.

If you use more ABASAGLAR than you should

- If you **have injected too much ABASAGLAR** or are unsure how much you have injected,, 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 box at the end of this leaflet.

If you forget to use ABASAGLAR

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

After injecting

If you are unsure how much you have injected then check your blood sugar levels before deciding if you need another injection.

If you stop using ABASAGLAR

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 ABASAGLAR 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 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 the action to increase your blood sugar levels **immediately**. Hypoglycaemia (low blood sugar) can be very serious and is very common with insulin treatment (may affect more than 1 in 10 people). Low blood sugar means that there is not enough sugar in your blood. If your blood sugar level falls too low, you may pass out

(become unconscious). 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 may include large-scale skin reactions (rash and itching all over the body), severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure with rapid heartbeat and sweating. Severe allergic reactions to insulins may 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 fatty tissue may shrink (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 build-up of a protein called amyloid (cutaneous amyloidosis, how often they occur is not known). 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.

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

- **Skin and allergic reactions at the injection site**

The signs may include reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. They can spread around the injection site. Most minor reactions to insulins usually disappear in a few days to a few weeks.

Rare side effects (may affect up to 1 in 1,000 people)

- **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.

- **General disorders**

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 side-effects (may affect up to 1 in 10,000 people)

In very rare cases, dysgeusia (taste disorders) 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. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ABASAGLAR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label of the pen after "EXP". The expiry date refers to the last day of that month.

Not in-use pens

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Do not put ABASAGLAR 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 28 days up to 30 °C and away from direct heat or direct light. The pen in use must not be stored in the refrigerator. Do not use it after this time period. The pen cap must be put back on the pen after each injection in order to protect from light.

Do not throw away any 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 ABASAGLAR contains

- The active substance is insulin glargine. Each millilitre of the solution contains 100 units of the active substance insulin glargine (equivalent to 3.64 mg).
- The other ingredients are: zinc oxide, metacresol, glycerol, sodium hydroxide (see section 2 "ABASAGLAR contains sodium"), hydrochloric acid and water for injections.
- The Tempo Pen contains a magnet (see section 2, "Warnings and precautions").

What ABASAGLAR looks like and contents of the pack

ABASAGLAR 100 units/mL solution for injection in a pre-filled pen, Tempo Pen, is a clear and colourless solution.

ABASAGLAR is available in packs containing 5 pre-filled pens and in multipacks comprising 2 cartons, each containing 5 pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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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 diabetic.

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,
- your insulin pen does not work properly,
- 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 section 2, "Other medicines and ABASAGLAR").

Warning symptoms of hyperglycaemia

Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heartbeat, 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 occur?

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 section 2, "Other medicines and ABASAGLAR").

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 ABASAGLAR, 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 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, 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, 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 if it develops slowly,
- 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 ABASAGLAR,
- you are taking or have taken certain other medicines (see section 2, "Other medicines and ABASAGLAR").

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.

The recovery of hypoglycaemia may be delayed because ABASAGLAR has a long action.'

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.