

# Inaglip 5 mg Film-coated Tablets

## Linagliptin

**Read all of this leaflet carefully before you start taking 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 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 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.

### What is in this leaflet

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

#### 1. What Inaglip is and what it is used for

Inaglip contains the active substance linagliptin which belongs to a group of medicines called “oral anti-diabetics”. Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

Inaglip is used for ‘type 2 diabetes’ in adults, if the disease cannot be adequately controlled with one oral anti-diabetic medicine (metformin or sulphonyl ureas) or diet and exercise alone. Inaglip may be used together with other anti-diabetic medicines e.g. metformin, sulphonyl ureas (e.g. glimepiride, glipizide), empagliflozin, or insulin.

It is important to keep following the advice about diet and exercise that you have been given by your doctor.

#### 2. What you need to know before you take Inaglip

##### Do not take Inaglip:

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

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Inaglip:

- If you have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting). Inaglip should not be used to treat these conditions.
- If you are taking an anti-diabetic medicine known as a ‘sulphonylurea’ (e.g. glimepiride, glipizide), your doctor may want to reduce your dose of sulphonyl urea when you take it together with Inaglip in order to avoid your blood sugar going too low.
- If you have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood.
- If you have or have had a disease of the pancreas.

If you have symptoms of acute pancreatitis, like persistent, severe stomach ache (abdominal pain), you should consult your doctor.

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid.

Your doctor may ask you to stop Inaglip.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor.

##### Children and adolescents

Inaglip is not recommended for children and adolescents under 18 years.

##### Other medicines and Inaglip

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should tell your doctor if you are using medicines containing any of the following active substances:

- Carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.

##### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is unknown if Inaglip is harmful to the unborn child. Therefore, it is preferable to avoid using Inaglip if you are pregnant.

It is not known if Inaglip passes into human breast milk. A decision must be made by your doctor whether to discontinue breast-feeding or to discontinue/abstain from Inaglip therapy.

##### Driving and using machines

Inaglip has no or negligible influence on the ability to drive and use machines.

Taking Inaglip in combination with medicines called sulphonylureas and/or insulin can cause too low blood sugar levels (hypoglycaemia), which may affect your ability to drive and use machines or work without safe foothold. However, more frequent blood glucose testing might be recommended to minimize the risk for hypoglycaemia, especially when Inaglip is combined with sulphonylurea and/or insulin.

#### 3. How to take Inaglip

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

The recommended dose of Inaglip is one 5 mg tablet once a day.

You can take Inaglip with or without food.

Your doctor may prescribe Inaglip together with another oral anti-diabetic medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

##### If you take more Inaglip than you should

If you take more Inaglip than you should, talk to a doctor immediately.

##### If you forget to take Inaglip

- If you forget to take a dose of Inaglip, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

##### If you stop taking Inaglip

Do not stop taking Inaglip without first consulting your doctor. Your blood sugar levels may increase when you stop taking Inaglip.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

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

##### Some symptoms need immediate medical attention

You should stop taking Inaglip and see your doctor immediately if you experience the following symptoms of low blood sugar: trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion (hypoglycaemia). Hypoglycaemia (frequency: very common, may affect more than 1 in 10 people) is an identified side effect when Inaglip is taken together with metformin and a sulphonylurea.

Some patients have experienced allergic reactions (hypersensitivity; frequency uncommon, may affect up to 1 in 100 people) while taking Inaglip alone or in combination with other medicinal products for the treatment of diabetes, which may be serious, including wheezing and shortness of breath (bronchial hyperreactivity; frequency not known, frequency cannot be estimated from the available data). Some patients experienced rash (frequency uncommon), hives (urticaria; frequency rare, may affect up to 1 in 1000 people), and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema; frequency rare). If you experience any of the signs of illness mentioned above, stop taking Inaglip and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced inflammation of the pancreas (pancreatitis; frequency rare, may affect up to 1 in 1000 people) while taking Inaglip alone or in combination with other medicinal products for the treatment of diabetes.

STOP taking Inaglip and contact a doctor immediately if you notice any of the following serious side effects:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

Some patients have had the following side effects while taking Inaglip alone or in combination with other medicinal products for the treatment of diabetes:

- Common: level of lipase in the blood increased.
- Uncommon: inflamed nose or throat (nasopharyngitis), cough, constipation (in combination with insulin), level of amylase in the blood increased.
- Rare: blistering of skin (bullous pemphigoid).

##### 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.

#### 5. How to store Inaglip

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Inaglip contains

- The active substance is linagliptin.

Each film-coated tablet contains 5 mg of linagliptin.

- The other ingredients are:

- Tablet core: pregelatinized starch, Corn starch, Copovidone, Mannitol, Magnesium stearate
- Film-coating: Hypromellose, Titanium dioxide, Polyethylene glycol, Red iron oxide.

##### What Inaglip looks like and contents of the pack

Inaglip tablets are: round, pink, plain film-coated tablets

Inaglip is available in three Alu/Alu blisters (10 film-coated tablets per blister) packed in a carton box with a leaflet.

##### Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

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Website: www.pharmaline.com.lb

Reg. No. for Inaglip 5 mg in Lebanon: 30420/1

##### This is a medicament:

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists

The leaflet was last revised in October 2021.