Package leaflet: Information for the patient

Eprocliv® 50/850 mg, filmomhulde tabletten
Eprocliv® 50/1000 mg, filmomhulde tabletten
sitagliptin/metformin hydrochloride

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, 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 {Nationally completed name]} is and what it is used for

{[Nationally completed name]} contains two different medicines called sitagliptin and metformin.
- sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called ‘type 2 diabetes mellitus’. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by your body.

Along with diet and exercise, this medicine helps lower your blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

What is type 2 diabetes?
Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take {Nationally completed name]}

Do not take {Nationally completed name]}:
- if you are allergic to sitagliptin or metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have severely reduced kidney function
- if you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- if you have a severe infection or are dehydrated
- if you are going to have an X-ray where you will be injected with a dye. You will need to stop taking {[Nationally completed name]} at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working
- if you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties
- if you have liver problems
- if you drink alcohol to excess (either every day or only from time to time)
- if you are breast-feeding

Do not take {[Nationally completed name]} if any of the above apply to you and talk with your doctor about other ways of managing your diabetes. If you are not sure, talk to your doctor, pharmacist or nurse before taking {[Nationally completed name]}.

Warnings and precautions
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving {[Nationally completed name]} (see section 4).

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 {[Nationally completed name]}.

Risk of lactic acidosis
{[Nationally completed name]} may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

Talk to your doctor promptly for further instructions if:
- You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

Stop taking {Nationally completed name]} for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking {Nationally completed name]} and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.
Symptoms of lactic acidosis include:
- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor or pharmacist before taking {[Nationally completed name]}:
- if you have or have had a disease of the pancreas (such as pancreatitis)
- if you have or have had gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis (see section 4)
- if you have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- if you have or have had an allergic reaction to sitagliptin, metformin, or {[Nationally completed name]} (see section 4)
- if you are taking a sulphonylurea or insulin, diabetes medicines, together with {[Nationally completed name]}, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin

If you need to have major surgery you must stop taking {[Nationally completed name]} during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your

treatment with {[Nationally completed name]}.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking {[Nationally completed name]}.

During treatment with {[Nationally completed name]}, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Children and adolescents
Children and adolescents below 18 years should not use this medicine. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Other medicines and {Nationally completed name]}
If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking {[Nationally completed name]} before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with {[Nationally completed name]}.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dose of {[Nationally completed name]}. It is especially important to mention the following:

- medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- specific medicines for the treatment of bronchial asthma (β-sympathomimetics)
- iodinated contrast agents or alcohol-containing medicines
- certain medicines used to treat stomach problems such as cimetidine
- ranolazine, a medicine used to treat angina
- dolutegravir, a medicine used to treat HIV infection
- vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer)
- digoxin (to treat irregular heart beat and other heart problems). The level of digoxin in your blood may need to be checked if taking with {[Nationally completed name]}.

{Nationally completed name]} with alcohol
Avoid excessive alcohol intake while taking {[Nationally completed name]} since this may increase the risk of lactic acidosis (see section “Warnings and precautions”).

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. You should not take this medicine during pregnancy or if you are breast-feeding. See section 2, **Do not take {[Nationally completed name]}**.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with sitagliptin, which may affect your ability to drive or use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

{[Nationally completed name]} contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take {Nationally completed name]}

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

- Take one tablet:
  - twice daily by mouth
  - with meals to lower your chance of an upset stomach.

- Your doctor may need to increase your dose to control your blood sugar.

- If you have reduced kidney function, your doctor may prescribe a lower dose.

You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

If you take more {Nationally completed name]} than you should
If you take more than the prescribed dose of this medicine, contact your doctor immediately. Go to

the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing (see section "Warnings and precautions").

If you forget to take {Nationally completed name]}
If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking {Nationally completed name]}
Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first. If you stop taking {[Nationally completed name]}, your blood sugar may rise again.

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.

STOP taking {[Nationally completed name]} 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 with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis).

{[Nationally completed name]} may cause a very rare (may affect up to 1 in 10,000 people), but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens, you must **stop taking {[Nationally completed name]} and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

If you have a serious allergic reaction (frequency not known), including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine 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 taking metformin have experienced the following side effects after starting sitagliptin:
Common (may affect up to 1 in 10 people): low blood sugar, nausea, flatulence, vomiting
Uncommon (may affect up to 1 in 100 people): stomach ache, diarrhoea, constipation, drowsiness

Some patients have experienced diarrhoea, nausea, flatulence, constipation, stomach ache or vomiting

when starting the combination of sitagliptin and metformin together (frequency is common).

Some patients have experienced the following side effects while taking this medicine with a sulphonylurea such as glimepiride:
Very common (may affect more than 1 in 10 people): low blood sugar
Common (may affect up to 1 in 10 people): constipation

Some patients have experienced the following side effects while taking this medicine in combination with pioglitazone:
Common (may affect up to 1 in 10 people): swelling of the hands or legs

Some patients have experienced the following side effects while taking this medicine in combination with insulin:
Very common: low blood sugar
Uncommon: dry mouth,
headache

Some patients have experienced the following side effects during clinical studies while taking sitagliptin alone (one of the medicines in {[Nationally completed name]}) or during post-approval use of {[Nationally completed name]} or sitagliptin alone or with other diabetes medicines:
Common: low blood sugar, headache, upper respiratory infection, stuffy or runny nose and sore throat, osteoarthritis, arm or leg pain
Uncommon: dizziness, constipation, itching
Rare: reduced number of platelets
Frequency not known: kidney problems (sometimes requiring dialysis), vomiting, joint pain, muscle pain, back pain, interstitial lung disease, bullous pemphigoid (a type of skin blister)

Some patients have experienced the following side effects while taking metformin alone:
Very common: nausea, vomiting, diarrhoea, stomach ache and loss of appetite. These symptoms may happen when you start taking metformin and usually go away
Common: a metallic taste
Very rare: decreased vitamin B12 levels, hepatitis (a problem with your liver), hives, redness of the skin (rash) or itching

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {Nationally completed name]}

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 carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

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 {Nationally completed name]} contains

- The active substances are sitagliptin and metformine hydrochloride.
  {[Nationally completed name] 50 mg/850 mg film-coated tablets}:
  Each tablet contains sitagliptin hydrochloride monohydrate equivalent to 50 mg sitagliptin, and 850 mg of metformin hydrochloride.
  {[Nationally completed name] 50 mg/1,000 mg film-coated tablets}:
  Each film-coated tablet contains sitagliptin hydrochloride monohydrate equivalent to 50 mg sitagliptin, and 1,000 mg of metformin hydrochloride.

- The other ingredients are: In the tablet core: Povidone (E1201) , sodium laurilsulfate, microcrystalline cellulose (E460) , croscarmellose sodium (E468), sodium stearyl fumarate. In the film-coating: Hypromellose (E464), hydroxypropylcellulose (E463), triethyl citrate (E1505), titanium dioxide (E171), talc (E553b), yellow iron oxide (E172), red iron oxide (E172).

What {Nationally completed name]} looks like and contents of the pack

{[Nationally completed name] 50 mg/850 mg film-coated tablets}:
Light orange film-coated tablet <(tablet)> of oval, biconvex shape (approximately 10 x 20 mm) , debossed with "SM 2" on one side.

{[Nationally completed name] 50 mg/1,000 mg film-coated tablets}:
Light red film-coated tablet <(tablet)> of oval, biconvex shape (approximately 10.5 x 21) , debossed with "SM 3" on one side.

The medicine is available in blisters (OPA/Aluminium/PVC//Aluminium blister or PVC/PE/PVDC//Aluminium transparent blister) packed in a carton.

[NL/H/4976-4978-4979+5233-5234/001-002]
Packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 112, 168, 180, 196 film-coated tablets.
Multi-packs containing 168 (2 packs of 84) and 196 (2 packs of 98) film-coated tablets.

Pack of 14 x 1, 28 x 1, 50 x 1, 56 x1, 60 x 1, 112 x 1, 168 x 1, 180 x 1(2 packs of 90 x 1), 196 x 1, 196 x 1 (2 packs of 98 x 1)film-coated tablets in perforated unit dose blisters.

[NL/H/4977/001]
Packs of 14, 20, 28, 30, 50, 56, 60, 90, 100, 112, 168, 180, 196 film-coated tablets.
Multi-packs containing 168 (2 packs of 84) and 196 (2 packs of 98) film-coated tablets.
Pack of 14 x 1, 28 x 1, 50 x 1, 56 x1, 60 x 1, 112 x 1, 168 x 1, 180 x 1 (2 packs of 90 x 1), 196 x 1, 196 x 1 (2 packs of 98 x 1) film-coated tablets in perforated unit dose blisters.

[NL/H/4977/002]
Packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 112, 168, 180, 196 film-coated tablets.
Multi-packs containing 168 (2 packs of 84) and 196 (2 packs of 98) film-coated tablets.
Pack of 14 x 1, 28 x 1, 50 x 1, 56 x1, 60 x 1, 112 x 1, 168 x 1, 180 x 1 (2 packs of 90 x 1), 196 x 1, 196 x 1 (2 packs of 98 x 1) film-coated tablets in perforated unit dose blisters.

[NL/H/4980/001-002]
Packs of 28 and 56 film-coated tablets.s

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant:
Lek d.d., pe proizvodnja Lendava
Trimlini 2D
9220 Lendava
Slovenië

Lek S.A.
ul. Podlipie 16
Strykow, 95-010
Polen

In het register ingeschreven onder:
Eprocliv 50/850 mg, filmomhulde tabletten RVG 125719
Eprocliv 50/1000 mg, filmomhulde tabletten RVG 125720

Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Estland:	Eprocliv
Griekenland:	Eprocliv
Spanje:	Eprocliv 50 mg/850, 50 mg/1.000mg comprimidos recubiertos con pelicula EFG
Hongarije:	Eprocliv 50 mg/850, 50 mg/1000 mg filmom obložene tablete
Litouwen:	Eprocliv 50 mg/850, 50 mg/1000 mg plėvele dengtos tabletės
Letland:	Eprocliv 50 mg/850, 50 mg/1000 mg apvalkotās tabletes
Nederland:	Eprocliv 50/850, 50/1000 mg, filmomhulde tabletten
Polen:	Eprocliv
Roemenië:	Eprocliv 50 mg/1000 mg Comprimate filmate
Slovenië:	Eprocliv 50 mg/850, 50 mg/1000 mg filmskoobložene tablete
Slowakije:	Eprocliv 50 mg/850, 50 mg/1000 mg filmom obalené tablety

Deze bijsluiter is voor het laatst goedgekeurd in maart 2025