

Package leaflet: Information for the patient

Sitagliptin/Metformin Clonmel 50 mg/850 mg film-coated tablets
Sitagliptin/Metformin Clonmel 50 mg/1000 mg film-coated tablets

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

1. What Sitagliptin/Metformin Clonmel is and what it is used for

Sitagliptin/Metformin Clonmel 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 Sitagliptin/Metformin Clonmel

DO NOT take Sitagliptin/Metformin Clonmel if you:

- are allergic to sitagliptin or metformin or any of the other ingredients of this medicine (listed in section 6)
- have severely reduced kidney function
- 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 which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell
- have a severe infection or are dehydrated
- are going to have an X-ray where you will be injected with a dye. You will need to stop taking Sitagliptin/Metformin Clonmel 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
- have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing

difficulties

- have liver problems
- drink alcohol to excess (either every day or on occasion)
- are breast-feeding

Do not take Sitagliptin/Metformin Clonmel 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 Sitagliptin/Metformin Clonmel.

Warnings and precautions

Inflammation of the pancreas (pancreatitis) has been reported in patients receiving sitagliptin/metformin (see section 4).

If you experience blistering of the skin it may be a sign of a condition called bullous pemphigoid. Your doctor may ask you to stop taking Sitagliptin/Metformin Clonmel.

Risk of lactic acidosis

Sitagliptin/metformin 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.

Stop taking Sitagliptin/Metformin Clonmel 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 Sitagliptin/Metformin Clonmel and contact a doctor or the nearest hospital immediately if you experience any 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 Sitagliptin/Metformin Clonmel if you:

- have or have had a disease of the pancreas (such as pancreatitis)
- 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)
- have type 1 diabetes. This is sometimes called insulin-dependent diabetes
- have or have had an allergic reaction to sitagliptin, metformin, or Sitagliptin/Metformin Clonmel (see section 4)
- are taking a sulphonylurea or insulin, other diabetes medicines, together with Sitagliptin/Metformin Clonmel, 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 Sitagliptin/Metformin Clonmel during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Sitagliptin/Metformin Clonmel.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Sitagliptin/Metformin Clonmel.

During treatment with Sitagliptin/Metformin Clonmel, 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 Sitagliptin/Metformin Clonmel

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 Sitagliptin/Metformin Clonmel before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Sitagliptin/Metformin Clonmel.

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 Sitagliptin/Metformin Clonmel. It is especially important to mention the following medicines:

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

Sitagliptin/Metformin Clonmel with alcohol

Avoid excessive alcohol intake (either every day or on occasion) while taking Sitagliptin/Metformin Clonmel 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 Sitagliptin/Metformin Clonmel.**

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 low blood sugar (hypoglycaemia), which may affect your ability to drive and use machines or work safely.

Sitagliptin/Metformin Clonmel contains sodium

This medicine contains 27.6 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.38 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 32.5 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.63 % of the recommended maximum daily dietary intake of sodium for an adult.

Sitagliptin/Metformin Clonmel 50 mg/850 mg contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Commented [MD1]: Strength added: Only 50/850 mg contains lactose (in film-coat)

3. How to take Sitagliptin/Metformin Clonmel

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

Dosage

The recommended dose is one tablet taken twice daily.

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

Method of administration

To be taken by mouth with meals to lower your chance of an upset stomach.

Kidney problems

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

Other medicines and recommendations

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 Sitagliptin/Metformin Clonmel 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 Sitagliptin/Metformin Clonmel

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 of this medicine.

If you stop taking Sitagliptin/Metformin Clonmel

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 Sitagliptin/Metformin Clonmel, 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 Sitagliptin/Metformin Clonmel and contact a doctor or the nearest hospital immediately if you notice the following very serious side effect:

Very rare (may affect up to 1 in 10,000 people)

- lactic acidosis (see section “Warnings and precautions”). Lactic acidosis may lead to coma

STOP taking Sitagliptin/Metformin Clonmel and contact a doctor immediately if you notice any of the following serious side effects:

Not known (frequency cannot be estimated from the available data)

- severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting. These could be signs of an inflamed pancreas (pancreatitis)

- serious allergic reaction, 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. 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 the following side effects when starting the combination of sitagliptin and metformin:

Common

- diarrhoea
- nausea
- flatulence
- constipation
- stomach ache
- vomiting

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

- constipation

Some patients have experienced the following side effects while taking this medicine in combination with pioglitazone:

Common

- 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 Sitagliptin/Metformin Clonmel) or during post-approval use of sitagliptin/metformin 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

Not known

- kidney problems (sometimes requiring dialysis)
- vomiting
- joint pain
- muscle pain
- back pain
- interstitial lung disease
- a type of skin blister (bullous pemphigoid)

Some patients have experienced the following side effects while taking metformin alone:

Very common

- nausea
- vomiting
- diarrhoea
- stomach ache
- loss of appetite

These symptoms may happen when you start taking metformin, and usually go away.

Common

- a metallic taste
- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Very rare

- hepatitis (a problem with your liver)
- hives
- redness of the skin (rash)
- 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:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sitagliptin/Metformin Clonmel

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

[Bottles]

Do not use this medicine after the expiry date, which is stated on the bottle and the carton after 'EXP'.

[Blister]

Do not use this medicine after the expiry date, which is stated on the blister and the carton after 'EXP'.

The expiry date refers to the last day of the month.

Do not store above 30° C.

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 Sitagliptin/Metformin Clonmel contains

- The active substances are sitagliptin and metformin. Each film-coated tablet (tablet) contains sitagliptin hydrochloride monohydrate equivalent to 50 mg of sitagliptin and 850 mg of metformin hydrochloride.
- The active substances are sitagliptin and metformin. Each film-coated tablet (tablet) contains sitagliptin hydrochloride monohydrate equivalent to 50 mg of sitagliptin and 1,000 mg of metformin hydrochloride.

- The other ingredients are:

Tablet core:

Cellulose microcrystalline, povidone (K29/32), sodium laurilsulfate, sodium stearyl fumarate.

Film coating:

Lactose monohydrate, hypromellose E464, titanium dioxide E171, triacetin, iron oxide red E172.

Polyvinyl alcohol E1203, macrogol E1521, talc E553b, titanium dioxide E171, iron oxide red E172, black iron oxide E172.

What Sitagliptin/Metformin Clonmel looks like and contents of the pack

Sitagliptin/Metformin Clonmel 50 mg/850 mg film-coated tablets are oval-shaped, biconvex, pink film-coated tablet of approximately 20.5 mm x 9.5 mm and with "S476" debossed on one side.

Sitagliptin/Metformin Clonmel 50 mg/1000 mg film-coated tablets are oval-shaped, biconvex, brown film-coated tablet of approximately 21.5 mm x 10 mm and with "S477" debossed on one side.

Pack sizes:

[Bottles]

Sitagliptin/Metformin Clonmel 50 mg/850 mg film-coated tablets are packed in high density polyethylene (HDPE) container and polypropylene (PP) screw cap with tamper-evident ring and silica gel desiccant contained in the PP cap.

Sitagliptin/Metformin Clonmel 50 mg/1000 mg film-coated tablets are packed in high density polyethylene (HDPE) container and polypropylene (PP) screw cap with tamper-evident ring and silica gel desiccant contained in the PP cap.

Pack size: 100, 196 tablets

[Blister]

Sitagliptin/Metformin Clonmel 50 mg/850 mg film-coated tablets are packed in hard aluminium/PVC/PVDC opaque blister strip.

Sitagliptin/Metformin Clonmel 50 mg/1000 mg film-coated tablets are packed in hard aluminium/PVC/PVDC opaque blister strip.

Pack sizes: 14, 28, 30, 56, 60, 196 (2x98), 196, 210 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Laboratorios Liconsa, S.A., Avda. Miralcampo, N° 7, Polígono Industrial Miralcampo, 19200 Azuqueca de Henares, Guadalajara, Spain

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands:	Sitagliptine/Metformine hydrochloride STADA 50 mg/850 mg, 50 mg/1000 mg filmomhulde tabletten
Austria:	Sitagliptin/Metformin STADA 50 mg/850 mg, 50 mg/1000 mg Filmtabletten
Czech Republic:	Sitagliptin/Metformin STADA
Denmark:	Sitagliptin/Metformin STADA
Finland:	Sitagliptin/Metformin STADA 50 mg/850 mg, 50 mg/1000 mg kalvopäällysteiset tabletit
France:	SITAGLIPTINE/METFORMINE EG 50 mg/1000 mg, comprimé pelliculé
Germany:	Sitagliptin/Metformin STADA 50 mg/850 mg, 50 mg/1000 mg Filmtabletten
Iceland:	Sitagliptin/Metformin STADA 50 mg/850 mg, 50 mg/1000 mg filmhúðaðar töflur
Ireland:	Sitagliptin/Metformin Clonmel 50 mg/850 mg, 50 mg/1000 mg film-coated tablets
Italy:	Sitagliptin e Metformina EG
Portugal:	Metformina + Sitagliptina Ciclum
Spain:	Sitagliptina/ metformina STADA 50 mg/850 mg, 50 mg/1000 mg comprimidos recubiertos con película EFG
Sweden:	Sitagliptin/Metformin STADA 50 mg/850 mg, 50 mg/1000 mg filmdragerade tabletter
Slovenia:	Sitagliptin/metforminijev klorid STADA 50 mg/850 mg, 50 mg/1000 mg filmsko obložene tablete
Slovakia:	Sitagliptin-Metformin STADA 50 mg/850 mg, 50 mg/1000 mg filmom obalené tablety

This leaflet was last revised in December 2023.