

Vipdomet® 12.5 mg/500 mg and 12.5 mg/1000 mg Film-coated Tablets

Alogliptin benzoate and Metformin hydrochloride

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

- This medicine is subject to additional monitoring. This will allow quick identification of new information. You can help by reporting any side effects you may get. See the end of section 6 for how to report side effects.
- 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. 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 "Possible side effects".

The product is known by the name above but will be referred to as Vipdomet throughout the rest of this leaflet. In this leaflet:

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

1. What Vipdomet is and what it is used for

What Vipdomet is

Vipdomet contains two different medicines called alogliptin and metformin in one tablet:

- Alogliptin belongs to a group of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Alogliptin works to increase the levels of insulin in the body after a meal and decrease the amount of sugar in the body.
 - Metformin belongs to a group of medicines called biguanides which also help to lower blood sugar by lowering the amount of sugar made in the liver and helping insulin to work more effectively.
- Both of these groups of medicines are 'oral anti-diabetics'.

What Vipdomet is used for

Vipdomet is used to lower blood sugar levels in adults with type 2 diabetes. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus or NIDDM.

Vipdomet is taken when your blood sugar cannot be adequately controlled by diet, exercise and other anti-diabetic medicines such as metformin alone, insulin alone, or metformin and pioglitazone taken together.

If you are already taking both alogliptin and metformin as single tablets, Vipdomet can replace them in one tablet.

It is important that you continue to follow the advice on diet and exercise that your nurse or doctor has given you.

2. What you need to know before you take Vipdomet

Do not take Vipdomet

- If you are allergic to alogliptin, metformin or any of the other ingredients of this medicine (listed in section 6).
- If you have had a serious allergic reaction to any other similar medicines that you take to control your blood sugar. Symptoms of a serious allergic reaction may include: rash, raised red patches on your skin (hives), swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. Additional symptoms may include general itching and feeling of heat especially affecting the scalp, mouth, throat, palms of hands and soles of feet (Stevens-Johnson syndrome).
- If you have severely reduced kidney function.
- If you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactate 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 seriously dehydrated (have lost a lot of water from your body).
- If you recently had a heart attack or have severe circulatory problems including shock.
- If you have severe breathing difficulties.
- If you have liver disease.
- If you drink alcohol excessively (either every day or in large quantities only from time to time).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Vipdomet:

- If you have type 1 diabetes (your body does not produce insulin).
- If you are taking Vipdomet with insulin or a thiazolidinedione. Your doctor may want to reduce your dose of insulin or a thiazolidinedione when you take it together with Vipdomet in order to avoid too low blood sugar (hypoglycaemia).
- If you are taking another medicine for diabetes that contains a 'sulphonylurea', you should not start taking Vipdomet.
- If you have or have had a disease of the pancreas.
- In case of symptoms suggestive of liver injury during Vipdomet therapy.

Risk of lactic acidosis

Vipdomet 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 Vipdomet 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 Vipdomet 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. Lactic acidosis is a medical emergency and must be treated in a hospital. If lactic acidosis is suspected, seek medical attention from a doctor or a hospital.

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
- If you need to have major surgery you must stop taking Vipdomet during and for some time before and after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Vipdomet. During treatment with Vipdomet, 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

Vipdomet is not recommended for children and adolescents under 18 years due to the lack of data in these patients.

Other medicines and Vipdomet

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

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 dosage of Vipdomet. It is especially important to mention the following:

- Hydrocortisone and prednisolone (corticosteroids), used to treat diseases that involve inflammation like asthma and arthritis
- Cimetidine, used to treat stomach problems
- Bronchodilators (beta-2 agonists), used to treat asthma
- 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 used for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- Medicines containing alcohol.

Vipdomet with alcohol

Avoid excessive alcohol intake while taking Vipdomet 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 use Vipdomet if you are pregnant.

Vipdomet is not recommended during breast-feeding since metformin passes into breast milk.

Driving and using machines

Alogliptin/metformin hydrochloride is not known to affect your ability to drive and use machines. Taking alogliptin/metformin hydrochloride in combination with medicines called pioglitazone or insulin can cause too low blood sugar levels (hypoglycaemia), which may affect your ability to drive and use machines.

3. How to take Vipdomet

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or

pharmacist if you are not sure.

Your doctor will tell you exactly how much Vipdomet you need to take. The amount of Vipdomet will vary depending on your condition and the doses you currently take of metformin alone, metformin in combination with pioglitazone, insulin and/or individual tablets of alogliptin and metformin.

The recommended dose is one tablet twice a day. If you have reduced kidney function, your doctor may prescribe a lower dose, which may need to be given as separate tablets of alogliptin and metformin.

Swallow your tablet(s) whole with water. You should take this medicine with food to reduce your chance of an upset stomach.

If you take more Vipdomet than you should

If you take more tablets than you should, or if someone else or a child takes your medicine, contact or go to your nearest emergency centre straight away. Take this leaflet or some tablets with you so that your doctor knows exactly what you have taken.

If you forget to take Vipdomet

If you forget to take a dose, take it as soon as you remember it. Do not take a double dose to make up for a forgotten dose.

If you stop taking Vipdomet

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

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 Vipdomet and contact a doctor or the nearest hospital immediately if you notice any of the symptoms of the following serious side effects:

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

- Lactic acidosis (a build-up of lactic acid in the blood) is a very serious side effect that may lead to coma. For symptoms see section "Warnings and precautions".

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

- An allergic reaction. The symptoms may include: a rash, hives, swallowing or breathing problems, swelling of your lips, face, throat or tongue and feeling faint.
- A severe allergic reaction: skin lesions or spots on your skin that can progress to a sore surrounded by pale or red rings, blistering and/or peeling of the skin possibly with symptoms such as itching, fever, overall ill feeling, achy joints, vision problems, burning, painfull or itchy eyes and mouth sores (Stevens-Johnson syndrome and Erythema multiforme).
- 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).

You should also discuss with your doctor if you experience the following side effects:

Very common (may affect more than 1 in 10 people):

- Stomach ache
- Diarrhoea
- Loss of appetite
- Feeling sick
- Being sick.

Common (may affect up to 1 in 10 people):

- Symptoms of low blood sugar (hypoglycaemia) may occur when alogliptin/metformin hydrochloride is taken in combination with insulin or sulphonylureas (e.g. gliclazide, tolbutamide, glibenclamide). Symptoms may include: trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or feeling confused. Your blood sugar could fall below the normal level, but it can be increased again by taking sugar. It is recommended that you carry some sugar lumps, sweets, biscuits or sugary fruit juice
- Cold symptoms such as sore throat, stuffy or blocked nose, feeling tired, fever, chills, dry cough
- Rash
- Itchy skin with or without hives
- Headache
- Indigestion, heartburn
- Vomiting and/or diarrhoea
- Metallic taste.

Very rare:

- Decreased vitamin B12 levels or anaemia; symptoms include tiredness, lethargy, feeling faint, becoming breathless
- Liver problems (hepatitis or liver function test abnormalities)
- Erythema (redness of skin).
- Not known:
- Liver problems such as nausea or vomiting, stomach pain, unusual or unexplained tiredness, loss of appetite, dark urine or yellowing of your skin or the whites of your eyes.

5. How to store Vipdomet

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

Do not store above 30°C.

Store in the original package.

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

Do not use this medicine if you notice visible signs of deterioration.

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 Vipdomet contains

The active substances are alogliptin benzoate and metformin hydrochloride.

Each Vipdomet 12.5 mg/500 mg Film-coated Tablets contains 17 mg alogliptin benzoate equivalent to 12.5 mg alogliptin and 500 mg metformin hydrochloride.

Each Vipdomet 12.5 mg/1000 mg Film-coated Tablets contains 17 mg alogliptin benzoate equivalent to 12.5 mg alogliptin and 1000 mg metformin hydrochloride.

The other ingredients are mannitol, microcrystalline cellulose, povidone, croscopolone, magnesium stearate, hypromellose 2910, talc, titanium dioxide and ferric oxide yellow.

What Vipdomet looks like and contents of the pack

Vipdomet 12.5 mg/500 mg Film-coated Tablets are pale yellow oblong biconvex film-coated tablets with "12.5/500" debossed on one side and "322M" debossed on the other side in aluminum/aluminum blisters.

Vipdomet 12.5 mg/1000 mg Film-coated Tablets are pale yellow oblong biconvex film-coated tablets with "12.5/1000" debossed on one side and "322M" debossed on the other side in aluminum/aluminum blisters.

Package size: 56 film-coated tablets.

Bulk Manufacturer, Marketing Authorization Holder and Batch Releaser

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Takeda Pharmaceuticals International AG, Switzerland

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder.

This leaflet was last revised in 09/2018; version number JO3.0.

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 (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

• Jordan

• Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance department.

e-mail: jpc@fdaj.jo

Website: www.fdaj.jo

Council of Arab Health Ministers, Union of Arab Pharmacists

THIS IS A MEDICAMENT

- 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 the experts in medicines, their 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.