Package leaflet: Information for the patient

Vipidia 25 mg film-coated tablets
alogliptin

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. See section 4.

What is in this leaflet

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

1. What Vipidia is and what it is used for

Vipidia contains the active substance alogliptin which belongs to a group of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) which are "oral anti-diabetics". It 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.

Vipidia works to increase the levels of insulin in the body after a meal and decrease the amount of sugar in the body. It must be taken together with other anti-diabetic medicines, which your doctor will have prescribed for you, such as sulphonylureas (e.g. glipizide, tolbutamide, glibenclamide), metformin and/or thiazolidinediones (e.g. pioglitazone) and metformin and/or insulin.

Vipidia is taken when your blood sugar cannot be adequately controlled by diet, exercise and one or more of these other oral anti-diabetic medicines. It is important that you continue to take your other anti-diabetic medicine, and 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 Vipidia

Do not take Vipidia:
- if you are allergic to alogliptin 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).

Warnings and precautions
Talk to your doctor or pharmacist before taking Vipidia:
- if you have type 1 diabetes (your body does not produce insulin)

- if you have diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to breakdown glucose because there is not enough insulin). Symptoms include excessive thirst, frequent urination, loss of appetite, nausea or vomiting and rapid weight loss
- if you are taking an anti-diabetic medicine known as sulphonylurea (e.g. glipizide, tolbutamide, glibenclamide) or insulin. Your doctor may want to reduce your dose of sulphonylurea or insulin when you take any of them together with Vipidia in order to avoid too low blood sugar (hypoglycaemia)
- if you have kidney disease, you can still take this medicine but your doctor may reduce the dose
- if you have liver disease
- if you suffer from heart failure
- if you are taking insulin or an anti-diabetic medicine, your doctor may want to reduce your dose of the other anti-diabetic medicine or insulin when you take either of them together with Vipidia in order to avoid low blood sugar
- if you have or have had a disease of the pancreas

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

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

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.

There is no experience of using Vipidia in pregnant women or during breast-feeding. Vipidia should not be used during pregnancy or breast-feeding. Your doctor will help you to decide whether to continue breast-feeding or to continue using Vipidia.

Driving and using machines
Vipidia is not known to affect your ability to drive and use machines. Taking Vipidia in combination with other anti-diabetic medicines called sulphonylureas, insulin or combination therapy with thiazolidinedione plus metformin can cause too low blood sugar levels (hypoglycaemia), which may affect your ability to drive and use machines.

3. How to take Vipidia

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 prescribe Vipidia together with one or more other medicines to control your blood sugar levels. Your doctor will tell you if you need to change the amount of other medicines you take.

The recommended dose of Vipidia is 25 mg once a day.

Patients with kidney disease
If you have kidney disease this medicine is not recommeded because you would require a dosage strength that is not available. The alogliptin tablets should not be split.

Patients with liver disease
If you have mildly or moderately reduced liver function, the recommended dose of Vipidia is 25 mg once a day. This medicine is not recommended for patients with severely reduced liver function due to the lack of data in these patients.

Swallow your tablet(s) whole with water. You can take this medicine with or without food.

If you take more Vipidia 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 Vipidia
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 Vipidia
Do not stop taking Vipidia without consulting your doctor first. Your blood sugar levels may increase when you stop taking Vipidia.

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 Vipidia 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):
- **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, painful 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:

Common (may affect up to 1 in 10 people):
- **Symptoms of low blood sugar** (hypoglycaemia) may occur when Vipidia is taken in combination with insulin or sulphonylureas (e.g. glipizide, 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 can be increased again by taking sugar. It is recommended that you carry some sugar lumps, sweets, biscuits or sugary fruit juice.
- Cold like symptoms such as sore throat, stuffy or blocked nose,
- Rash
- Itchy skin
- Headache
- Stomach ache
- Diarrhoea
- Indigestion, heartburn

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.

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.

5. How to store Vipidia

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

Store at temperature not exceeding 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 Vipidia contains
- The **active substance** is alogliptin.

Each 25 mg tablet contains alogliptin benzoate equivalent to 25 mg alogliptin,
- The **other ingredients** are: mannitol, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171), red iron oxide (E172), macrogol 8000, shellac and black iron oxide (E172).

What Vipidia looks like and contents of the pack
- Vipidia 25 mg film-coated tablets (tablets) are light red, oval (approximately 9.1 mm long by 5.1 mm wide), biconvex, film-coated tablets, with “TAK” and “ALG-25” printed in grey ink on one side.
-

Vipidia is available in blister packs containing 28, tablets.

Marketing Authorisation Holder
Takeda Pharmaceuticals U.S.A Inc
One Takeda Parkway, Deerfield
IL 60015, USA

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