

VIDASTEAD-M Film-Coated Tablets

Vildagliptin and Metformin fixed combination (50mg/850mg, 50mg/1000mg)

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What VIDASTEAD-M is used for

VIDASTEAD-M is available as tablets. Each VIDASTEAD-M tablet contains two active substances: vildagliptin and metformin hydrochloride. Both substances belong to a group of medicines called 'oral antidiabetics'.

Two dosage strengths are available (vildagliptin/metformin hydrochloride) 50mg/850mg and 50mg/1000mg.

VIDASTEAD-M is a medicine used to treat type 2 diabetes. It helps to control the level of sugar in the blood. It is prescribed as an adjunct to diet and exercise to improve control over body sugar levels

- as a first diabetes treatment in patients whose diabetes is not adequately controlled by diet and exercise alone
- in patients who have already received treatment with vildagliptin and metformin hydrochloride together as separate tablets
- or whose diabetes is not adequately controlled with metformin hydrochloride or vildagliptin alone, in combination with other medicinal products for the treatment of diabetes, including insulin when these do not provide adequate glycaemic control

How VIDASTEAD-M works

VIDASTEAD-M works by making the pancreas produce more insulin and less glucagon (effect of vildagliptin) and also by helping the body to make better use of the insulin it produces (effect of metformin hydrochloride).

VIDASTEAD-M helps to control the blood sugar level. It is important that you continue to follow the diet and/or exercise recommended to you while you are on treatment with VIDASTEAD-M.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use VIDASTEAD-M

Follow all of the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

- When you must not use it

- If you are allergic (hypersensitive) to vildagliptin, metformin hydrochloride or to any other ingredients of VIDASTEAD-M. If you think you may be allergic, ask your doctor for advice
- If you have severely reduced kidney function (this will be decided by your doctor)
- If you recently had a heart attack, have heart failure, or if you have serious problems with your blood circulation, including shock, or breathing difficulties
- If you have lactic acidosis [too much lactic acid in the blood (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 of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe)

Pregnant women

Tell your doctor if you are pregnant, if you think you might be pregnant, or if you are planning to become pregnant. Your doctor will discuss with you the potential risk of taking VIDASTEAD-M during pregnancy. Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

Breast-feeding mothers

Do not breast-feed during treatment with VIDASTEAD-M. Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

- Before you start to use it

Risk of lactic acidosis

VIDASTEAD-M 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, 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 VIDASTEAD-M 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 VIDASTEAD-M 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
- stomachache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing

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

During treatment with VIDASTEAD-M, 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.

Take special care with VIDASTEAD-M

VIDASTEAD-M is not a substitute for insulin. You should therefore neither receive VIDASTEAD-M for

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the treatment of type 1 diabetes (i.e. your body does not produce insulin at all) nor for the treatment of a condition called diabetic ketoacidosis.

Monitoring your VIDASTEAD-M treatment

Your doctor should ensure that the following tests are performed:

- Blood and urine tested for sugar regularly
- Check your kidney functions:
 - at start of treatment
 - at least once a year while you are on treatment
 - more frequently if you are elderly or if your kidney function is worsening
- Check your liver functions:
 - at start of treatment
 - every 3 months during the first year of treatment and regularly thereafter
 - if your doctor has told you to stop your treatment with VIDASTEAD-M because of liver problems, you should never start taking VIDASTEAD-M again
- General blood test at least once a year
- A check of vitamin B12 levels may also be carried out at least every two to three years

VIDASTEAD-M and older people (65 years of age or above)

Your doctor will check how well your kidneys work. You may need more frequent checks if you have kidney problems.

VIDASTEAD-M and children and adolescent (below 18 years)

There is no information available on the use of VIDASTEAD-M in children and adolescents (aged below 18 years). The use of VIDASTEAD-M in these patients is therefore not recommended.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This is particularly important with the following medicines:

- certain medicines used to treat inflammation (e.g. corticosteroids)
- certain medicines used to treat high blood pressure (e.g. a nifedipine, enalapril, losartan, diuretics)
- certain medicines used to reduce pain (e.g. diclofenac)
- certain medicines used to treat angina (e.g. ranolazine)
- certain medicines used to treat HIV infection (e.g. dolutegravir)
- certain medicines used to treat a specific type of thyroid cancer (medullary thyroid cancer) (e.g. vandetanib)
- certain medicine used to treat stomach disorders (e.g. cimetidine)
- certain medicines used to treat some psychiatric disorders (e.g. phenothiazine)
- certain medicines used to treat thyroid disorders
- oral contraceptives, certain medicines used to reduce symptoms in women experiencing menopause or osteoporosis (e.g. estrogen)

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

How to use VIDASTEAD-M

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not exceed the recommended dose prescribed by your doctor.

- How much to use

Your doctor will tell you exactly how many tablets of VIDASTEAD-M to take. The usual dose of VIDASTEAD-M is one or two tablets a day. Do not exceed two tablets a day. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

If you have reduced kidney function, your doctor may prescribe a lower dose. Also if you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Your doctor will prescribe VIDASTEAD-M either alone or in combination with other antidiabetics, depending on your condition.

- When to use it

VIDASTEAD-M should be taken in the morning and/or in the evening. It is recommended that you take your tablets either with or just after taking the food.

This will reduce the chance of getting an upset stomach. The tablets should be swallowed whole with a glass of water.

- How long to use it

Continue taking VIDASTEAD-M every day for as long as your doctor tells you. You may have to stay on this treatment for a long period of time. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. If your doctor has told you to stop treatment with VIDASTEAD-M because of liver problems, you should never start taking VIDASTEAD-M again. If you have questions about how long to take VIDASTEAD-M, talk to your doctor or your pharmacist.

- If you forget to use it

It is recommended to take your medicine at the same time each day. If you forget to take VIDASTEAD-M, take it as soon as you remember. Then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

- If you use too much (overdose)

If you have accidentally taken too many VIDASTEAD-M tablets, or if someone else has taken your medicine, talk to a doctor straight away. You may require medical attention. Show the doctor the pack if possible.

While you are using VIDASTEAD-M

- Things you must do

- If you experience one or more of the following symptoms: feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, dizziness, irregular heartbeat, or rapid breathing. Very rarely, patients taking metformin (one of the active substances of VIDASTEAD-M)

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have experienced a condition called lactic acidosis (too much lactic acid in the blood). This is more likely to occur in patients whose kidneys are not working properly

- If you experience nausea, sweating, weakness, dizziness, trembling, headache (signs of low blood sugar), which could be due to lack of food, too strenuous exercise without sufficient food intake, or excessive alcohol intake (usually not with VIDASTEAD-M alone)
- If your diabetes worsens suddenly, or if you have abnormal blood sugar tests or feel ill, contact your doctor

If any of these apply to you, tell your doctor immediately.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not drink alcohol excessively or take medicines that contain alcohol while taking VIDASTEAD-M.

Do not give VIDASTEAD-M to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- If you are going to have an operation under general anaesthetic, you must stop taking VIDASTEAD-M for a couple of days before and after the procedure. Your doctor will decide when you must stop and when to restart your treatment with VIDASTEAD-M
- If you are going to have a contrast x-ray (a specific type of x-ray involving an injectable dye), you must stop taking VIDASTEAD-M before or at the time of and for a few days after the procedure
- If you are taking any medicines to treat angina or HIV infection or thyroid cancer (medullary thyroid cancer)
- If you drink alcohol excessively, either every day or only from time to time
- If you have liver or kidney problems

If any of these apply to you, tell your doctor or pharmacist or healthcare provider before taking VIDASTEAD-M.

Side effects

Like all medicines, VIDASTEAD-M can cause side effects, although not everybody gets them.

Some side effects could be serious

STOP taking VIDASTEAD-M and seek medical help immediately if you experience any of the following:

- Feeling cold and uncomfortable, muscle pain, drowsiness, severe nausea or vomiting, abdominal pain, unexplained weight loss, dizziness, irregular heartbeat, or rapid breathing (symptoms of lactic acidosis). If this happens you must stop taking VIDASTEAD-M and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma
- Swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction called 'angioedema')
- Yellow skin and/or eyes, nausea, loss of appetite, dark urine (possible symptoms of liver problems)
- Severe upper stomach pain (possible symptoms of inflamed pancreas)
- Headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, feeling jittery (possible symptoms of low level of sugar in the blood known as hypoglycaemia)

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

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

- Nausea, vomiting, diarrhoea, abdominal pain, loss of appetite

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

- Dizziness, headache, trembling, metallic taste in the mouth
- 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

Uncommon (may affect up to 1 in every 100 people)

- Constipation, swollen hands, ankles or feet (oedema)

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

- Skin reddening, itching, decrease in the level of vitamin B12 in the blood, abnormal liver function test results

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, please inform your doctor, pharmacist or healthcare provider.

Common side effects (likely to occur in fewer than 1 in 10 patients)

Uncommon side effects (likely to occur in fewer than 1 in 100 patients)

Some patients have had the following side effects while taking VIDASTEAD-M and insulin:

- Common: Headache, chills, nausea, heartburn, decreased blood sugar
- Uncommon: Diarrhoea, flatulence

Some patients have had the following side effects while taking VIDASTEAD-M and a sulfonylurea:

- Common: Dizziness, trembling, weakness, excessive sweating

Some patients have experienced other side effects while taking VIDASTEAD-M alone or in combination with another antidiabetic medication:

- Itchy rash, areas of peeling skin or blisters, joint pain

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of VIDASTEAD-M

Storage

Store below 30°C.

Store in the original package to protect from light and moisture.

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

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help protect the environment.

Product Description

- *What it looks like*

VIDASTEAD-M 50mg/850mg:

Yellow coloured, oval shaped, biconvex, film-coated tablet, debossed with 'GG2' on one side and plain on other side.

VIDASTEAD-M 50mg/1000mg:

Dark yellow coloured, oval shaped, biconvex, film-coated tablet, debossed with 'GG3' on one side and plain on other side.

- *Ingredients*

- *Active ingredient:*

Vildagliptin and Metformin hydrochloride

- *Inactive ingredients:*

Microcrystalline cellulose, Magnesium stearate, Low substituted HPC, Hypromellose, Hydroxypropylcellulose, Talc, Macrogol, Iron oxide yellow, Titanium dioxide

MAL number

MAL24096060AZ (50mg/850mg)

MAL24096061AZ (50mg/1000mg)

Manufacturer

Intas Pharmaceuticals Limited
Plot No. 457, 458 Matoda, Plot No. 191/218P, Chacharwadi Sarkhej Bavla Highway, Ahmedabad, 382 210, India

Product Registration Holder

Lotus Healthcare Malaysia Sdn. Bhd.
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