

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **DAGFOTIN 50/850 – 590343; DAGFOTIN 50/1000 - 590344**

Dosage form and strength: **Each film coated tablet contains vildagliptin and metformin Hydrochloride 50 mg/ 850 mg and 50 mg/ 1000 mg**

PATIENT INFORMATION LEAFLET FOR

DAGFOTIN 50/850 (film-coated tablet)

DAGFOTIN 50/1000 (film-coated tablet)

Vildagliptin and metformin Hydrochloride

SCHEDULING STATUS

S3

DAGFOTIN 50/850 (film-coated tablet)

DAGFOTIN 50/1000 (film-coated tablet)

DAGFOTIN contains vildagliptin and metformin hydrochloride.

DAGFOTIN is sugar free.

Read all of this leaflet carefully before you start taking DAGFOTIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DAGFOTIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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1. What DAGFOTIN is and what it is used for

DAGFOTIN contains two active substances, vildagliptin and metformin hydrochloride, and it is used in the treatment of type 2 diabetes.

DAGFOTIN together with diet and exercise helps to control the level of sugar in the blood. Your doctor has prescribed DAGFOTIN for you if your blood sugar level has been controlled when you take vildagliptin and metformin hydrochloride as separate tablets and at the same dosages.

DAGFOTIN can be used alone or with other medicines for diabetes such as insulin, sulphonylureas.

2. What you need to know before you take DAGFOTIN

Do not take DAGFOTIN:

- if you are allergic (hypersensitive) to vildagliptin, metformin hydrochloride or any of the other ingredients of DAGFOTIN (see section 6).
- if you have severely reduced kidney function (this will be decided by your doctor).
- if you have a problem with your liver.
- if you have recently had a heart attack, have a heart failure, or if you have serious problems with your blood circulation, including shock or breathing difficulties.
- if you have or have had serious complications of your diabetes, such as diabetic ketoacidosis (a complication of diabetes involving rapid weight loss, nausea or vomiting) or diabetic coma.

Warnings and precautions

Take special care with DAGFOTIN:

DAGFOTIN is not a substitute for insulin in patients requiring insulin. DAGFOTIN should not be used in patients with type 1 diabetes (i.e., your body does not produce insulin at all) nor for the treatment of a condition called diabetic ketoacidosis.

Tell your doctor or health care provider:

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- 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. Patients taking metformin (one of the active substances of DAGFOTIN) 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 level of sugar (glucose) in the blood) which could be due to lack of food, too strenuous exercise without sufficient food intake, excessive alcohol intake (usually not with DAGFOTIN alone).
- If you are going to have a contrast X-ray (a specific type of X-ray involving an injectable dye). You will need to temporarily stop taking DAGFOTIN before or at the time of and for a few days after the procedure.

If you experience some of these symptoms, stop taking DAGFOTIN and consult a doctor immediately:

- If you are going to have an operation under general anaesthetic, you may need to stop taking DAGFOTIN 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 DAGFOTIN.
- If you drink alcohol excessively, either every day or only from time to time.
- If you have a liver disease.
- If your diabetes control worsens suddenly or if you have abnormal blood sugar tests or feel ill, contact your doctor.
- If you experience joint pain, sometimes severe.

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

Monitoring your DAGFOTIN treatment:

Your doctor should ensure the following:

- your blood and urine should be tested for sugar regularly.

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- your kidney function should be checked at start of treatment and at least once a year whilst you are on treatment, especially if you are elderly or if your kidney function starts to decrease.
- your liver function should be checked at start of treatment and every 3 months during the first year of treatment, and regularly thereafter.
- if your doctor told you to stop your treatment with DAGFOTIN because of liver problems, you should never start taking DAGFOTIN again.
- a general blood test at least once a year.
- a check of vitamin B12 levels at least every two to three years.

DAGFOTIN and older people:

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

Children and adolescents

DAGFOTIN should not be used in children below 18 years of age as safety and efficacy have not been established.

Other medicines and DAGFOTIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

DAGFOTIN may affect how well other medicines work and some medicines can also affect how well DAGFOTIN works.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including the following medicines:

- certain medicines used to treat infections (e.g., vancomycin, trimethoprim)
- certain medicines used to treat inflammation (e.g., corticosteroids)
- certain medicines used to treat high blood pressure (e.g., amiloride, triamterene, nifedipine, enalapril, losartan, diuretics)

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- certain medicines used to treat irregular heartbeat (e.g., digoxin, quinidine)
- certain medicines used to reduce pain (e.g., morphine, diclofenac)
- certain medicines used to treat stomach disorders (e.g., cimetidine, ranitidine)
- certain medicines used to treat some psychiatric disorders (e.g., phenothiazine)
- certain medicines used to treat thyroid disorders (e.g., levothyroxine, liothyronine, carbimazole, methimazole, propylthiouracil (PTU))
- oral contraceptives, certain medicines used to reduce symptoms in women experiencing menopause or osteoporosis (e.g., oestrogen)

Do not drink alcohol excessively or take medicines that contain alcohol whilst taking DAGFOTIN tablets.

DAGFOTIN with food

It is recommended that you take your tablets either with or just after food. This will reduce the chance of you getting an upset stomach.

Pregnancy, breastfeeding and fertility

You should not take DAGFOTIN if you are pregnant or if you are breast-feeding as safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DAGFOTIN.

Driving and using machines

DAGFOTIN may cause dizziness. If you experience dizziness, you should avoid driving vehicles or using machines.

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3. How to use DAGFOTIN

Do not share medicines prescribed for you with any other person.

Always use DAGFOTIN 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 many tablets of DAGFOTIN to take. 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. If you are taking an anti-diabetic medicine known as a sulphonylurea your doctor may prescribe a lower dose.

Do not take more DAGFOTIN than your doctor has prescribed.

If you take more DAGFOTIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DAGFOTIN

If you forget to take a dose of DAGFOTIN, 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.

4. Possible side effects

DAGFOTIN can have side effects.

Not all side effects reported for DAGFOTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DAGFOTIN, please consult your health care provider for advice.

If any of the following happens, stop taking DAGFOTIN and tell your doctor immediately or go to the

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casualty department at your nearest hospital:

- swelling of face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives (symptoms of severe allergic reaction).

These are all very serious side effects. If you have them, you may have had a serious reaction to DAGFOTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice 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),
- yellow skin and eyes, nausea, loss of appetite, dark urine (symptoms of liver problems),
- severe upper stomach pain (possible sign 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').

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- nausea,
- vomiting,
- abdominal pain,
- loss of appetite,
- dizziness,
- headache,
- involuntary trembling,

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- metallic taste in the mouth,
- chills,
- heartburn,
- decreased blood glucose,
- excessive sweating,

Less frequent side effects

- diarrhoea,
- constipation,
- swollen hands, ankle or feet (oedema),
- skin reddening, itching, areas of peeling skin or blisters,
- decrease in the level of vitamin B12 in the blood (anaemia),
- abnormal liver function test results.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA using the Med Safety App (MedSafety X SAHPRA) or the eReporting platform (who-umc.org) available on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of DAGFOTIN.

You may also report side effects directly to the Holder of Certificate of Registration at:

pvg.cdma@heterogroups.com

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5. How to store DAGFOTIN

Store all medicines out of reach of children.

Store at or below 25°C.

6. Contents of the pack and other information

What DAGFOTIN contains

The active substances are vildagliptin and metformin hydrochloride.

The other ingredients are:

Tablet core

Microcrystalline cellulose; Hydroxypropyl cellulose; Magnesium stearate

Film-coating

Opadry II white/ pink; Polyvinyl alcohol-part hydrolysed; Titanium dioxide; Macrogol/PEG; Talc; Iron oxide red.

What DAGFOTIN looks like and contents of the pack

DAGFOTIN 50/850:

Light pink to pink oval shaped, bevelled edge biconvex film coated tablets, debossed with "V16" on one side and "H" on the other side.

DAGFOTIN 50/1000:

White to off white oval shaped, bevelled edge biconvex film coated tablets, debossed with "V17" on one side and "H" on the other side.

10's Blister pack Alu-Alu

10 tablets packed in aluminium foil blister, form-pack film with desiccant.

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50's count HDPE container

High density polyethylene container 120 cc with 38 mm child resistant cap with pulp liner, with 2g of silica gel sachet.

50's count HDPE container with molecular sieve canister

High density polyethylene container 120 cc with 38 mm child resistant cap with pulp liner, with 2g of molecular sieve canister.

100's count HDPE container

High density polyethylene container 250 cc with 53 mm child resistant cap with pulp liner, with 2g of silica gel sachet.

100's count HDPE container with molecular sieve canister

High density polyethylene container 250 cc with 53 mm child resistant cap with pulp liner, with 2g of molecular sieve canister.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

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This leaflet was last revised in

27 January 2026

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Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd

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