

ENVLO[®] 0.3mg film-coated tablets

ENAVOGLIFLOZIN (0.3mg)

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What ENVLO is used for

ENVLO is used in adults with type 2 diabetes mellitus as adjunct to diet and exercise to improve glycemic control.

How ENVLO works

ENVLO contains the active substance Enavogliflozin. It belongs to a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors. They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

By inhibiting SGLT-2 and inducing excretion of glucose, Enavogliflozin drops blood glucose level.

Before you use ENVLO

- When you must not use it

Do not take this medicine if:

- You are allergic to Enavogliflozin or any other ingredients of this medicine (listed in Product Description)
- You have type 1 diabetes or a serious condition called diabetic ketoacidosis (a build-up of acid in the blood).
- You have severe kidney problems, such as an eGFR (a measure of kidney function) less than 30 mL/min/1.73m², end-stage kidney disease, or if you are on dialysis
- You have moderate to severe liver problems

- Before you start to use it

Check with your doctor or pharmacist before taking ENVLO if you:

- Have kidney problems
ENVLO works through your kidneys. If your kidneys are not working well, this medicine may not work properly or could be harmful.
Your doctor will check your kidney function before and during treatment.
If your doctor has told you that your eGFR is below 60mL/min/1.73 m², you may need extra monitoring.
- Have heart problems or heart failure
ENVLO has not been well studied in people with serious heart failure. Talk to your doctor if you have been diagnosed with heart problems
- Are at risk of low blood sugar (hypoglycemia)
You may be at risk if you:
Have a hormone problem (such as adrenal or pituitary issues)
Skip meals, eat irregularly, or have poor nutrition
Exercise a lot or very hard
Drink too much alcohol

If you feel shaky, dizzy, tired, hungry, or sweaty — tell your doctor.

- Are at risk of dehydration
ENVLO may cause you to urinate more, which can lead to dehydration.

Be extra careful if you:

- Are elderly
- Take water pills (diuretics)
- Have very high blood sugar or have been sick with vomiting/diarrhea

Drink enough fluids and tell your doctor if you feel dizzy or weak

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a

pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- Lithium because SGLT2 inhibitors can lower the amount of lithium in your blood

How to use ENVLO

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

- The recommended dose is one ENVLO 0.3 mg tablet each day
- Swallow the tablet whole with water
- You can take your tablet with or without food.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using ENVLO

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using ENVLO.	sensation when passing water (urinating), pain in your back or side)	Pale-orange, biconvex, triangular, film-coated tablets with “D” on one side and “I3” on the other side.
Tell your doctor immediately if you become pregnant while using this medication.	• passing urine more often than usual • headache • dizziness • low blood sugar levels (hypoglycaemia) • back pain	- <u>Ingredients</u> - Active ingredient(s) • Enavogliflozin 0.3 mg in each ENVLO 0.3 mg film-coated tablet
Take ENVLO only with a doctor’s prescription.		- Excipients
It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.	Uncommon (may affect up to 1 in 100 people using this medicine)	Table core:
- <u>Things you must not do</u> Do not stop using the medicine unless advised by your doctor.	• kidney infection (pyelonephritis) • passing urine at night (nocturia) • dizziness when standing up (postural hypotension) • skin infection (folliculitis) • cough • constipation • changes in liver enzymes	• Microcrystalline cellulose • Colloidal silicon dioxide • Hydroxypropylcellulose • Magnesium stearate • Croscarmellose sodium
Do not use any new medicines without consulting your doctor or pharmacist.		Film-coating:
Do not give ENVLO to anyone else, even if they have the same symptoms or condition as you.	Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.	• Opadry Orange 03B630036: Hypromellose 2910, Titanium dioxide, polyethylene glycol 400, Iron oxide yellow, Iron oxide red, alcohol, purified water
- <u>Things to be careful of</u> Driving and using machines		- <u>MAL number(s):</u>
This medicine may affect your ability to drive or use machines. Taking this medicine with other medicines called sulphonylureas or with insulin can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines. Do not drive or use machines and contact your doctor immediately.	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)].	MAL*****
Side effects Like all medicines, ENVLO can cause side effects, although not everybody gets them.	Storage and Disposal of ENVLO	Manufacturer
Possible side effects are: Common (may affect up to 1 in 100 to 1 in 10 people using this medicine) • genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour) • urinary tract infection (signs may include fever and/or chills, burning	- <u>Storage</u> Keep out of the reach and sight of children. Store below 30°C in original packaging. - <u>Disposal</u> 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 to protect the environment. Product Description - <u>What it looks like</u>	DAEWOONG PHARMACEUTICAL CO., LTD., 1, Osongsaengmyeong 2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea Product Registration Holder TAEVAS LIFE SCIENCES SDN. BHD., Suite 163E, Level 16 Gurney Paragon Office Tower, Jalan Kelawei, 10250 Georgetown, Pulau Pinang, Malaysia. Date of revision 18/05/2026 Serial Number NPRA (R1) 26/003