

**Presentation:**  
Boxes with 30 tablets.

***If you take higher doses of ELANT than you should***

If you have taken too many ELANT tablets, or if someone else has taken your medication, consult your doctor immediately. You may need medical attention. If you are going to visit a doctor or go to the nearest hospital, take the medicine box with you. In the event of overdose, go to the nearest hospital or contact the Toxicology Centers:  
A. Posadas Hospital: (011) 4654-6648/4658-7777  
Ricardo Gutiérrez Pediatric Hospital: (011) 4962-6666/2247  
Optionally other Toxicological Centers

**"This medication has been prescribed only for your current medical problem.  
Do not recommend it to other people."  
"If any inconvenience with the product, the patient may fill in the  
form that is on the website of ANMAT  
<http://anmat.gov.ar/farmacovigilancia/Notificar.asp> or call  
ANMAT responds 0800-333-1234"**

Technical Director: Dr. Luis M. Radici – Pharmacist.  
MEDICAL SPECIALTY AUTHORIZED BY THE MINISTRY OF HEALTH.  
Certificate N° 58.170  
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Boyacá 237 – Ciudad Autónoma de Buenos Aires – Argentina.

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CASASCO

# ELANT®

## TENELIGLIPTIN



COATED TABLETS

### PATIENT INFORMATION - CONSULT YOUR DOCTOR -

Rx only - Argentine Industry

Read this patient information before taking ELANT and every time you repeat the recipe, as there may be new information. This information does not replace your conversation with your doctor about your illness or treatment.

**Formula**

Each coated tablet contains: TENELIGLIPTIN 20.00 mg (as teneligliptin hydrobromide 31 mg). Excipients: microcrystalline cellulose; mannitol; crospovidone; hydroxypropyl cellulose; croscarmellose sodium; talc; magnesium stearate. Coating: polyvinyl alcohol; titanium dioxide; polyethylene glycol 3000; talc; polyethylene glycol 6000.

**What is ELANT and what is it used for?**

ELANT contains teneligliptin as active ingredient, which belongs to a group of medicines called "oral antidiabetics". Oral antidiabetics are used to reduce high blood sugar (glucose) levels.  
ELANT is used to treat adult patients with type 2 diabetes when diabetes can not be controlled only by diet and exercise. Your doctor may prescribe ELANT alone or in combination with other antidiabetic medications you are already taking, if these are not effective enough to control diabetes.  
Type 2 diabetes is a metabolism disorder characterized by high levels of blood sugar (hyperglycemia) caused by insulin resistance or its relative lack.  
Insulin is a substance that helps reduce blood sugar levels, especially after meals.  
Glucagon is a substance that promotes production of sugar by liver and increases blood sugar levels. Both substances are produced in the pancreas.

**Before using ELANT**

**Do not take ELANT**

- If you are allergic to teneligliptin or any of the other ingredients of this medicine. If you think you might be allergic to teneligliptin or any other component of ELANT, do not take this medicine and consult your doctor.
- If you have type 1 diabetes (that is, your body does not produce insulin).
- If you have a situation called diabetic ketoacidosis (a serious complication of diabetes).
- If you have serious infections.
- Before or after surgical operations or serious trauma.
- During breastfeeding or lactation

**Take special care with ELANT**

- If you are taking an antidiabetic medicine known as a sulfonylurea (ex. glimepiride, glipizide). Your doctor may want to reduce your sulfonylurea dose when you take it together with ELANT to prevent blood glucose levels from falling too low [hypoglycemia].
- If you have problems with the functioning of the pituitary, thyroid, adrenal glands; weakening, malnutrition, irregular and / or insufficient feeding problems, you practice intense muscle exercise or consume alcohol excessively.

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- If you suffer from severe liver disease.
- If you suffer from a severe heart disorder (heart failure or arrhythmias).
- If you have had allergic reactions to any other medication you take to control the amount of blood sugar
- If you have a history of abdominal surgery or intestinal obstruction.
- If you have diabetic skin lesions, a frequent complication of this condition. It is advisable to follow the recommendations on skin and foot care indicated by your doctor

**Pregnancy**

If you are pregnant, think you may be pregnant or intend to get pregnant, tell your doctor or pharmacist before using this medicine.  
The use of ELANT should be avoided during pregnancy, unless the doctor considers it essential.

**Lactation**

The active substance of ELANT passes into breast milk and can cause problems in the infant. You should not take ELANT if you are breastfeeding or plan to breastfeed.

**How to use ELANT?**

**Adults**

A 20 mg tablet is usually given once a day. However, in cases of insufficient effect, your doctor may increase the dose to two tablets (40 mg) once a day, carefully observing the evolution.  
ELANT can be administered at any time of the day, with food or away from it.

**Use in children and adolescents**

The safety of teneligliptin in children under 18 years of age has not been determined.

**Use in the elderly**

It is not necessary to adjust the dose. However, because the physiological functions may be diminished in the elderly, it is recommended to take it with caution.

**Use in patients with kidney problems**

Your doctor should decide if you can take ELANT and the appropriate dose

**Use in patients with liver problems**

Your doctor should decide if you can take ELANT and the appropriate dose.

**Effects on the ability to drive vehicles**

ELANT has no influence on the ability to drive vehicles and use machines. However, when taking ELANT in combination with other medications called sulfonylureas and / or insulin can produce too low blood sugar levels in (hypoglycemia) that can affect your ability to drive and use machines without a sure point of support. Do not drive vehicles or operate dangerous machinery if you do not feel well or if you are dizzy taking ELANT.

**Simultaneous taking of other medicines**

Tell your doctor or pharmacist if you are using, have recently used or could have to use any other medication, even those without prescription and herbal medications.  
Your doctor may change your dose of ELANT if you are taking other medications such as:  
- Other diabetes medications, especially sulfonylureas, thiazolidinediones, biguanides, alpha glucosidase inhibitors, drugs that interact with GLP-1 and SGLT-2 receptors as they could increase hypoglycemia risk (low blood sugar)  
- Other medicines that favor hypoglycemia (beta-blockers, salicylates, antihypertensives,

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monoamine oxidase inhibitors).  
- Other medicines that can increase blood levels of teneligliptin (ketoconazole, itraconazole, clarithromycin, HIV drugs as protease inhibitors).  
- antiarrhythmic medications, as they can alter the electrocardiogram (QT prolongation)

**Appropriate use of ELANT**

**If you forgot to take ELANT**

If you forget to take a dose of this medicine, take it as soon as you remember.  
Then take the next dose at your usual time. If it is almost time for the next dose, skip the missed dose.  
Do not take a double dose to make up for forgotten doses.

**To consider while taking ELANT**

**Undesirable effects (adverse)**

Like all medications, this medication may have adverse effects, although not all people suffer them.

**Some symptoms require immediate medical attention**

You should stop taking ELANT and see your doctor immediately if you experience any of the following adverse effects:

- Hypoglycemia: symptoms of a drop in blood sugar such as tremor, sweating, anxiety, blurred vision, tickling lips, paleness, changes in mood or confusion
- Hypersensitivity: angioedema (rare: may affect up to 1 in 1,000 people): symptoms that include swollen face, tongue or throat, difficulty swallowing, difficulty breathing, sudden onset of rash or hives, which may be indicative of a reaction called "angioedema."
- Pancreatitis: inflammation of the pancreas (frequency not known): symptoms that include intense and persistent pain in the abdomen (stomach area), which can reach your back, as well as nausea and vomiting.
- Intestinal obstruction: high degree of constipation, abdominal distension, persistent abdominal pain
- Hepatic dysfunction: general malaise, loss of appetite, yellowing of the skin and sclera (white part of the eye)
- Interstitial pneumonia: cough, shortness of breath, fever
- Loss of skin of extremities and auricular pavilion

**Other adverse effects**

The following adverse reactions were reported with a frequency less than 1% without having confirmed the relationship with the drug in all cases:

- **Digestive:** constipation, abdominal distension, abdominal discomfort, nausea, abdominal pain, flatulence, inflammation of the mouth, duodenal ulcer, pancreas inflammation.
- **Hepatic:** elevation of liver enzymes (TGO, TGP and gamma GTP)
- **Of Kidney:** proteins in the urine (proteinuria); blood in urine not visible to the naked eye.
- **Of Skin:** eczema, rash, pruritus, allergic dermatitis.
- **Others:** decay, increased blood potassium.

If constipation occurs, the risk of intestinal obstruction may increase. If you have severe constipation, bloating, persistent abdominal pain or vomiting, stop taking the medication and consult the doctor

**How to store ELANT?**

- Store in a dry place at temperature below 30°C.
- Keep out of reach of children.

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