Package leaflet: Information for the patient

Gladexa 30 mg modified-release capsules, hard
Gladexa 60 mg modified-release capsules, hard

Dexlansoprazole

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 Gladexa is and what it is used for

Gladexa contains the active substance dexlansoprazole, which is a proton pump inhibitor (PPI).
PPIs reduce the amount of acid that your stomach makes.

Gladexa is used in adults for the following:
- Treatment of erosive reflux oesophagitis (inflammation with damage to the lining of the oesophagus (food pipe))
- Maintenance of healed erosive reflux oesophagitis and maintenance of relief of heartburn
- Short-term treatment of heartburn and acid regurgitation associated with symptomatic non-erosive gastro-oesophageal reflux disease (GORD). GORD is a condition where stomach acid leaks out of the stomach and comes up into the oesophagus (acid reflux).

By reducing the amount of stomach acid Gladexa can heal the damage of the oesophagus and relieve symptoms that can happen with the above conditions and stop them from coming back.

2. What you need to know before you take Gladexa

Do NOT take Gladexa if you are:
- allergic to dexlansoprazole or any of the other ingredients of this medicine (listed in section 6).
- taking a medicine containing the active substance atazanavir or nelfinavir (used in the treatment of HIV).

Warnings and precautions
Talk to your doctor before taking Gladexa if you:
- have liver problems. Your doctor may have to adjust your dosage.
- have stomach problems. Your doctor may perform an additional investigation called an endoscopy (where a very small camera is inserted down your oesophagus to look into your stomach), which can help to exclude more serious causes of your symptoms.
- take a proton pump inhibitor like Gladexa, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- take Gladexa on a **long-term basis** (longer than 1 year). Your doctor will probably ask to see you regularly so he can check how well you are doing. Tell your doctor if you notice any new symptoms or if any of your symptoms are getting worse.
- take other medicines such as digoxin (for the treatment of heart problems) or diuretics ('water tablets'). Your doctor will probably monitor the magnesium levels in your blood periodically.

Children and adolescents
Do not give this medicine to children or adolescents under 18 years.

Other medicines and Gladexa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because dexlansoprazole can affect the way some other medicines work. Also, some medicines can affect the way dexlansoprazole works.

Do NOT take Gladexa if you are taking a medicine containing the active substance atazanavir or nelfinavir (used in the treatment of HIV).

Check with your doctor before taking Gladexa if you are taking any of the following medicines:
- ketoconazole, itraconazole, rifampicin (to treat infections)
- erlotinib (to treat cancer)
- digoxin (to treat heart problems)
- tacrolimus (to prevent transplant rejection)
- fluvoxamine (to treat depression and other psychiatric diseases)
- warfarin (to prevent thrombosis)
- antacids (to treat heartburn or acid regurgitation)
- sucralfate (for healing ulcers)
- St John's wort (*Hypericum perforatum)* (to treat mild depression)
- methotrexate (to treat cancer)

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 for advice before taking this medicine.

Driving and using machines
Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking Gladexa. If you experience side effects like these you should take caution as your ability to react may be decreased.
You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines.
Descriptions of these effects can be found in other sections.
Read all the information in this leaflet for guidance.
Discuss with your doctor if you are unsure about anything.

Gladexa contains sucrose
Sucrose - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Gladexa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsules whole with a glass of water. You can take the capsules with or without food. If you have trouble swallowing Gladexa capsules whole, you can open the capsules and sprinkle the contents on a tablespoon of apple purée (such as apple sauce). Be sure to swallow the apple mixture right away. Do not chew the mixture. Do not store for later use.

The recommended dose is as follows:
- **Treatment of erosive reflux oesophagitis:** take 60 mg once daily for 4 weeks. Your doctor may prescribe an additional 4 weeks.
- **Maintenance of healed erosive reflux oesophagitis and maintenance of relief of heartburn in patients where prolonged acid suppression is needed:** take 30 mg once daily for up to 6 months.
- **Treatment of heartburn and acid regurgitation associated with symptomatic non-erosive gastro-oesophageal reflux disease (GORD):** take 30 mg once daily for up to 4 weeks.

Elderly and patients with liver problems: Your doctor may prescribe a lower dose.

Your doctor will advise you how long to take Gladexa.

If necessary your doctor may tell you to take a different dose.

If you take more Gladexa than you should
If you accidentally take multiple capsules (overdose), or if someone else takes multiple doses of your medicine at the same time, talk to a doctor immediately.
The following symptoms have been reported in patients who had taken large doses of dexlansoprazole:
- high blood pressure, hot flushes, bruises, throat pain and weight loss.

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THIS ARTWORK IS PROPERTY OF:
TAKEDA

PRODUCT NAME:
I-Gladexa
30 mg - 60 mg

PRODUCT CODE:
ZTAK040

SEPARATIONS:
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MEASURES (mm): **185x297**
DECA CODE (mm):
(X=1,5mm /I=0,5mm/spazi=1 mm)
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If you forget to take Gladexa
If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If this happens, skip the missed dose and carry on with your next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Gladexa
Do not stop treatment early because you feel better. Your condition may not have been fully resolved and may return if you do not finish your course of treatment. Talk to your doctor before stopping this treatment.

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.

In clinical studies side effects associated with Gladexa treatment were mostly mild or moderate.

If you get any of the following side effects, stop taking these capsules and tell your doctor immediately, or contact the casualty department at your nearest hospital:
- hypersensitivity or serious allergic reactions (frequency not known) such as rash, face swelling, throat tightness, difficulty breathing
- anaphylactic shock or serious, severe and sudden allergic reaction (frequency not known) with symptoms such as shortness of breath, confusion, pale colour, severe skin eruptions, throat tightness, weakness, gasping for air and unconsciousness

The most frequently reported side effects (common – may affect up to 1 in 10 people) were:
- diarrhoea, abdominal pain, headache, feeling sick (nausea), abdominal discomfort, gas (flatulence) and constipation.

Some patients experienced the following other side effects with Gladexa:

Uncommon (may affect up to 1 in 100 people):
- difficulty in sleeping
- depression
- dizziness
- altered taste
- high blood pressure
- hot flushes
- cough
- vomiting
- dry mouth
- liver function test abnormalities
- hives
- itching
- rash
- feeling of weakness
- appetite changes
- fracture of hip, wrist or spine

Rare (may affect up to 1 in 1,000 people):
- hallucinations involving the hearing of voices or sounds
- convulsion
- tingling or numbness
- visual disturbance
- feeling of dizziness or “spinning”
- yeast infections

Not known (frequency cannot be estimated from the available data):
- reduced number of red blood cells. This may cause paleness, weakness, intolerance to physical activity, dizziness, tiredness and confusion
- bruising or bleeding caused by abnormally low platelet count of unknown cause
- severe skin reactions
- blurred vision
- deafness
- hepatitis caused by medicines (with symptoms such as loss of appetite, headache, nausea, fatigue, fever, jaundice, pale or clay-coloured stools, dark urine)
- If you are on Gladexa for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gladexa
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 blister and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25°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 Gladexa contains
- The **active substance** is dexlansoprazole. Each modified-release capsule contains 30 mg or 60 mg of dexlansoprazole.
- The **other ingredients (excipients)** are:
  - ***Capsule content:*** Silica colloidal anhydrous, hydroxypropyl cellulose, hypromellose, low-substituted hydroxypropyl cellulose, magnesium carbonate heavy, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent (methacrylic acid units, ethyl acrylate units, sodium laurilsulfate, polysorbate 80), methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), macrogol 8000, polysorbate 80, sucrose (see section 2 “Gladexa contains sucrose”), sugar spheres (sucrose, corn starch), talc, titanium dioxide (E171), triethyl citrate
  - ***Capsule shell 30 mg:*** Carrageenan (E407), titanium dioxide (E171), hypromellose, potassium chloride, water purified, indigotine (E132), iron oxide black (E172)
  - ***Capsule shell 60 mg:*** Carrageenan (E407), titanium dioxide (E171), hypromellose, potassium chloride, water purified, indigotine (E132)
  - ***Printing ink:*** Iron oxide red (E172), iron oxide yellow (E172), indigotine (E132), carnauba wax, shellac, glycerol mono-oleate

What Gladexa looks like and contents of the pack
Gladexa is a modified-release hard capsule.
- Each 30 mg capsule (size 3) is non-transparent with a blue cap and a grey body with “TAP” imprinted on the cap and “30” on the body.
- Each 60 mg capsule (size 2) is non-transparent with a blue cap and body with “TAP” imprinted on the cap and “60” on the body.

The capsules are supplied in plastic-aluminium blister packs containing 14, 28, 56 or 98 capsules of Gladexa 30 mg or 14 or 28 capsules of Gladexa 60 mg.”
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
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Manufacturer
Takeda Italia S.p.A.
Via Crosa, 86
28065 - Cerano (NO)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Germany, Greece, Hungary, Lithuania, Poland, Portugal, Romania, Sweden: Dexilant.
Ireland, Italy, Spain: Gladexa.
Slovenia: Dexilanz 30 mg trde kapsule s prirejenim sproščanjem / Dexilanz 60 mg trde kapsule s prirejenim sproščanjem.
France: Gordian
Latvia: Gerdian.

This leaflet was last revised in December 2014.

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