

# DEXILANT

Dexlansoprazole delayed-release capsules (30mg and 60mg)

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## What Dexilant is used for

Dexilant is a prescription medicine called a proton pump inhibitor (PPI). Dexilant is used in adults:

- for up to 8 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE).
- for up to 6 months to continue healing of erosive esophagitis and relief of heartburn.
- For 4 weeks to treat heartburn related to symptomatic non-erosive gastroesophageal reflux disease (GERD) in children 12 years of age or older.

GERD happens when acid from your stomach enters the tube (esophagus) that connects your mouth to your stomach. This may cause a burning feeling in your chest or throat, sour taste or burping. In some cases, acid can damage the lining of your esophagus. This damage is called erosive esophagitis or EE.

## How Dexilant works

Dexilant reduces the amount of acid in your stomach. Dexilant may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

## Before you use Dexilant

### - When you must not use it

You should not take Dexilant if you are allergic to dexlansoprazole or any of the other ingredients of this medicine.

### - Before you start to use it

Before you take Dexilant, tell your doctor if you:

- Have low magnesium levels in your blood
- have liver problems
- have any other medical conditions
- Are pregnant or plan to become pregnant. It is not known if Dexilant can harm your unborn baby.
- are breast-feeding or planning to breast-feed. You and your doctor should decide if you will take Dexilant or breast-feed. You should not do both without first talking with your doctor.
- Are due to have a specific blood test (Chromogranin (A))

### - Taking other medicines

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Dexilant may affect how other medicines work, and other medicines may affect how Dexilant works. Especially tell your doctor if you take:

- Ampicillin ester
- Atazanavir or nelfinavir
- Digoxin
- A product that contains iron
- Ketoconazole
- Warfarin
- Tacrolimus
- methotrexate

## How to use Dexilant

### - How much to use

- Take Dexilant 60mg 1

time each day for healing of EE.

- Take Dexilant 30mg 1 time each day for maintenance of healed EE and relief of heartburn
- Take Dexilant 30mg 1 time each day for symptomatic non-erosive GERD

### - When to use it

Dexilant may be taken with or without food.

### - How long to use it

Take Dexilant exactly as your doctor tells you to take it.

### - If you forget to use it

If you miss a dose, 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 take the next dose at your regular time. Do not take 2 doses of Dexilant at the same time.

### - If you use too much (overdose)

If you take too much Dexilant, call your doctor or go to the nearest hospital emergency room right away.

## While you are using it

### - Things you must do

Dexilant should be swallowed whole.

### - Things you must not do

Dexilant should not be chewed.

### - Things to be careful of

Stop taking Dexilant 14 days before Chromogranin A (CgA) measurements because it may interfere with the investigations for neuroendocrine tumor.

## Side Effects

The most common side effects of Dexilant include:

- Diarrhea

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- Stomach pain
- Nausea
- Common cold
- Vomiting
- Gas
- Benign polyps in the stomach

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- **Subacute Cutaneous Lupus Erythematosus (SCLE).**  
Rash (especially in areas exposed to the sun), possibly with pain in the joints. SCLE frequency “not known”.
- **Kidney problems (Interstitial Nephritis)**  
Fever that do not go away, extreme tiredness, pus/blood in urine
- **Hypomagnesaemia.**  
Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood (hypomagnesaemia). Frequency “not known”
- **Serious allergic reactions**
  - Rash

- Face swelling
- Throat tightness
- Difficulty breathing
- **Bone fracture.** People who are taking multiple daily doses of proton pump inhibitor medicines for a long period of time may have an increased risk of fractures of 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). Frequency “uncommon”
- **Vitamin B-12 Absorption.** Malabsorption of vitamin B-12 may happen if you are taking acid-suppressing medications for a long period of time (e.g longer than 3 years).
- ***Clostridium Difficile* Diarrhea**  
Watery stool, stomach pain and fever that do not go away. Severe diarrhea which may caused by an infection (*Clostridium difficile*) in your intestines.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [np.ra.moh.gov.my](http://np.ra.moh.gov.my) (Public → Reporting Medicinal Problems/ Side Effects/ AEFI/ Vaccine Safety)

## Storage and Disposal of Dexilant

- **Storage**  
Store Dexilant below 30°C. Keep Dexilant and all medicines out of the reach of children.
- **Disposal**  
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.

## Product Description

### - What it looks like

Dexilant is supplied as capsules that are opaque:

- 30mg – blue and gray with TAP and “30” imprinted on the capsule.
- 60mg – blue with TAP and “60” imprinted on the capsule.

### - Ingredients

- Active ingredient

Dexlansoprazole

- Inactive ingredients

Sugar spheres, magnesium carbonate, sucrose, low-substituted hydroxypropyl cellulose, titanium dioxide, hydroxypropyl cellulose, hypromellose 2910, talc, methacrylic acid copolymers, polyethylene glycol 8000, triethyl citrate, polysorbate 80, and colloidal silicon dioxide. The capsule shell is made of hypromellose, carrageenan and potassium chloride. Based on the capsule shell color, blue contains FD&C Blue No. 2 aluminum lake; gray contains black ferric oxide.

### - MAL Number

Dexilant Delayed Release Capsules 30mg - MAL14015012AZ  
Dexilant Delayed Release Capsules 60mg - MAL14015010AZ

## Manufacturer

Takeda Pharmaceutical Company Limited, Osaka Plant,  
17-85, Jusohonmachi 2-chome,  
Yodogawa-ku, Osaka, Japan

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**Product Registration Holder**

Takeda Malaysia Sdn Bhd  
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Tower B, Plaza 33,  
No. 1, Jalan Kemajuan,  
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46200 Petaling Jaya, Selangor,  
Malaysia.

**Date of Revision**

24/08/2018 (CCDS v6.0,  
CCDS v7.0 and Bil15 and 16  
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