Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is to be supplied upon physician's prescription only

DEXILANT™ 30 mg, modified-release capsules
DEXILANT™ 60 mg, modified-release capsules

Composition:
Active ingredient
- each capsule of Dexilant 30 mg contains 30 mg of dexlansoprazole.
- each capsule of Dexilant 60 mg contains 60 mg of dexlansoprazole.

Inactive ingredients and allergens: See chapter 2 **'Before using this medicine'** under 'Important information about some of this medicine's ingredients' and chapter 6 '**Additional information**'**.**

Read the entire leaflet carefully before you start using this medicine. This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.
The medicine is intended for adults and adolescents over the age of 12 years.

1. What is this medicine intended for?

Dexilant is intended for the use of adults and adolescents aged 12 to 17 years for the following:
- Treatment of erosive reflux oesophagitis (inflammation with damage to the lining of the oesophagus (food pipe)).
- Maintenance treatment of healed erosive reflux oesophagitis and maintenance treatment following 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). Such leakage may cause a sensation of burning in the chest or throat, may create a sour taste or cause belching.

By reducing the amount of stomach acid, Dexilant can heal the damage caused to the oesophagus and relieve symptoms that can happen with the above conditions and stop them from coming back, but you may still suffer from severe gastric problems.

Therapeutic group:
Proton pump inhibitor (PPI).
PPIs reduce the amount of acid that your stomach produces.

2. Before using this medicine

Do NOT take Dexilant if you are:
- sensitive (allergic) to dexlansoprazole or to any of the other ingredients of this medicine (listed in chapter 6: **"Additional information"**).
- taking a medicine that contains the active ingredient rilpivirine (used to treat HIV – Human Immunodeficiency Virus).

Special warnings regarding the use of this medicine

Before using Dexilant, tell your physician if:

- You have been told that you have low magnesium levels in your blood.
- You have liver problems.
- You have ever suffered from a skin reaction following treatment with a medicine similar to Dexilant, reducing gastric acidity.
- You are pregnant or planning to become pregnant. Dexilant may harm your unborn baby. Talk to your doctor about the possible risks to an unborn baby if Dexilant is taken during pregnancy.
- You are breastfeeding or planning to breastfeed. It is not known if Dexilant passes in your breast milk or if it will affect your baby or breast milk.
  Consult your physician regarding the best way for you to feed your baby, if you are taking Dexilant.

Additional warnings:

- If you develop a skin rash, especially in areas exposed to the sun, inform the physician as soon as possible since you may need to stop the treatment with Dexilant. You should also remember to mention any other concomitant side effect, such as joint pain.
- In adults, if adequate response to treatment with Dexilant is not achieved or if the symptoms return quickly after completion of treatment, consult with your doctor to rule out the presence of malignancy in the stomach.
- **Stomach growths (fundic gland polyps)** - Patients who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growth called fundic gland polyps, especially after taking PPI medicines for more than 1 year.

Tests and follow up

- The physician may refer you to a test of magnesium level in your body prior to starting treatment with Dexilant or during the treatment if you will be taking Dexilant for a long period of time.
- An increase in CgA (Serum chromogranin A) level is possible during treatment with Dexilant. Your doctor may instruct you to stop taking Dexilant at least 14 days before assessing CgA levels and consider repeating the test if the level is high.
- For a secretin stimulation test, your doctor may instruct you to stop taking Dexilant at least 30 days before the test.
- There may be false positive urine screening test for tetrahydrocannabinol (THC).

Drug Interactions

If you are taking, or have recently taken other medicines, including non-prescription medications and food supplements, inform your physician or pharmacist. This is because Dexilant can affect the way some other medicines work. Also, other medicines can affect the way Dexilant works.

In particular inform the physician and the pharmacist if you are taking:

- Methotrexate (to treat rheumatoid arthritis, psoriasis and cancer)
- Rilipivirine, atazanavir, nelfinavir, saquinavir, ritonavir (used to treat HIV)
- Erlotinib (to treat cancer)
- Digoxin (to treat heart problems)
- Iron containing product
- Ketoconazole, itraconazole, voriconazole (to treat fungal infections)
- Warfarin (to prevent thrombosis)
- Tacrolimus, mycophenolate mofetil (to prevent rejection of transplant organs)
- A preparation that contains the herb, St. John’s wort, to treat depression
- Rifampin (rifampicin), an antibiotic used to treat various infections (such as tuberculosis)

Know the medicines that you take. Keep a list of them to show your physician and pharmacist when you receive a new medicine.

Using the medicine and food
Swallow the capsule whole with a glass of water. Do not chew the capsule or the granules inside it.
You can take the capsule with or without food.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, or think you may be pregnant or are planning to have a baby, ask your physician for advice before taking this medicine.
Dexilant may harm your unborn baby. Talk to your doctor about the possible risks to an unborn baby if you take Dexilant during pregnancy.

Driving and using machines
Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking Dexilant. 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 chapter 4: **"Side effects"**.
Read all the information in this leaflet for guidance.
Discuss with your physician if you are unsure about anything.

Important information about some of this medicine's ingredients
Sucrose - if you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicine.

3. How should you use this medicine?

Always use this medicine according to the physician's instructions. Check with your physician or pharmacist if you are not sure about your dosage or manner of treatment. The dosage and manner of treatment will be determined only by the physician.

The recommended dose is usually:
- **Treatment of erosive reflux oesophagitis:** take a dose of 60 mg once daily for up to 8 weeks.
- **Maintenance of healed erosive reflux oesophagitis and maintenance of relief of heartburn in patients where prolonged acid suppression treatment is needed:** take a dose of 30 mg once daily for up to 6 months in adults and for up to 16 weeks in adolescents aged 12 to 17 years.
- **Treatment of heartburn and acid regurgitation associated with symptomatic non-erosive gastro-oesophageal reflux disease (GORD):** take a dose of 30 mg once daily for 4 weeks.

Do not exceed the recommended dose.

Your physician will advise you how long to take Dexilant.
If necessary your physician may tell you to take a different dose.

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

If you have accidentally taken a higher dose:
If you accidentally take multiple capsules (overdose), or if someone else takes multiple capsules of your medicine at the same time or if a child has accidentally swallowed some medicine, go immediately to a physician or to a hospital emergency room and bring the medicine package with you.

Signs of overdose include:
- high blood pressure
- hot flushes
- bruises
- throat pain
- weight loss

If you forget to take Dexilant at the scheduled time
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, take the next dose at the usual time, and consult your doctor. Do not take a double dose to make up for a forgotten dose. Adhere to the treatment as recommended by your doctor.

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

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, ask your physician or pharmacist.

4. Side effects

Like all medicines, this medicine can cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Stop the treatment and contact the physician immediately or go to the emergency room of the nearest hospital if you experience acute allergic (hypersensitivity) reactions:
- rash
- face swelling
- throat tightness
- difficulty breathing

The physician may ask you to stop using the medicine if these symptoms occur.

Dexilant may cause severe side effects including:
- **Acute tubulointerstitial nephritis** – Some people who take proton pump inhibitor (PPI) medicines, including Dexilant, may develop acute tubulointerstitial nephritis, that can happen at any time during treatment with PPI medicines. Contact your physician immediately if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea** – Dexilant may increase the risk of getting severe diarrhea. This diarrhea may be caused by an infection (*Clostridium difficile*) in your intestines. Contact your physician immediately if you have watery stool, abdominal pain and fever that does not go away.
- **Bone fractures** – Patients taking multiple daily doses of PPI medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. You should take Dexilant exactly as prescribed, at the lowest dose possible for

your treatment, and for the shortest period required. Consult your physician regarding your risk of bone fractures if you take Dexilant.

- **Certain types of lupus erythematosus** – Lupus erythematosus is an autoimmune disease (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Contact your physician immediately if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.
- **Vitamin B-12 deficiency** – Dexilant reduces the amount of acid in your stomach. The acid is required for proper absorption of vitamin B-12. Consult your physician regarding possible vitamin B-12 deficiency if you are taking Dexilant for a long period of time (more than 3 years).
- **Low levels of magnesium in the body** – A decrease in magnesium level can happen in some patients who take proton pump inhibitor PPI medicines for at least 3 months. The decrease in magnesium levels usually occurs after treatment for 1 year. You may or may not suffer from low magnesium levels.
- **Stomach growths (fundic gland polyps)** - Patients who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growth called fundic gland polyps, especially after taking PPI medicines for more than 1 year.

Contact the physician immediately if you develop any of the following symptoms:

- Seizures
- Dizziness
- Irregular or fast heartbeat
- Jitteriness
- Jerking movements or shaking (tremors)
- Muscle weakness
- Spasms of the hands and feet
- Cramps or muscle aches
- Spasms of the voice box

Your physician may check the level of magnesium in your body before you start taking Dexilant, or during treatment, if you are taking Dexilant for a long period of time.

Additional side effects

<u>Common side effects in adults occur in more than 2 users out of 100:</u>

- diarrhea
- abdominal pain
- nausea
- upper respiratory tract infections
- vomiting
- flatulence

<u>Common side effects in adolescents aged 12 to 17 years - occur in more than 5 users out of 100:</u>

- headache
- abdominal pain
- diarrhea
- pain or swelling (inflammation) in your mouth, nose or throat

<u>Uncommon side effects occur in less than 2 users out of 100:</u>

- difficulty falling asleep, insomnia
- depression
- dizziness
- altered taste
- high blood pressure
- hot flushes
- cough

- dry mouth
- liver function test abnormalities
- urticaria
- pruritis
- rash
- asthenia
- altered appetite
- headache
- constipation
- abdominal discomfort
- hallucinations involving the hearing of voices or sounds
- convulsions
- tingling
- eye swelling or irritation
- vertigo, feeling of dizziness or “head-spinning”
- candida infections
- fractures

Side effects of unknown frequency (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 blood 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)
- rash, which may be accompanied by joint pain
- stomach growths (fundic gland polyps)

If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting side effects:
Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to Drug Treatment" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomitting without an explicit instruction from the physician.
- 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 discard the medicine via wastewater or household waste. Consult the pharmacist about how to dispose of the medicine. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:
- **Inactive ingredients:**

sucrose, sugar spheres (sucrose, corn starch),talc, methacrylic acid-methyl methacrylate copolymer (1:2), magnesium carbonate, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent (methacrylic acid units, ethyl acrylate units, sodium dodecylsulfate, polysorbate 80), low-substituted hydroxypropyl cellulose , hypromellose, titanium dioxide (E171), methacrylic acid-methyl methacrylate copolymer (1:1), triethyl citrate, macrogol 8000, polysorbate 80, hydroxypropyl cellulose and Silica colloidal anhydrous.
The capsule shell is made of hypromellose, carrageenan (E407) and potassium chloride, water, purified. Based on the capsule shell color, blue contains Indigotine (E132); gray contains Iron oxide black (E172); and both contain titanium dioxide (E171). Printing ink: Iron oxide red (E172), iron oxide yellow (E172), indigotine (E132), carnauba wax, shellac, glycerol mono-oleate.

Each capsule of 30 mg contains 68 mg of sucrose.
Each capsule of 60 mg contains 76.3 mg of sucrose.

What Dexilant looks like and contents of the pack:
Dexilant is a modified-release hard capsule.
- Each 30 mg capsule is an opaque blue and grey capsule, with the word "TAP" and the number "30" imprinted on it.
- Each 60 mg capsule is an opaque blue capsule, with the word "TAP" and the number "60" imprinted on it.

The capsules are marketed in plastic and aluminium blister packs containing 14 or 28 capsules of either Dexilant 30 mg or Dexilant 60 mg.
Not all pack sizes may be marketed.

Registration holder:
Takeda Israel Ltd.,
25 Efal, P.O.B 4140, Petach Tikva 4951125

Manufacturer:
Takeda GmbH,
Byk-Gulden-Straβe 2,
78467 Konstanz,
Germany

Registration number of the medicine in the National Drug Registry of the Minstry of Health:
Dexilant 30 mg - 155-45-34383
Dexilant 60 mg - 155-46-34387

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