

SCHEDULING STATUS

4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DEXILANT 30 mg (modified-release capsule)

DEXILANT 60 mg (modified-release capsule)

Dexlansoprazole

Contains sucrose:

Each 30 mg modified-release capsule contains 68 mg of sucrose.

Each 60 mg modified-release capsule contains 76 mg of sucrose.

Read all of this leaflet carefully before you start taking DEXILANT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DEXILANT has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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 DEXILANT is and what it is used for
2. What you need to know before you take DEXILANT
3. How to take DEXILANT
4. Possible side effects
5. How to store DEXILANT
6. Contents of the pack and other information

1. What DEXILANT is and what it is used for

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

Dexilant is used in adults and adolescents aged 12 years and above for the following:

- Treatment of erosive reflux oesophagitis (inflammation with damage to the lining of the oesophagus (food pipe) for up to 8 weeks
- Maintenance of healed erosive reflux oesophagitis and maintenance of relief of heartburn. For up to 6 months in adults and up to 4 months in adolescents.
- 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). For up to 4 weeks.

By reducing the amount of stomach acid DEXILANT 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

Do not take DEXILANT

If you are allergic to dexlansoprazole or any of the other ingredients of this medicine (listed in section 6)

If you are taking rilpivirine-containing medicines. Rilpivirine is an anti - HIV medicine of the protease inhibitor class of medicines.

Warnings and precautions

Take special precaution with DEXILANT:

- If you have a decrease in urine volume or suspect that there is blood in your urine.
- contact your doctor if you have decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness.
- if you have liver problems. Your doctor may have to adjust your dosage.
- if you 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.
- if you take a proton pump inhibitor like DEXILANT, 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).
- if you take DEXILANT 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.
- if you 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.
 - if you have low vitamin B-12 levels or have risk factors for low vitamin B-12 levels and receive long-term treatment with DEXILANTAs with all acid reducing agents, DEXILANT may lead to a reduced absorption of vitamin B-12.
 - if you have ever had a skin reaction after treatment with a medicine similar to DEXILANT that reduces stomach acid.
 - If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with DEXILANT. Remember to also mention any other ill-effects like pain in your joints.
 - DEXILANT can cause rare but severe skin reactions that may affect any part of your body (see also section 4). These serious skin reactions may need to be treated in a hospital and may be life threatening; Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet). You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes. Stop taking DEXILANT and call your doctor right away. These symptoms may be the first sign of a severe skin reaction
 - if you are due to have a specific blood test (Chromogranin A).

Children

Do not give this medicine to children under 12 years

Other medicines and DEXILANT

Tell your doctor 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.

Check with your doctor before taking Dexilant if you are taking any of the following medicines:

- HIV protease inhibitors such as atazanavir and nelfinavir (to treat HIV)
- 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, breast-feeding and fertility

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 Dexilant. If you experience side effects like these, you should avoid driving or use machines.

Discuss with your doctor if you are unsure about anything.

Dexilant 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 DEXILANT

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 DEXILANT 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 for adults 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 in adults and up to 4 months in adolescents

- **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.

The recommended dose for adolescents aged 12 to 17 years 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. Your doctor will define total treatment time.
- **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 DEXILANT.

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

If you take more DEXILANT 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 your doctor or pharmacist immediately. If neither available contact your nearest hospital or poison centre.

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.

If you forget to take DEXILANT

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 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 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

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

Frequent side-effects

- diarrhoea, abdominal pain, headache, feeling sick (nausea), abdominal discomfort, gas (flatulence), constipation and benign polyps in the stomach.

Some patients experienced the following other side effects with DEXILANT:

Less frequent side-effects

- 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
- 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 (Stevens-Johnson syndrome), toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme, and subacute cutaneous lupus erythematosus). You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes
- 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, possibly with pain in the joints
- If you are on DEXILANT 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.
- Visual hallucinations

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or health care provider. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index.8>. By reporting side effects, you can help provide more information on the safety of DEXILANT

5. How to store DEXILANT

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, wallet 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 DEXILANT 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 “Dexilant 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 DEXILANT looks like and contents of the pack

Dexilant 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 Dexilant 30 mg or 14 or 28 capsules of Dexilant 60 mg.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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