Patient package insert according to Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold with a physician's prescription only

PREGABALIN DEXCEL 25, 50, 75, 100, 150, 200, 225, 300 mg, CAPSULES

Active ingredient: Each capsule contains Pregabalin at a dose of 25, 50, 75, 100, 150, 200, 225, 300 mg, respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

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

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for treatment of children and adolescents under 18 years of age.

1. What is the medicine intended for?

For the treatment of neuropathic pain in adults, for the treatment of Fibromyalgia and for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Therapeutic group: A gamma aminobutyric acid analog.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (Pregablin) or to any of the other ingredients this medicine contains (see section 6).

Special warnings regarding the use of the medicine

Refer to your doctor before taking the medicine.

- Some patients taking Pregabalin have reported allergic effects. These effects include swelling of the face, lips, tongue and throat, as well as diffuse skin rash. If you experience one or more of these effects, refer to a doctor immediately.
- Serious skin rashes such Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with pregabalin using. Stop using the medicine and seek medical attention immediately if you experience any of the symptoms related to serious skin reactions described in section 4.
- The medicine may cause dizziness and somnolence, such that elderly patients taking the medicine are at increased risk of falls and injuries. Exercise caution until you become accustomed to the effect of the medicine on you.
- The medicine may cause blurring or loss of vision, or other changes in eyesight, most of which are transient. Inform the doctor immediately of any change in your vision.
- In some patients with diabetes, who gain weight while taking the medicine, the dosage of medicines for lowering the blood sugar level may have to be adjusted.
- Certain side effects, such as sleepiness, may be more common, because patients with spinal cord injury may be taking other medicines to treat pain and spasticity, which have side effects similar to those of Pregabalin and their severity may increase when these are taken together.
- Heart failure has been reported in a number of patients who took Pregabalin, mostly in elderly patients with heart and cardiovascular diseases. **Before starting use of the medicine, inform the doctor if you are suffering, or have suffered in the past, from a heart disease.**
- A few cases of kidney failure associated with treatment with Pregabalin have been reported. If you notice decreased urination during the treatment with the medicine, inform the doctor, as discontinuation of treatment with the medicine may bring an improvement.
- In some patients who were treated with anti-epileptic medicines such as Pregabalin, thoughts of harming themselves or suicidal thoughts or suicidal behavior have been reported. In case of onset of such thoughts or behavior at any stage, refer to the doctor immediately.
- Combination of Pregabalin with other medicines which might cause constipation (e.g., certain types of analgesics), may cause gastrointestinal problems (e.g., constipation, blocked or paralyzed bowel). Inform the doctor if you are suffering from constipation, especially if you are prone to constipation.
- Before commencing use of the medicine, inform the doctor if you are suffering, or have suffered in the past, from addiction to or dependence on alcoholic beverages, drugs or any medicines. Do not take a higher dosage than that which has been prescribed for you.
- Convulsions may occur during treatment with the medicine or immediately after its discontinuation - inform the doctor immediately if you are suffering from convulsions.
- Reduced brain functioning (encephalopathy) has been reported in a number of patients with other underlying ailments. Inform the doctor if you are aware of any serious medical conditions, including liver or kidney diseases.
- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or you are older than 65, your doctor may prescribe you a different dosing regimen. Consult your doctor if you experience difficulty breathing or shallow breaths.

Drug interactions

If you are taking, or if you have recently taken other medicines, including non- prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially, if you are taking:

Pregabalin and certain other medicines may have mutual influences on activity. If Pregabalin is taken with certain medicines which have sedative effects (including opioids), Pregabalin may potentiate these effects and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregabalin is taken together with:

- Oxycodone - a painkiller
- Lorazepam - a medicine for treating anxiety
- Alcohol

Pregabalin may be taken with oral contraceptives.

Use of the medicine and food

The medicine can be taken without regard to meals.

Use of the medicine and alcohol consumption

Do not consume alcohol during the treatment with the medicine.

Pregnancy, breastfeeding and fertility

Do not use Pregabalin during pregnancy or when breastfeeding, unless the doctor has instructed you to do so after consulting with him. Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 babies in every 100 had such birth defects. This compares to 4 babies in every 100 born to women not treated with pregabalin in the study. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Women who may become pregnant during the treatment with the medicine must use effective contraceptive measures. Consult a doctor or pharmacist before using the medicine if you are pregnant or breastfeeding, if you suspect that you are pregnant or you are planning to become pregnant.

Driving and using machines

Do not drive or operate dangerous machinery until you know how the medicine affects you, since use of this medicine may cause dizziness, drowsiness or decreased concentration.

Important information about some of the ingredients of the medicine

Pregabalin Dexcel 50 mg contains Allura red AC (E129), which may cause allergic reactions.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the treatment regimen of the medicine.

The dosage and the treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose!

Swallow the capsule whole. There is no information regarding the opening and dispersing the contents of the capsule, since such forms of administration have not been tested.

Swallow the medicine with water.

If you have accidentally taken a higher dose, you may suffer from the following effects: sleepiness, confusion, agitation, restlessness. In addition, there have been reports of fits (convulsions).

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the required time

It is important to take the medicine every day at a set time. If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If a decision is made to discontinue treatment, discontinuation of treatment with the medicine must be gradual, over a period of at least one week.

After stopping treatment with the medicine (whether the treatment was short-term or long-term), you may experience: insomnia, headaches, nausea, anxiety, flu-like symptoms, convulsions, nervousness, depression, pain, dizziness, sweating and diarrhea. These effects may be more common and more severe if the medicine has been taken for a longer period of time.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of Pregabalin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if you suffer from swelling of the face or tongue or a severe skin reaction (the skin reddens and becomes covered with blisters or peels).

Very common side effects (effects that occur in more than 1 out of 10 users):
Dizziness, drowsiness, headaches.

Common side effects (effects that occur in 1-10 out of 100 users):

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Concentration or memory impairment, memory loss, clumsiness, tremor, speech disturbance, tingling sensation, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- Blurred vision, double vision.
- Vertigo, balance disorders, falls.
- Dry mouth, constipation, vomiting, flatulence, diarrhea, nausea, swollen abdomen.
- Erection problems.
- Swelling of the body including the extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramps, joint pain, back and limb pains.
- Sore throat.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users)

- Loss of appetite, weight loss, decreased blood sugar level, increased blood sugar level.
- Change in self-perception, restlessness, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attacks, apathy, aggression, elevated mood, mental impairment, difficulty with thinking, increase in sexual interest, problems with sexual functioning, including inability to achieve a sexual climax, delayed ejaculation.
- Vision changes including loss of peripheral vision, nystagmus, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, skin sensitivity, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling or pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low or high blood pressure, changes in heartbeat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numbness around the mouth.
- Sweating, rash, chills, fever.
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- Breast pain.
- Difficulty with or painful urination, incontinence.
- Weakness, thirst, chest tightness.
- Changes in blood and liver function tests (increase in blood creatine phosphokinase, increased liver enzymes, decreased platelets, neutropenia, increase in blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- Painful menstrual periods.
- Cold hands and feet.

Rare side effects (effects that occur in 1-10 out of 10,000 users)

- Abnormal sense of smell, swinging vision, change in depth perception, visual brightness, vision loss.
- Dilated pupils, crossed eyes.
- Cold sweat, irritation of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slower or reduced movement of the body.
- Difficulty with writing.
- Edema in the abdominal area.
- Fluid in the lungs.
- Convulsions.
- Changes in ECG which correspond to heart rhythm disturbances.
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in men.
- Menstrual period disturbances.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count in blood test.
- Abnormal behavior, suicidal behavior, suicidal thoughts.
- Allergic reactions (may be manifested by: breathing difficulties, inflammation of the eyes [keratitis] and a serious skin reaction characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, peeling skin, ulcers of mouth, throat, nose, genitals and eyes). These serious skin effects can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Jaundice (yellowing of the skin and the whites of the eyes).
- Parkinsonism, that is symptoms resembling Parkinson's disease; such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare side effects (effects that occur in less than 1 out of 10,000 users)

- Liver failure.
- Viral inflammation of the liver (hepatitis).

Certain side effects, such as sleepiness, may be more common, because patients with spinal cord injury may be taking additional medicines to treat pain and spasticity, which have side effects similar to those of Pregabalin and their severity may increase when these are taken together.

The following side effects have been reported post-marketing: difficulty breathing and shallow breaths.

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a temperature below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Gelatine, starch pregelatinized, magnesium stearate, titanium dioxide (E171), printing ink: shellac (E904), propylene glycol (E1520), strong ammonia solution (E527), potassium hydroxide (E525), black iron oxide (E172).

Pregabalin Dexcel 25 and **50 mg** capsules also contain: Mannitol.
Pregabalin Dexcel 50 mg capsules also contain: Allura red AC (E129), brilliant blue FCF (E133).
Pregabalin Dexcel 75, 100, 200, 225, 300 mg capsules also contain: Yellow iron oxide (E172), red iron oxide (E172).
Pregabalin Dexcel 75, 100 and 300 mg also contain: Black iron oxide (E172).

What the medicine looks like and contents of the package:
Pregabalin Dexcel 25 mg: a white capsule with the word "DP25" imprinted.
Pregabalin Dexcel 50 mg: a white and grey capsule with the word "DP50" imprinted.
Pregabalin Dexcel 75 mg: a white and brown capsule with the word "DP75" imprinted.
Pregabalin Dexcel 100 mg: a brown capsule with the word "DP100" imprinted.
Pregabalin Dexcel 150 mg: a white capsule with the word "DP150" imprinted.
Pregabalin Dexcel 200 mg: an orange capsule with the word "DP200" imprinted.
Pregabalin Dexcel 225 mg: an orange and white capsule with the word "DP225" imprinted.
Pregabalin Dexcel 300 mg: a brown and white capsule with the word "DP300" imprinted.

Approved package size: 56 capsules.

Revised in October 2022 according to MOH guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Pregabalin Dexcel 25 mg: 158-72-34727-00
Pregabalin Dexcel 50 mg: 158-73-34728-00
Pregabalin Dexcel 75 mg: 158-74-34729-00
Pregabalin Dexcel 100 mg: 158-75-34730-00
Pregabalin Dexcel 150 mg: 158-76-34731-00
Pregabalin Dexcel 200 mg: 158-77-34732-00
Pregabalin Dexcel 225 mg: 158-78-34733-00
Pregabalin Dexcel 300 mg: 158-79-34695-00

Manufacturer and registration holder:
Dexcel® Ltd.
1 Dexcel St., Or Akiva 3060000, Israel.