

2023 ספטמבר

Cymbalta 30 mg, Cymbalta 60 mg
Gastro Resistant Capsules
duloxetine (as hydrochloride)

התוויה המאושרת לתכשיר:

- Cymbalta is indicated for the treatment of major depressive episodes.
- Cymbalta is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy.
- Cymbalta is indicated for the treatment of generalized anxiety disorder (GAD).
- Cymbalta is indicated for the management of fibromyalgia.
- Cymbalta is indicated for the management of chronic musculoskeletal pain when other therapies have failed or are contra-indicated. This has been established in studies in patients with chronic low back pain (CLBP) and chronic pain due to osteoarthritis.

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

חברת אלי לילי מבקשת להודיעכם על עדכון העלונים לרופא ולצרכן של התכשירים Cymbalta 30 & 60 mg בהודעה זו מצוינים רק הסעיפים בהם נעשה שינוי המהווה החמרה המסומן בצהוב. קיימים עדכונים נוספים. טקסט שהתווסף מודגש בקו תחתון, טקסט שנמחק מסומן בקו חוצה. העלונים המעודכנים מפורסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום: אלי לילי ישראל בע"מ, השיזף 4, רעננה, טל': 09-9606234.

בברכה,
יצחק תירוש
רוקח ממונה

להלן העדכונים העיקריים בעלון לרופא:

5 WARNINGS AND PRECAUTIONS

[...]

5.4 Serotonin Syndrome

Serotonin-norepinephrine reuptake inhibitors (SNRIs), including CYMBALTA, can precipitate serotonin syndrome. The development of a potentially life-threatening condition. serotonin syndrome has been reported with SNRIs and SSRIs, including CYMBALTA, alone but particularly The risk is increased with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, **meperidine, methadone,** tryptophan, buspirone, amphetamines, and St. John's Wort) and with drugs that impair metabolism of serotonin, i.e., (in particular, MAOIs, [see Contraindications (4), Drug Interactions (7.13).] both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). **Serotonin syndrome can also occur when these drugs are used alone.**

Serotonin signs and syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). ~~Patients should be monitored for the emergence of serotonin syndrome.~~

The concomitant use of CYMBALTA with MAOIs antidepressants is contraindicated. In addition, do not initiate CYMBALTA should also not be started in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue. All reports with methylene blue that provided information on the route of administration involved intravenous administration in the dose range of 1 mg/kg to 8 mg/kg. No reports involved the administration of methylene blue by other routes (such as oral tablets or local tissue injection) or at lower doses. There may be circumstances when If it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking CYMBALTA, CYMBALTA should be discontinued before initiating treatment with the MAOI [see Dosage and Administration (2.9, 2.10), and Contraindications (4) and Drug Interactions (7.13)].

Monitor all patients taking CYMBALTA for the emergence of serotonin syndrome. Discontinue treatment with CYMBALTA and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of CYMBALTA with other serotonergic drugs including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, tryptophan, amphetamines, and St. John's Wort is clinically warranted, inform patients should be made aware of a potential of the increased risk for serotonin syndrome and monitor for symptoms, particularly during treatment initiation and dose increases. Treatment with CYMBALTA and any concomitant serotonergic agents, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.

7 DRUG INTERACTIONS

[...]

7.14 Other Serotonergic Drugs

The concomitant use of serotonergic drugs (including other SNRIs, SSRIs, triptans, tricyclic antidepressants, opioids, lithium, buspirone, amphetamines, tryptophan, and St. John's Wort) with CYMBALTA increases the risk of serotonin syndrome. Monitor patients for signs and symptoms of serotonin syndrome, particularly during treatment initiation and dosage increases. If serotonin syndrome occurs, consider discontinuation of CYMBALTA and/or concomitant serotonergic drugs [see Warnings and Precautions (5.4)].

[See Dosage and Administration (2.9, 2.10), Contraindications (4), and Warnings and Precautions (5.4)].

להלן העדכונים העיקריים בעלון לצרכן:

2. לפני השימוש בתרופה

[...]

תגובות בין תרופתיות:

אם אתה לוקח, או אם לקחת לאחרונה, תרופות אחרות כולל תרופות ללא מרשם ותוספי תזונה, ספר על כך לרופא או לרוקח. במיוחד יש ליידע את הרופא אם אתה לוקח:

[...]

- משככי כאבים חזקים כגון טראמאדול (tramadol), פנטניל (fentanyl), מפירידין (meperidine), מתאדון (methadone), או אופיואידים אחרים.