

יולי 2025

רופא/ה נכבד/ה

רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלונים של התכשירים:

Zyprexa 5 mg (104-84-28857-21)

Tablets

Zyprexa 7.5 mg (104-85-28858-21)

Tablets

Zyprexa 10 mg (104-86-28859-21)

Tablets

Zyprexa Velotab 5 mg (130-75-30740-00)

Orodispersible tablets

Zyprexa Velotab 10 mg (130-76-30741-00)

Orodispersible tablets

המאושרים להתוויה הבאה:

Acute and maintenance treatment of schizophrenia.

Zyprexa is indicated for the management of the manifestations of psychotic disorders.

Zyprexa is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

Prevention of recurrence in bipolar disorder:

In patients whose manic episode has responded to olanzapine treatment, Zyprexa is indicated for the prevention of recurrence in patients with bipolar disorder.

Combination therapy in bipolar I disorder:

The combination of Zyprexa with lithium or valproate is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

עלוני התכשירים התעדכנו בעקבות מידע בטיחותי חדש, להלן עיקרי המידע שעודכן:

עלון לרופא:

5.15 Hyperprolactinemia

As with other drugs that antagonize dopamine D₂ receptors, olanzapine elevates prolactin levels, and the elevation persists during chronic administration. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion.

This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects.

Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. As is common with compounds which increase prolactin release, an increase in mammary gland neoplasia was observed in the olanzapine carcinogenicity studies conducted in mice and rats [see *Nonclinical Toxicology (13.1)*]. ~~Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time.~~ Published epidemiologic studies have shown inconsistent results when exploring the potential association between hyperprolactinemia and breast cancer.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of ZYPREXA. Because these reactions are reported voluntarily from a population of uncertain size, it is difficult to reliably estimate their frequency or evaluate a causal relationship to drug exposure.

Adverse reactions reported since market introduction that were temporally (but not necessarily causally) related to ZYPREXA therapy include the following: allergic reaction (e.g., anaphylactoid reaction, angioedema, pruritus or urticaria), cholestatic or mixed liver injury, diabetic coma, diabetic ketoacidosis, discontinuation reaction (diaphoresis, nausea or vomiting), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), hepatitis, jaundice, neutropenia, pancreatitis, priapism, rash, restless legs syndrome, rhabdomyolysis, salivary hypersecretion stuttering, venous thromboembolic events (including pulmonary embolism and deep venous thrombosis), **fecal incontinence, and somnambulism**. Random cholesterol levels of ≥ 240 mg/dL and random triglyceride levels of ≥ 1000 mg/dL have been reported.

עלון לצרכן:

תופעות לוואי בשכיחות שאינה ידועה:

תגובה אלרגית (כגון תגובה אנאפילקטית, התנפחות הפנים או הגרון (אנגיודמה), גרד, פריחה), תרדמת הקשורה לסוכרת, קטואצידוזיס סוכרתי, תופעות לוואי שעלולות להופיע בעת הפסקת טיפול (בחילה, הקאה והזעה), צהבת, דלקת בלבב ובכבד, פגיעה בכבד, תסמונת הרגליים העצבניות (restless legs syndrome), זקפה כואבת וממושכת (פריאפיזם), פגיעה בשרירים הגורמת לכאבים (רבדומיוליזיס), פקקת ורידים, גמגום, הצטברות חומצות מרה, **דליפת צואה וסהרורות**.

לשאר העדכונים בעלון יש לעיין בעלון המלא שנשלח לפרסום במאגר התרופות באתר משה"ב. ניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו פארמה בע"מ בטלפון 073-7151111 או באימייל בכתובת info.pharma@tzamal-medical.co.il.

בברכה,
צמל ביו-פארמה בע"מ