

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לצרכן ובעלון לרופא של התכשיר:

NAXYN® 500 mg Tablets

נקסין® 500 מ"ג טבליות

Contains: Naproxen 500 mg

עדכונים בעלון לצרכן ובעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

- Relief of the signs and symptoms of rheumatic diseases including osteoarthritis ankylosing spondylitis of rheumatoid arthritis both in the treatment of acute flares and in the long-term management of the disease.
- Juvenile Rheumatoid Arthritis.
- Periarticular and musculoskeletal disorders
- Relief of pain in bursitis tendinitis synovitis tenosynovitis and lumbago.
- Relief of pain, swelling, tenderness and fever in acute gouty Arthritis.
- Relief of symptoms of primary dysmenorrhea.

ברצוננו להודיע שהעלון לצרכן עודכן בהרחבת תיאור ההתוויות של התרופה בעלון לצרכן, בהוספת המינון המקובל בעלון לצרכן (בהתאם לעלון לרופא) ובהוספת מידע בטיחותי.

בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

עדכונים בעלון לרופא

4.6 Fertility, pregnancy and lactation

Pregnancy

[...]

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal



lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

[...]

In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, naproxen should not be given unless clearly necessary. If naproxen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to naproxen for several days from gestational week 20 onward. Consider ultrasound monitoring of amniotic fluid if naproxen treatment extends beyond 5 days. Naproxen should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

העלון לרופא נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

וניתן לקבלו מודפס ע"י פניה לחברת טבע. <http://www.health.gov.il>