



ינואר 2025

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 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

4.2 Posology and method of administration

Rheumatic Diseases

The recommended daily dosage is 500 or 1000 mg taken as a single dose in the morning or in the evening. Alternatively, 250 or 500 mg may be taken twice daily at 12-hour intervals, morning and evening. **If a dose of 250 mg is required, an alternative medical product should be considered.**

In patients who tolerate lower doses well and have no history of gastrointestinal disease, the dose may be increased to 1500 mg/day for flare-ups or acute exacerbations of disease, for no longer than two weeks. Increased gastrointestinal side effects have been reported with these higher doses.



Juvenile Rheumatoid Arthritis

In children over 5 years of age: the recommended dosage is 10 mg/kg body weight per day, taken in 2 doses at 12-hour intervals. For children who, based on their weight, a dose lower than 500 mg is required, an alternative treatment should be considered.

Periarticular and Musculoskeletal Disorders

500 mg initially, followed thereafter by 250 mg at 8-12 hour intervals. For dose of 250 mg of naproxen, an alternative medical product should be considered.

Acute Gouty Arthritis

750 mg initially followed 8 hours later by 500 mg and thereafter by 250 mg 8-hourly, until the attack has passed. For doses requiring 250 mg of naproxen, an alternative medical product should be considered.

Primary Dysmenorrhea

500 mg at the onset of menstrual pain, followed by 250 mg every 6 hours until symptoms have subsided, up to a total of 1250 mg daily. For doses requiring 250 mg of naproxen, an alternative medical product should be considered.

Special populations

Renal/hepatic impairment

A lower dose should be considered in patients with renal or hepatic impairment. Naprosyn is contraindicated in patients with baseline creatinine clearance less than 30 ml/minute because accumulation of naproxen metabolites has been seen in patients with severe renal failure or those on dialysis (see section 4.3).

Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or intolerance occurs.

Elderly population

Due to the increased risk for adverse effects, prolonged use of NSAIDs in elderly patients is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

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