

אוקטובר 2024

Doxylin 100, Tablets

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלונים לרופא ולצרכן של התכשיר **דוקסילין 100**. בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלונים.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים ע"י פנייה לבעל הרישום:
דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000

הרכב התכשיר:

Each tablet contains Doxycycline (as Hyclate) 100 mg

ההתוויה המאושרת:

Doxycycline has been found clinically effective in the treatment of a variety of infections caused by susceptible strains of Gram-positive and Gram-negative bacteria and certain other microorganisms.

Respiratory tract infections: Pneumonia and other lower respiratory tract infections due to susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis* and other organisms. *Mycoplasma pneumoniae*. Treatment of chronic bronchitis, sinusitis.

Urinary tract infections: Infections caused by susceptible strains of *Klebsiella* species, *Enterobacter* species, *Escherichia coli*, *Streptococcus faecalis* and other organisms.

Sexually transmitted diseases: Infections due to *Chlamydia trachomatis* including uncomplicated urethral, endocervical or rectal infections. Non-gonococcal urethritis caused by *Ureaplasma urealiticum* (T-mycoplasma). Doxylin 100 is also indicated in infections due to *Calymmatobacterium granulomatis*. Doxylin is an alternative drug in the treatment of gonorrhoea and syphilis.

Since Doxycycline is a member of the tetracycline series of antibiotics, it may be expected to be useful in the treatment of infections which respond to other tetracyclines, such as:

Ophthalmic infections: Treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence. Inclusion conjunctivitis may be treated with oral Doxycycline alone or in combination with topical agents.

Rickettsial infections: Rocky Mountain spotted fever, typhus group, Q fever, *Coxiella endocarditis*.

Other infections: Psittocosis, brucellosis (in combination with streptomycin), cholera, bubonic plague, louse and tick-borne relapsing fever including stage 1 and stage 2 Lyme disease, leptospirosis, tularaemia glanders, chloroquine-resistant falciparum malaria and acute intestinal amoebiasis (as an adjunct to amoebicides).

Infections due to susceptible strains of *Bacteroides* species and *Listeria* species.

Doxylin is an alternative drug in the treatment of leptospirosis, gas gangrene and tetanus.

Doxylin is indicated for prophylaxis in the following conditions: Scrub typhus, traveller's diarrhoea (enterotoxigenic *Escherichia coli*), leptospirosis, malaria and cholera.

Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post exposure): to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*.

העלון לרופא עודכן באוקטובר 2024 להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

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4.8 Undesirable Effects

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Skin and Subcutaneous Tissue Disorders:

Rare $\geq 1/10,000$ to $<1/1,000$: Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, dermatitis exfoliative, **fixed drug eruption**, skin hyperpigmentation, photoonycholysis

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5.2 Pharmacokinetic Properties

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Children and Adolescents (2 to 18 years of age)

Population pharmacokinetic analysis of sparse concentration-time data of doxycycline following standard of care intravenous (IV) and oral dosing in 44 paediatric patients (2-18 years of age) showed that allometrically-scaled clearance (CL) of doxycycline in paediatric patients ≥ 2 to ≤ 8 years of age (median [range] 3.58 [2.27-10.82] L/h/70 kg, N=11) did not differ significantly from paediatric patients >8 to 18 years of age (3.27 [1.11-8.12] L/h/70 kg, N=33). For paediatric patients weighing ≤ 45 kg, body weight normalized doxycycline CL in those ≥ 2 to ≤ 8 years of age (median [range] 0.071 [0.041-0.202] L/kg/h, N=10) did not differ significantly from those >8 to 18 years of age (0.081 [0.035-0.126] L/kg/h, N=8). In paediatric patients weighing >45 kg, no clinically significant differences in body weight normalized doxycycline CL were observed between those ≥ 2 to ≤ 8 years (0.050 L/kg/h, N=1) and those >8 to 18 years of age (0.044 [0.014-0.121] L/kg/h, N=25). No clinically significant difference in CL between oral and IV dosing was observed in the small cohort of paediatric patients who received the oral (N=19) or IV (N=21) formulation alone.

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העלון לצרכן עודכן באוקטובר 2024 להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

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4. תופעות לוואי

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תופעות לוואי נדירות (תופעות שמופיעות ב 10-1 משתמשים מתוך 10,000):

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- כתמים עגולים או אובאליים של אדמומיות ונפיחות של העור, שלפוחיות וגרד, שחוזרים בדרך כלל באותו מיקום בחשיפה חוזרת לתרופה (fixed drug eruption)

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