פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

מרץ 2020

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא עבור התכשירים הבאים:

Dalacin C 150mg/ml

המרכיב הפעיל:

Clindamycin phosphate

התוויה: For the treatment of infections caused by susceptible anaerobic bacteria

להלן העדכונים העיקריים בעלון לרופא:

4.3 Contraindications

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Dalacin® C 150mg/ml solution for injection must not be given to premature babies or neonates because of the benzyl alcohol content (see section 4.6).

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4.4 Special warnings and special precautions for use

The clindamycin phosphate injectable formulation contains benzyl alcohol (9mg/ml). Intravenous administration of the preservative benzyl alcohol has been associated with serious adverse events, and death in paediatric patients including neonates characterized by central nervous system depression, metabolic acidosis, gasping respirations, cardio-vascular failure and haematological anomalies ("gasping syndrome"). Although normal therapeutic doses of this product ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. Use only if it is necessary and if there are no alternatives possible. If given in high volumes, should be used with caution and preferably for short term treatment in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis) due to benzoic acid (a metabolite of benzyl alcohol).

Premature and low-birth weight infants may be more likely to develop toxicity. Benzyl alcohol containing products should not be used in pre-term or full-term neonates unless strictly necessary.

Benzyl alcohol can cross the placenta and clindamycin should only be used during pregnancy if clearly needed (see section 4.6).

Severe hypersensitivity reactions, including severe skin reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP) have been reported in patients receiving clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, clindamycin should be discontinued and appropriate therapy should be initiated (see sections 4.3 and 4.8).

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It is important to consider the diagnosis of CDAD in patients who present with diarrhoea subsequent to the administration of antibacterial agents. This may progress to colitis, including pseudomembranous colitis (see section 4.8), which may range

from mild to fatal colitis. If antibiotic-associated diarrhoea or antibiotic-associated colitis is suspected or confirmed, ongoing treatment with antibacterial agents, including clindamycin, should be discontinued and adequate therapeutic measures should be initiated immediately. When 125 mg to 500 mg of vancomycin are administered orally four times a day for 7 - 10 days, there is a rapid observed disappearance of the toxin from faecal samples and a coincident clinical recovery from the diarrhoea. Drugs inhibiting peristalsis are contraindicated in this situation.

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4.5 Interaction with other medicinal products and other forms of interaction

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Co-administration of clindamycin with inhibitors of CYP3A4 and CYP3A5
Clindamycin is metabolized predominantly by CYP3A4, and to a lesser extent by CYP3A5, to the major metabolite clindamycin sulfoxide and minor metabolite N desmethylclindamycin. Therefore inhibitors of CYP3A4 and CYP3A5 may reduce clindamycin clearance and inducers of these isoenzymes may increase clindamycin clearance. In the presence of strong CYP3A4 inducers such as rifampicin, monitor for loss of effectiveness.

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4.8 Undesirable effects

System Organ Class	**Common ≥ 1/100 to < 1/10**	**Uncommon ≥ 1/1 000 to <1/100**	**Rare ≥ 1/10 000 to <1/1 000**	**Very Rare < 1/10 000**	**Not Known (cannot be estimated from available data)**
Immune System Disorders					anaphylactic shock*, anaphylactoid reaction*, anaphylactic reaction*, hypersensitivity*
……	…….	……..	…….	…….	……..
Skin and Subcutaneous Tissue Disorders	rash maculopapular	urticaria erythema multiforme, pruritus			toxic epidermal necrolysis (TEN)*, Stevens-Johnson syndrome (SJS)*, drug reaction with eosinophilia and systemic symptom (DRESS)*, acute generalised exanthematous pustulosis (AGEP)*, dermatitis exfoliative*, dermatitis bullous*, rash morbilliform*,

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים בעלון לרופא הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. בהודעה זו מצוינים רק העדכונים העיקריים .קיימים עדכונים נוספים.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ
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הרצליה פיתוח, 46725.
בברכה,
עשת אושרית
רוקחת ממונה