

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 24.12.2014

שם תכשיר באנגלית ומספר הרישום

PerioChip (062 94 27005 00)

שם בעל הרישום דקסל פארמה טכנולוגיות בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
Known sensitivity to chlorhexidine or hypersensitivity to chlorhexidine digluconate or to any of the excipients listed in section 6.1-`List of excipients`.	Hypersensitivity to chlorhexidine digluconate or to any of the excipients.	contraindications
<u>Dosage</u> Adults including the elderly: Following mechanical debridement, a PerioChip is placed in each of the periodontal pockets to be treated. One PerioChip is inserted into a periodontal pocket with probing pocket depth (PD) 5 mm or greater . Up to 8 chips may be inserted in a single visit. Retreatment with PerioChip following mechanical plaque removal at 3 month intervals may provide additional benefit if pocket depth remains \geq 5mm. The PerioChip biodegrades in the periodontal pocket over about a 7-day period and no return visit to the dental clinic to remove the dental insert is necessary. The patient should be instructed to continue normal oral hygiene procedures. No restrictions on dietary habits	<u>Dosage</u> Adults including the elderly: Following mechanical debridement, a PerioChip is placed in each of the periodontal pockets to be treated. Retreatment with PerioChip following mechanical plaque removal at 3 month intervals may provide additional benefit if pocket depth remains \geq 5mm. The PerioChip biodegrades in the periodontal pocket over about a 7-day period and	Posology, dosage & administration

<p>are needed.</p> <p><i>Children and adolescents:</i> PerioChip is not indicated in children and adolescents, since data on safety and efficacy in this age group have not been established.</p> <p><u>Method of administration</u></p> <p>Isolate the periodontal pocket and dry the periodontal pocket and the surrounding area. Open a blister cavity containing one PerioChip. Pick up the dental insert with a pair of forceps so that the rounded end points away from the forceps. Rapidly insert the dental insert, curved end first, into the periodontal pocket to its maximum depth and release. The dental insert can be further manoeuvred into position using the tips of the forceps or a flat plastic instrument. After proper insertion, PerioChip should rest subgingivally at the base of the pocket. PerioChip insertion into periodontal pockets is rapid. The dental insert's consistency allows placement into the pocket with little discomfort to the patient.</p> <p>In the unlikely event of PerioChip dislodgement, several actions are recommended, depending on the day of PerioChip loss. If dislodgement occurs 7 days or more after placement, the dentist should consider the subject to have received a full course of treatment. If dislodgement occurs within 48 hours after placement, a new PerioChip should be inserted. If dislodgement occurs more than 48 hours after placement, the dentist should not replace the PerioChip, but reevaluate the patient at 3 months and insert a new PerioChip if the pocket depth has not been reduced to less than 5 mm.</p>	<p>no return visit to the dental clinic to remove the dental insert is necessary. The patient should be instructed to continue normal oral hygiene procedures. No restrictions on dietary habits are needed.</p> <p><i>Children and adolescents:</i> PerioChip is not indicated in children and adolescents, since data on safety and efficacy in this age group have not been established.</p> <p><u>Method of administration</u></p> <p>Isolate and dry the periodontal pocket. Open an aluminium blister cavity containing one PerioChip. Pick up the dental insert with a pair of forceps so that the rounded end points away from the forceps. Rapidly insert the dental insert into the pocket to its maximum depth and release. The dental insert can be further manoeuvred into position using the tips of the forceps or a flat plastic instrument. PerioChip insertion into periodontal pockets is rapid. The dental insert's consistency allows placement into the pocket with little discomfort to the patient.</p>	
<p>Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving products containing chlorhexidine. These usually occur from within minutes to a few hours of dosing. Patients should therefore be instructed to seek immediate medical attention if they develop allergic symptoms such as skin rash,</p>	<p>There have been individual reports of systemic hypersensitivity following placement of PerioChip. Local hypersensitivity reactions such as gingival swelling are common.</p>	<p>Special Warnings and Special Precautions for Use</p>

<p>itch, generalised swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or diarrhoea.</p> <p>The use of PerioChip in an acutely abscessed periodontal pocket has not been studied and therefore is not recommended. Infectious events including abscesses and cellulitis, which have been reported after scaling and root planning alone, have also been reported with the adjunctive placement of the PerioChip post scaling and root planing. Management of patients with periodontal disease should include consideration of potentially contributing medical disorders, such as cancer, diabetes, and immunocompromised status.</p> <p>There have been individual reports of systemic hypersensitivity following placement of PerioChip. Local hypersensitivity reactions such as gingival swelling are common.</p> <p>Patients should be advised to report any signs of local adverse reactions to their dentists.</p> <p>Patients should also be advised that, although some mild to moderate sensitivity is normal during the first week after placement of PerioChip, they should notify the dentist promptly if pain, swelling, or other problems occur.</p> <p>Patients should be instructed exactly where PerioChip was inserted. Patients should avoid dental floss at the site of PerioChip insertion for 10 days after placement, because flossing might dislodge the chip. All other oral hygiene may be continued as usual. No restrictions regarding dietary habits are needed. Patients should be instructed to notify the dentist promptly if the PerioChip dislodges.</p> <p>See also section 4.5 - `Interaction with other medicinal products and other forms of interaction`.</p> <p><u>Pediatric Use:</u></p> <p>Data on safety and efficacy in children and adolescents have not been established.</p> <p><u>Geriatric Use:</u></p> <p>Although subjects aged 65 years and over</p>		
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<p>were included in clinical studies of PerioChip, there were not sufficient numbers of these subjects to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Overall differences in safety or effectiveness have not been identified between the elderly and younger patients.</p>		
		<p>Interaction with Other Medicaments and Other Forms of Interaction</p>
<p><u>Fertility and pregnancy</u></p> <p>In reproduction and fertility studies with chlorhexidine digluconate, no evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day, and no evidence of harm to the fetus was observed in rats and rabbits at doses up to 300 mg/kg/day and 40 mg/kg/day, respectively.</p> <p>In clinical studies, placement of four chips within periodontal pockets resulted in plasma concentrations of chlorhexidine that were at or below the limit of detection. However, it is not known whether PerioChip can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.</p> <p>Since controlled studies in pregnant women have not been conducted, the expected benefits of the medicinal product to the mother should be weighed against possible risks to the fetus. PerioChip should be used in a pregnant woman only if clearly needed.</p> <p><u>Lactation</u></p> <p>...</p>	<p><u>Pregnancy</u></p> <p>In reproduction and fertility studies with chlorhexidine digluconate, no evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day, and no evidence of harm to the fetus was observed in rats and rabbits at doses up to 300 mg/kg/day and 40 mg/kg/day, respectively.</p> <p>Since controlled studies in pregnant women have not been conducted, the expected benefits of the medicinal product to the mother should be weighed against possible risks to the fetus.</p> <p><u>Lactation</u></p> <p>...</p>	<p>Pregnancy and Fertility, Lactation</p>
<p>Approximately one third of patients experience adverse reactions, usually transient, during the first few days after chip insertion. These may also be due to the mechanical placement of the dental insert in the periodontal pocket or as a result of the preceding scaling procedure. The most commonly reported are gastrointestinal</p>	<p>Approximately one third of patients experience adverse reactions, usually transient, during the first few days after chip insertion. These may also be due to the mechanical placement</p>	<p>Adverse events</p>

<p>system disorders: dental, gingival or oral soft tissue reactions or are otherwise described as application site reactions.</p> <p>Adverse reactions have been ranked under headings of frequency using the following convention:</p> <p>very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); frequency not known (cannot be estimated from the available data)</p> <p>Infections and infestations:</p> <p>Uncommon: Upper respiratory tract infection</p> <p>Immune disorders:</p> <p>Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4)</p> <p>Blood and lymphatic system disorders:</p> <p>Uncommon: Lymphadenopathy</p> <p>Nervous system disorders:</p> <p>Uncommon: Dizziness, neuralgia</p> <p>Gastrointestinal disorders:</p> <p>Very common: Toothache</p> <p>Common: Gingival swelling, gingival pain, gingival bleeding</p> <p>Uncommon: Gingival hyperplasia, gingival recession, gingival pruritus, mouth ulceration, sensitivity of teeth</p> <p>Skin disorders:</p> <p>Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters</p> <p>General disorders and administration site conditions:</p> <p>Uncommon: Malaise, influenza like illness, pyrexia</p>	<p>of the dental insert in the periodontal pocket or as a result of the preceding scaling procedure. The most commonly reported are gastrointestinal system disorders: dental, gingival or oral soft tissue reactions or are otherwise described as application site reactions.</p> <p>Adverse reactions have been ranked under headings of frequency using the following convention:</p> <p>very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$)</p> <p>Infections and infestations:</p> <p>Uncommon: Upper respiratory tract infection</p> <p>Blood and lymphatic system disorders:</p> <p>Uncommon: Lymphadenopathy</p> <p>Nervous system disorders:</p> <p>Uncommon: Dizziness, neuralgia</p> <p>Gastrointestinal disorders:</p> <p>Very common: Toothache</p> <p>Common: Gingival swelling, gingival pain, gingival bleeding</p> <p>Uncommon: Gingival hyperplasia, gingival</p>	
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<p>In respect to toothache, the following adverse reactions were also observed in clinical trials: dental or mouth pain, tenderness, aching, throbbing, soreness, or discomfort.</p> <p>The following adverse events were observed in clinical trials with no significance when compared to placebo: headache, sinusitis, back pain, tooth disorder (Includes broken, cracked or fractured teeth, mobile teeth, and lost bridges, crowns, or fillings), bronchitis, abscess, pain, allergy, myalgia, pharyngitis, arthralgia, dysmenorrhea, dyspepsia, rhinitis, coughing, arthrosis, hypertension, stomatitis ulcerative, tendinitis.</p> <p>The following adverse reactions have been derived from post-marketing reports on Periochip: systemic hypersensitivity, anaphylactoid reaction, soft tissue necrosis, cellulitis and abscess related to the application site, loss of taste and gingival discoloration.</p> <p><u>Reporting of suspected adverse reactions</u></p> <p>Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL) and also to Dexcel® Pharma Technologies Ltd. (see address at the end of the leaflet).</p>	<p>recession, gingival pruritus, mouth ulceration, sensitivity of teeth</p> <p>General disorders and administration site conditions:</p> <p>Uncommon: Malaise, influenza like illness, pyrexia</p> <p>The following adverse reactions have been derived from post-marketing reports: systemic hypersensitivity, soft tissue necrosis, cellulitis and abscess related to the application site, loss of taste and gingival discoloration.</p>	
		Overdose