



תאריך: 05/06/2019

**הודעה לצוות הרפואי**

**הנדון:**

**החמרות שנוספו לעלון לרופא של התכשירים הנ"ל:**

**שם התכשיר ומספר הרישום:**

**NEXOBRID 2 G POWDER AND 20 G GEL**

**נקסובריד 2 גר' אבקה ו20 גר' ג'ל**

**152-30-33685-00**

**NEXOBRID 5 G POWDER AND 50 G GEL**

**נקסובריד 5 גר' אבקה ו50 גר' ג'ל**

**152-31-33686-00**

**התוויה:**

NexoBrid is indicated for removal of eschar in adults with deep partial- and full-thickness thermal burns.

**הרכב:**

Concentrate of proteolytic enzymes enriched in Bromelain.

**שם בעל הרישום:**

**MEDIWOUND LTD, ISRAEL – מדיוונד ישראל בע"מ**



**מהות ופירוט השינויים:**

פרק בעלון	טקסט נוכחי	טקסט חדש
<b>Posology, dosage &amp; administration</b>	<p><i>Renal impairment</i> There is no information on the use of NexoBrid in patients with renal impairment</p> <p><i>Hepatic impairment</i> There is no information on the use of NexoBrid in patients with hepatic impairment.</p> <p><i>Preparation of patient and wound area</i> To prevent possible irritation of abraded skin by inadvertent contact with NexoBrid, such areas can be protected by a layer of a sterile fatty ointment.</p>	<p><i>Renal impairment</i> There is no information on the use of NexoBrid in patients with renal impairment. <b>These patients should be carefully monitored.</b></p> <p><i>Hepatic impairment</i> There is no information on the use of NexoBrid in patients with hepatic impairment. <b>These patients should be carefully monitored.</b></p> <p><i>Preparation of patient and wound area</i> To prevent possible irritation of abraded skin <b>by inadvertent contact with NexoBrid and possible bleeding from the wound bed, acute wound areas such as lacerations or escharotomy incisions should be protected by a layer of a sterile fatty ointment or fatty dressing (e.g. petrolatum gauze).</b></p>



<p><b>Special Warnings and special Precautions for Use</b></p>	<p>There is limited information on the use of NexoBrid on facial burn wounds. NexoBrid must be used with caution in such patients.</p> <p><u>Hypersensitivity reactions, skin exposure</u></p> <p>There are limited clinical data to assess the sensitisation potential of NexoBrid. Allergic reactions to bromelain (including anaphylactic reactions and other immediate-type reactions with manifestations such as bronchospasm, angiooedema, urticaria, and mucosal and gastrointestinal reactions) have been reported in the literature. Suspected sensitisation following oral exposure and following repeated occupational airway exposure has been reported. In addition, a delayed-type allergic skin reaction (cheilitis) after longer-term dermal exposure (mouthwash) has been reported.</p>	<p>There is limited information on the use of NexoBrid on facial burn wounds. NexoBrid must be used with caution in such patients.</p> <p><b>NexoBrid must be used with caution in such patients. Eyes should be carefully protected during treatment of facial burns using adhesive barrier petroleum ointment.</b></p> <p><u>Hypersensitivity reactions, skin exposure</u></p> <p><b>There have been reports of serious allergic reactions including anaphylaxis (with manifestations such as rash, erythema, hypotension, tachycardia) in patients undergoing debridement with NexoBrid. Allergic reactions to bromelain have been reported in the literature (including anaphylactic reactions and other immediate-type reactions with manifestations such as bronchospasm, angiooedema, urticaria, and mucosal and gastrointestinal reactions). In addition, a delayed-type allergic skin reaction (cheilitis) after longer-term dermal exposure (mouthwash) as well as suspected sensitisation following oral exposure and following repeated occupational airway exposure have been reported.</b></p>
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<b>Interaction with Other Medicaments and Other Forms of Interaction</b>	<p>Bromelain may enhance the actions of fluorouracil and vincristine.</p> <p>Bromelain may enhance the hypotensive effect of ACE inhibitors, causing larger decreases in blood pressure than expected.</p> <p>Bromelain may increase drowsiness caused by some medicinal products (e.g., benzodiazepines, barbiturates, narcotics and antidepressants).</p>	<p>Bromelain may enhance the actions of fluorouracil and vincristine. <b>Patients should be monitored for increased toxicity.</b></p> <p>Bromelain may enhance the hypotensive effect of ACE inhibitors, causing larger decreases in blood pressure than expected. <b>Blood pressure should be monitored in patients receiving ACE inhibitors.</b></p> <p>Bromelain may increase drowsiness caused by some medicinal products (e.g., benzodiazepines, barbiturates, narcotics and antidepressants). <b>This should be taken into account when dosing such products.</b></p>
<b>Pregnancy and Fertility, Lactation</b>	<p>It is unknown whether concentrate of proteolytic enzymes enriched in bromelain or its metabolites are excreted in human milk. A risk to newborns/infants cannot be excluded. Breast-feeding should be discontinued for at least 4 days after NexoBrid application.</p>	<p>It is unknown whether concentrate of proteolytic enzymes enriched in bromelain or its metabolites are excreted in human milk. A risk to newborns/infants cannot be excluded. Breast-feeding should be discontinued <b>at least 4 days form NexoBrid application initiation.</b></p>



<b>Adverse events</b>	<i>Skin and subcutaneous tissue disorders/ Injury, poisoning and procedural complications</i>	<i>Skin and subcutaneous tissue disorders\ <del>Injury, poisoning and procedural complications</del></i>  <b>New text: <i>Immune system disorders</i></b>  <b>Not known:      Serious allergic reactions including anaphylaxis</b>
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העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.