

הנדון: שינוי באביזר המצורף לאריזת התכשיר

Octaplex 500 IU (138-74-31775)
POWDER AND SOLVENT FOR SOLUTION FOR INFUSION

Active ingredients:

חומרים פעילים:

COAGULATION FACTOR IX (HUMAN) (after reconstitution with 20 ml solvent)	25 IU/ML
COAGULATION FACTOR II (HUMAN) (after reconstitution with 20 ml solvent)	14 – 38 IU/ML
COAGULATION FACTOR VII (HUMAN) (after reconstitution with 20 ml solvent)	9 – 24 IU/ML
COAGULATION FACTOR X (HUMAN) (after reconstitution with 20 ml solvent)	18-30 IU/ML
PROTEIN (after reconstitution with 20 ml solvent)	13-41 MG/ML
PROTEIN C (after reconstitution with 20 ml solvent)	13-31 IU/ML
PROTEIN S ANTIGEN (after reconstitution with 20 ml solvent)	12-32 IU/ML

להלן נוסח ההתוויה המאושר לתכשיר:

Treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors such as deficiency caused by treatment with vitamin K antagonists or in case of overdose of vitamin K antagonists when rapid correction of the deficiency is required. Treatment of bleeding and perioperative prophylaxis in congenital deficiency of any of the vitamin K dependent coagulation factors when purified specific coagulation factor product is not available.

חברת דובר מבקשת להודיע על שינוי באריזות התכשיר Octaplex 500 IU : האריזות יכללו מעתה את אביזר ההעברה* Nextaro במקום האביזר Mix2Vial אשר נכלל בהן עד כה.

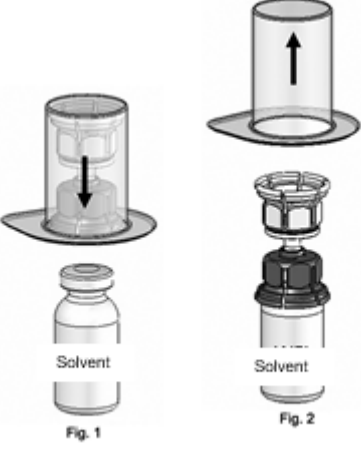
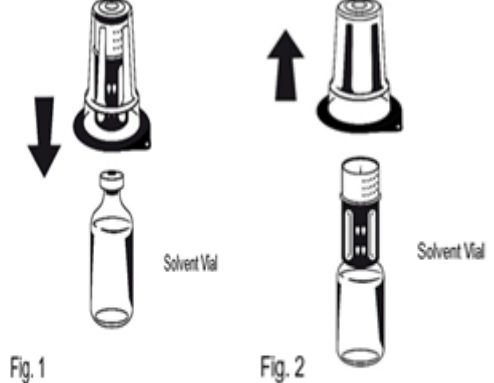
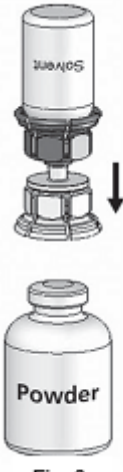
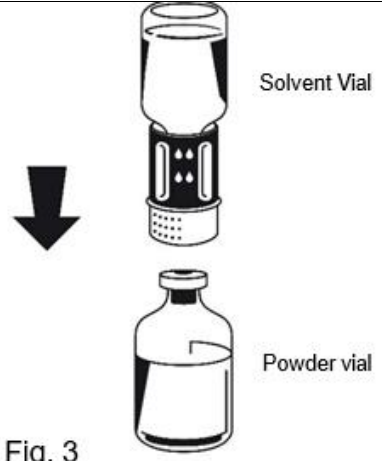
* אביזר העברה הינו האביזר המשמש להעברת הממס לאבקה בעת הכנת התכשיר.


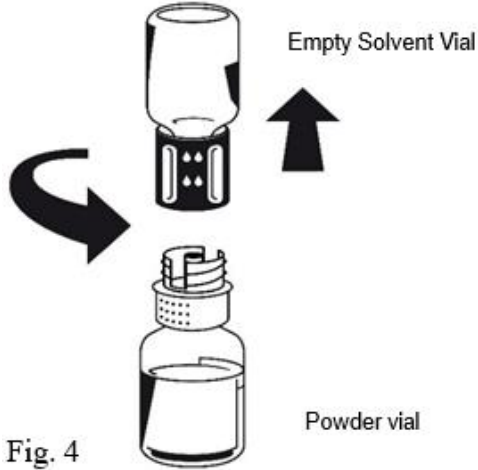
האביזר החדש אושר על ידי משרד הבריאות. עלון התכשיר עודכן בהתאם והוא נשלח לפרסום ב"מאגר התרופות" שבאתר משרד הבריאות. ניתן לקבל את העלון המודפס על ידי פנייה לבעל הרישום: דובר מכשור רפואי ומדעי בע"מ, רח' המעלות 11, הרצליה.

אופן השימוש באביזר החדש (Nextaro) כפי שמופיע בעלון המעודכן וכן השוואה לשימוש כפי שנעשה באביזר הקודם מפורט בטבלה המופיעה בהמשך הודעה זו: העדכונים הרלוונטיים מופיעים מסומנים בעמודה "NEW".

בברכה,
רבקה סלונים, רוקחת ממונה

Current	NEW
<p>6.5 Nature and contents of container</p> <p>One package of Octaplex 500 IU contains:</p> <ul style="list-style-type: none"> - Powder in a vial (type I glass) with a stopper (halobutyl rubber) and a flip off cap (aluminium) - 20 mL of Water for Injections in a vial (type I glass) with a stopper (halobutyl rubber) and a flip off cap (aluminium) - 1 Transfer set Mix2Vial™. 	<p>6.5 Nature and contents of container</p> <p>One package of Octaplex 500 IU contains:</p> <ul style="list-style-type: none"> - Powder in a vial (type I glass) with a stopper (halobutyl rubber) and a flip off cap (aluminium) - 20 mL of Water for Injections in a vial (type I glass) with a stopper (halobutyl rubber) and a flip off cap (aluminium) - 1 <u>Nextaro® transfer device</u> Transfer set Mix2Vial™.
<p>6.6 Instructions for use and handling and disposal [...]</p>	<p>6.6 Instructions for use and handling and disposal [...]</p>
<p><u>Instructions for reconstitution:</u></p> <p>1. If necessary, allow the solvent (Water for Injections) and the powder in the closed vials to reach room temperature. This temperature should be maintained during reconstitution. If a water bath is used for warming, care must be taken to avoid water coming into contact with the rubber stoppers or the caps of the vials. The temperature of the water bath should not exceed 37°C.</p>	<p><u>Instructions for reconstitution:</u></p> <p>1. If necessary, allow the solvent (Water for Injections) and the powder in the closed vials to reach room temperature. This temperature should be maintained during reconstitution. If a water bath is used for warming, care must be taken to avoid water coming into contact with the rubber stoppers or the caps of the vials. The temperature of the water bath should not exceed 37°C.</p>
<p>2. Remove the caps from the powder vial and the water vial and clean the rubber stoppers with an alcohol swab.</p>	<p>2. Remove the <u>flip off</u> caps from the powder vial and the <u>water-solvent</u> vial and <u>clean/disinfect</u> the rubber stoppers with an alcohol swab <u>appropriately</u>.</p>
<p>3. Peel away the lid of the outer package of the Mix2Vial™. Place the solvent vial on an even surface and hold it firmly. Place the blue part of the Mix2Vial™ on top of the solvent vial and press firmly down until it snaps (Fig. 1). While holding onto the solvent vial, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ attached firmly to the solvent vial (Fig. 2).</p>	<p>3. Peel away the lid of the outer package of the <u>Nextaro® Mix2Vial™</u>. Place the solvent vial on an even <u>-</u>surface and hold it firmly. Place the blue part of the Mix2Vial™ on top of the solvent vial and press firmly down until it snaps (Fig. 1). While holding onto the solvent vial, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ attached firmly to the solvent vial (Fig. 2).</p> <p><u>Without removing the outer package, place the blue part of the Nextaro® on top of the solvent vial and press firmly down until it snaps (Fig. 1). Do not twist while attaching!</u></p>

	<p><u>While holding onto the solvent vial, carefully remove the outer package from the Nextaro®, being careful to leave the Nextaro® attached firmly to the solvent vial (Fig. 2).</u></p>
 <p>Fig. 1</p> <p>Fig. 2</p>	 <p>Fig. 1</p> <p>Fig. 2</p>
<p>4. Place the powder vial on an even surface and hold it firmly. Take the solvent vial with the attached Mix2Vial™ and turn it upside down. Place the transparent part on top of the powder vial and press firmly down until it snaps (Fig. 3). The solvent flows automatically into the powder vial.</p>	<p>4. Place the powder vial on an even surface and hold it firmly. Take the solvent vial with the attached <u>Nextaro® Mix2Vial™</u> and turn it upside down. Place the <u>whitetransparent</u> part of the <u>Nextaro® connector</u> on top of the powder vial and press firmly down until it snaps (Fig. 3). <u>Do not twist while attaching!</u> The solvent flows automatically into the powder vial</p>
 <p>Fig. 3</p>	 <p>Fig. 3</p>
<p>5. With both vials still attached, gently swirl the powder vial until the product is dissolved. Octaplex 500 IU dissolves quickly at room temperature to a colourless to slightly blue solution. Unscrew the Mix2Vial™ into two parts (Fig. 4). Dispose the empty solvent vial with the blue part of the Mix2Vial™.</p>	<p>5. With both vials still attached, gently swirl the powder vial until the product is dissolved. Octaplex 500 IU dissolves quickly at room temperature to a colourless to slightly blue solution. Unscrew the <u>Nextaro® Mix2Vial™</u> into two parts (Fig. 4). Dispose the empty solvent vial with the blue part of the <u>Nextaro® Mix2Vial™</u>.</p>

 <p>Fig. 4</p>	 <p>Fig. 4</p>
<p>If the powder fails to dissolve completely or an aggregate is formed, do not use the preparation.</p>	<p>If the powder fails to dissolve completely or an aggregate is formed, do not use the preparation.</p>
<p><u>Instructions for infusion:</u> As a precautionary measure, the patients pulse rate should be measured before and during the infusion. If a marked increase in the pulse rate occurs the infusion speed must be reduced or the administration must be interrupted.</p> <ol style="list-style-type: none"> 1. Attach a 20 ml syringe to the transparent part of the Mix2Vial™. Turn the vial upside down and draw the solution into the syringe. Once the solution has been transferred, firmly hold the plunger of the syringe (keeping it facing down) and remove the syringe from the Mix2Vial™. Dispose the Mix2Vial™ and the empty vial. 	<p><u>Instructions for infusion:</u> As a precautionary measure, the patients pulse rate should be measured before and during the infusion. If a marked increase in the pulse rate occurs the infusion speed must be reduced or the administration must be interrupted.</p> <ol style="list-style-type: none"> 1. Attach a 20 ml syringe to the <u>luerlock outlet on the white part of the Nextaro® transparent part of the Mix2Vial™</u>. Turn the vial upside down and draw the solution into the syringe. <p>Once the solution has been transferred, firmly hold the plunger of the syringe (keeping it facing down) and remove the syringe from the <u>Nextaro® Mix2Vial™</u>. Dispose the <u>Nextaro® Mix2Vial™</u> and the empty vial.</p>
<ol style="list-style-type: none"> 2. Disinfect the intended injection site with an alcohol swab 	<ol style="list-style-type: none"> 2. Disinfect the intended injection site <u>appropriately with an alcohol swab</u>
<ol style="list-style-type: none"> 3. Inject the solution intravenously at a slow speed: Initially 1 ml per minute, not faster than 2 - 3 ml per minute. <p>No blood must flow into the syringe due to the risk of formation of fibrin clots. The Mix2Vial™ is for single use only.</p>	<ol style="list-style-type: none"> 3. Inject the solution intravenously at a slow speed: Initially 1 ml per minute, not faster than 2 - 3 ml per minute. <p>No blood must flow into the syringe due to the risk of formation of fibrin clots. The <u>Nextaro® Mix2Vial™</u> is for single use only.</p>