

הודעה על החמרה (מידע בטיחות) בעלון לצרכן (מעודכן 05.2013)

תאריך 17/04/2016

שם תכשיר באנגלית ומספר הרישום Intratect 145-64-33138-00

שם בעל הרישום Kamada Ltd

טופס זה מיועד לפרוט החמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
		שם התכשיר וצורתו
		למה מיועדת התרופה
		אזהרות מיוחדות הנוגעות בשימוש בתרופה
		הריון והנקה:
		מידע חשוב לגבי חלק ממרכיבי התרופה
		כיצד תשתמש בתרופה
		אופן השימוש בתכשיר
<p>Tabulated list of adverse reactions</p> <p>Details of further spontaneously reported adverse reactions:</p> <p>Cardiac disorders: Angina pectoris (very rare)</p> <p>General disorders and administrations site conditions: Rigors (very rare)</p> <p>Immune system disorders: Anaphylactic shock (very rare), allergic reaction (very rare)</p> <p>Investigations: Blood pressure decreased (very rare)</p> <p>Musculoskeletal and connective tissue disorders: Back pain (very rare)</p> <p>Respiratory, thoracic and mediastinal disorders: Dyspnoe NOS (very rare)</p> <p>Vascular disorders: Shock (very rare)</p> <p>***</p>	<p>Details of further spontaneously reported adverse reactions:</p> <p>Cardiac disorders: Angina pectoris (very rare)</p> <p>General disorders and administrations site conditions: Rigors (very rare)</p> <p>Immune system disorders: Anaphylactic shock (very rare), allergic reaction (very rare)</p> <p>Investigations: Blood pressure decreased (very rare)</p> <p>Musculoskeletal and connective tissue disorders: Back pain (very rare)</p> <p>Respiratory, thoracic and mediastinal disorders: Dyspnoe NOS (very rare)</p> <p>Vascular disorders: Shock (very rare)</p> <p>***</p>	תופעות לוואי

<p>Tabulated list of adverse reactions</p> <p>The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level).</p> <p>Frequencies have been evaluated according to the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from the available data).</p> <p>***</p> <p>Details of further spontaneously reported adverse reactions:</p> <p>Frequency: not known (cannot be estimated from the available data)</p> <p>Cardiac disorders: Angina pectoris</p> <p>General disorders and administrations site conditions: Rigors</p> <p>Immune system disorders: Anaphylactic shock, allergic reaction</p> <p>Investigations: Blood pressure decreased</p> <p>Musculoskeletal and connective tissue disorders: Back pain</p> <p>Respiratory, thoracic and mediastinal disorders: Dyspnoe NOS</p> <p>Vascular disorders: Shock</p> <p>Blood and lymphatic system disorders: leukopenia</p> <p>Description of selected adverse reactions</p> <p>Product specific adverse reactions have not been reported.</p> <p>The reported adverse reactions for Intratect are in the expected profile for human normal immunoglobulins.</p>	<p>Tabulated list of adverse reactions</p> <p>The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level).</p> <p>Frequencies have been evaluated according to the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from the available data).</p> <p>***</p> <p>Description of selected adverse reactions</p> <p>Product specific adverse reactions have not been reported.</p> <p>The reported adverse reactions for Intratect are in the expected profile for human normal immunoglobulins.</p>	<p>איך לאחסן את התרופה</p>
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