

הנדון:

Entresto 50mg, 100mg, 200mg, film-coated tablets
אנטרסטו 50מ"ג, 100מ"ג, 200מ"ג, טבליות מצופות**התכשיר שבנדון רשום בישראל להתוויה הבאה:**

Entresto is indicated for the treatment of heart failure (NYHA class II-IV) in patients with systolic dysfunction.

Entresto has been shown to reduce the rate of cardiovascular death and heart failure hospitalisation compared to angiotensin-converting enzyme (ACE) inhibitor therapy.

המרכיבים הפעילים:

Entresto 50 mg film-coated tablet contains 24 mg sacubitril and 26 mg valsartan as sodium salt complex.

Entresto 100mg film-coated tablet contains 49 mg sacubitril and 51 mg valsartan as sodium salt complex.

Entresto 200mg film-coated tablet contains 97 mg sacubitril and 103 mg valsartan as sodium salt complex.

ברצוננו להודיעכם על עדכונים בעלון לרופא ובעלון לצרכן של התכשיר שבנדון.

העדכונים מפורטים להלן (קו תחתי משמעו תוספת טקסט, קו-מצה משמעו מחיקת טקסט, **החמרות** מודגשות בצהוב):

4.6 Fertility, pregnancy and lactation

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Breast-feeding

Limited data show that sacubitril and its active metabolite LBQ657 are excreted in human milk in very low amounts with an estimated relative infant dose of 0.01% for sacubitril and 0.46% for the active metabolite LBQ657 when administered to breast-feeding women at a dose of 24 mg/26 mg sacubitril/valsartan, twice daily. In the same data, valsartan was under the limit of detection. There is insufficient information on the effects of sacubitril/valsartan in newborns/infants.

~~It is not known whether sacubitril/valsartan is excreted in human milk. The components of Entresto, sacubitril and valsartan, were excreted in the milk of lactating rats (see section 5.3). Because of the potential risk for adverse reactions in breast-fed newborns/infants, Entresto is not recommended in women who are during breast-feeding. A decision should be made whether to abstain from breast feeding or to discontinue Entresto while breast feeding, taking into account the importance of sacubitril/valsartan to the mother.~~

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4.8 Undesirable effects

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Tabulated list of adverse reactions

Adverse reactions are ranked by System organ class and then by frequency with the most frequent first, using 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 (frequency cannot be estimated from the available data). Within each frequency

grouping, adverse reactions are ranked in order of decreasing seriousness.

Table 1 List of adverse reactions

System organ class	Preferred term	Frequency category
Blood and lymphatic system disorders	Anaemia	Common
Immune system disorders	Hypersensitivity	Uncommon
Metabolism and nutrition disorders	Hyperkalaemia*	Very common
	Hypokalaemia	Common
	Hypoglycaemia	Common
	Hyponatraemia	Uncommon
Psychiatric disorders	Hallucinations**	Rare
	Sleep disorders	Rare
	Paranoia	Very rare
Nervous system disorders	Dizziness	Common
	Headache	Common
	Syncope	Common
	Dizziness postural	Uncommon
	Myoclonus	Not known
Ear and labyrinth disorders	Vertigo	Common
Vascular disorders	Hypotension*	Very common
	Orthostatic hypotension	Common
Respiratory, thoracic and mediastinal disorders	Cough	Common
Gastrointestinal disorders	Diarrhoea	Common
	Nausea	Common
	Gastritis	Common
	Intestinal angioedema	Very rare
Skin and subcutaneous tissue disorders	Pruritus	Uncommon
	Rash	Uncommon
	Angioedema*	Uncommon
Renal and urinary disorders	Renal impairment*	Very common
	Renal failure (renal failure, acute renal failure)	Common
General disorders and administration site conditions	Fatigue	Common
	Asthenia	Common

עדכונים בעלון לצרכן**4. תופעות לוואי**

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תופעות לוואי ששכיחותן אינה ידועה *לא ניתן להעריך את התדירות מהנתונים הזמינים)
• **עוויתות שרירים פתאומיות ולא רצוניות (myoclonus)**

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העלונים לרופא ולצרכן כוללים שינויי עריכה / שינויים נוספים שאינם החמרות.

מומלץ לקרוא בעיון את כל תוכן העלונים, נא לעדכן את המטופלים במידע הרלוונטי להם.

העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על-ידי פניה לבעל הרישום.

בברכה,
נוברטיס ישראל בע"מ