מאי 2022

Praluent 75mg, 150mg

חומר פעיל:

Praluent 75mg - Alirocumab 75mg / 1mL
Praluent 150mg - Alirocumab 150mg / 1mL

ההתוויה המאושרת:

Primary hypercholesterolaemia and mixed dyslipidaemia

Praluent is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Established atherosclerotic cardiovascular disease

Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:

- in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לרופא.

העדכונים העיקריים הם:

5.1 Pharmacodynamic properties

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Neurocognitive function

A 96 week, randomized, double-blinded, placebo-controlled trial evaluated the effect of alirocumab on neurocognitive function after 96 weeks of treatment (~2 years) in patients with heterozygous familial hypercholesterolemia (HeFH) or non-familial hypercholesterolemia at high or very high cardiovascular risk.

Neurocognitive function was assessed using the Cambridge Neuropsychological Test Automated Battery (CANTAB). A total of 2171 patients were randomized; 1087 patients were treated with alirocumab 75 mg and/or 150 mg every 2 weeks and 1084 patients were treated with placebo. A majority (>80%) of patients in each group completed the 96-week,

double-blind treatment period.

Over the 96 weeks of treatment, alirocumab showed no effect on neurocognitive function. The percentage of patients who experienced neurocognitive disorders was low in the alirocumab (1.3%) treatment groups and comparable to placebo (1.7%). No safety concerns related to neurocognitive function were observed in patients treated with alirocumab who experienced either 2 consecutive LDL-C values <25 mg/dL (<0.65 mmol/L) or <15 mg/dL (<0.39 mmol/L) during the treatment period.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700 .

להלן הקישור לאתר משרד הבריאות: https://www.gov.il/he/service/israeli-drug-index

בברכה,

חברת סאנופי-אוונטיס ישראל בע"מ