יולי 2019

רופא/ה נכבד/ה

רוקח/ת נכבד/ה

חברת לילי מבקשת להודיעכם כי העלון לרופא של התכשירים Trulicity 0.75 mg ו-Trulicity 1.5 mg עודכן.

טקסט שהתווסף מודגש באדום וטקסט שהוסר מודגש ~~בכחול~~.

העלון המעודכן לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום:

אלי לילי ישראל בע"מ, השיזף 4, רעננה , טל': 09-9606234

בברכה,

ד"ר שוקן אבנר
רוקחת ממונה

Trulicity 0.75 mg, 1.5 mg solution for injection in pre filled pen
טרוליסיטי 0.75 מ"ג, 1.5 מ"ג תמיסה להזרקה בעט מוכן לשימוש

Each pre-filled pen contains: 0.75 mg Dulaglutide in 0.5 ml solution

Each pre-filled pen contains: 1.5 mg Dulaglutide in 0.5 ml solution

ההתוויה המאושרת לתכשיר:

Trulicity is indicated in adults with type 2 diabetes mellitus to improve glycaemic control as:

Monotherapy:

When diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to intolerance or contraindications.

Add on therapy:

In combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

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העדכונים העיקריים בעלון לרופא הינם:

4.2 Posology and method of administration

Posology

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Renal impairment

No dosage adjustment is required in patients with mild, ~~or~~ moderate or severe renal impairment (eGFR <90 to ≥15 mL/min/1.73m^2).

There is very limited experience in patients with ~~severe renal impairment (eGFR [by CKD-EPI] < 30 ml/min/1.73 m^2) or~~ end stage renal disease (<15 ml/min/1.73m^2), therefore Trulicity ~~is~~ can not be recommended in this population (see sections 5.1 and 5.2).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Special populations

Use in patients with renal impairment

In a 52 week study, Trulicity 1.5 mg and 0.75 mg were compared to titrated insulin glargine as add-on to prandial insulin lispro to evaluate the effect on glycaemic control and safety of patients with moderate to severe chronic kidney disease (eGFR [by CKD-EPI] <60 and ≥15 mL/min/1.73 m^2). Patients discontinued their prestudy insulin regimen at randomisation. At baseline, overall mean eGFR was 38 mL/min/1.73 m^2, 30% of patients had eGFR < 30 mL/min/1.73 m^2.

At 26 weeks, both Trulicity 1.5 mg and 0.75 mg were non-inferior to insulin glargine in lowering of HbA1c and this effect was sustained at 52 weeks. A similar percentage of patients achieved HbA1c targets of < 8.0 % at 26 and 52 weeks with both dulaglutide doses as well as insulin glargine.

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Table 10: Results of a 52 week active controlled study with two doses of dulaglutide in comparison to insulin glargine (in patients with moderate to severe chronic kidney disease)

	Baseline HbA1c (%)	Mean change in HbA1c (%)	Patients at target HbA1c <8.0% (%)	Change in FBG (mmol/L)	Change in body weight (kg)
26 weeks					
Dulaglutide 1.5 mg once weekly (n=192)	8.60	-1.19†	78.3	1.28##	-2.81##
Dulaglutide 0.75 mg once weekly (n=190)	8.58	-1.12†	72.6	0.98##	-2.02##
Insulin glargine+ once daily (n=194)	8.56	-1.13	75.3	-1.06	1.11
52 weeks					
Dulaglutide 1.5 mg once weekly (n=192)	8.60	-1.10†	69.1	1.57##	-2.66##
Dulaglutide 0.75 mg once weekly (n=190)	8.58	-1.10†	69.5	1.15##	-1.71##
Insulin glargine+ once daily (n=194)	8.56	-1.00	70.3	-0.35	1.57

† 1-sided p-value < 0.025, for non-inferiority of dulaglutide to insulin glargine

p < 0.001 dulaglutide treatment group compared to insulin glargine

+ Insulin glargine doses were adjusted utilizing an algorithm with a fasting plasma glucose target of ≤ 8.3 mmol/L

The rates of documented symptomatic hypoglycaemia with Trulicity 1.5 mg and Trulicity 0.75 mg, and insulin glargine were 4.44, 4.34, and 9.62 episodes/patient/year, respectively. No patients reported cases of severe hypoglycaemia with Trulicity 1.5 mg, six with Trulicity 0.75 mg, and seventeen with insulin glargine. The safety profile of Trulicity in patients with renal impairment was similar to that observed in other studies with Trulicity.

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