אפריל 2023

TOUJEO solution for injection

חומר פעיל: INSULIN GLARGINE 300 U/ML

חברת סאנופי אוונטיס מבקשת להודיע על שכך שאושרה הרחבת ההתוויה לטיפול בתכשיר לילדים מגיל 6 שנים.

ההתוויה העדכנית הינה:

Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

עלוני התכשיר עודכנו בהתאם באפריל 2023.

העדכונים העיקריים **בעלון לרופא** הינם:

4.1 Therapeutic indications

Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

4.2 Posology and method of administration

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Special populations

Toujeo can be used in elderly people, renal and hepatic impaired patients, and children and adolescents from the age of 6 years.

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Paediatric population

Toujeo can be used in adolescents and children from the age of 6 years based on the same principles as for adult patients (see sections 5.1and 5.2). When switching basal insulin to Toujeo, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to mimimize the risk of hypoglycaemia (see section 4.4). The safety and efficacy of Toujeo in children below 6 years of age have not been established. No data are available

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4.8 Undesirable effects

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Paediatric population

Safety and efficacy of Toujeo have been demonstrated in a study in children aged 6 to less than 18 years. The frequency, type and severity of adverse reactions in the paediatric population do not indicate differences to the experience in the general diabetes population (see section 5.1). Clinical study safety data are not available for children under 6 years.

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5.1 Pharmacodynamic properties

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Pediatric population
The efficacy and safety of Toujeo have been studied in a 1:1 randomized controlled open label clinical trial in children and adolescents with type 1 diabetes mellitus for a period of 26 weeks (n=463). Patients in the Toujeo arm included 73 children aged <12 years and 160 children aged >12 years.
Toujeo dosed once daily showed similar reduction in HbA1c and FPG from baseline to week 26 compared to insulin glargine 100 units/mL.

The dose-response analysis showed that following the initial titration phase, the body weight adjusted doses in pediatric patients are higher than in adult patients at steady state.

Overall the incidence of hypoglycaemia in patients in any category was similar in both treatment groups, with 97.9% of patients in the Toujeo group and 98.2% in the insulin glargine 100 units/mL group reporting at least one event. Similarly, nocturnal hypoglycaemia was comparable in the Toujeo and insulin glargine 100 units/mL treatment groups. The percentage of patients reporting severe hypoglycaemia was lower in patients in the Toujeo group as compared to patients in the insulin glargine 100 units/mL group, 6% and 8.8% respectively. The percentage of patients with hyperglycaemic episodes with ketosis was lower for Toujeo versus insulin glargine 100 units/mL, 6.4% and 11.8%, respectively. No safety issues were identified with Toujeo with respect to adverse events and standard safety parameters. Antibody development was sparse and had no clinical impact. Efficacy and safety data for paediatric patients with type 2 diabetes mellitus have been extrapolated from data for adolescent and adult patients with type 1 diabetes mellitus and adult patients with type 2 diabetes mellitus. Results support the use of Toujeo in paediatric patients with type 2 diabetes mellitus.

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העדכונים העיקריים **בעלון לצרכן** הינם:

1. למה מיועדת התרופה?

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טוג'או משמשת לטיפול בסוכרת במבוגרים, מתבגרים וילדים מגיל 6 שנים. סוכרת הינה מחלה שבה הגוף לא מייצר מספיק אינסולין לשליטה על סוכר בדם.

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2. לפני השימוש בתרופה

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ילדים ומתבגרים
תרופה זו אינה מיועדת לילדים ומתבגרים מתחת לגיל 6 שנים. זאת כיוון שלא קיים נסיון עם טוג'או בקבוצת גיל זו.

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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים 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