יום שני 23 מרץ 2020

רופא/ה, רוקח/ת נכבד/ה,

הנדון: Simulect® 20 mg, Powder and solvent for solution for injection or infusion
מספר רישום 113-38-29524

אנו מבקשים להודיעך כי העלון לרופא לתכשיר שבנדון עודכן, כך שהינו נסמך על העלון לרופא התואם אשר אושר על-ידי רשות הבריאות האירופאית (EMA).

התכשיר מתווה בישראל להתוויה כדלקמן:

Simulect is indicated for the prophylaxis of acute organ rejection in de novo renal transplantation in combination with ciclosporin and corticosteroid based immunosuppression.

מרכיב פעיל: basiliximab

צורת מינון: Powder and solvent for solution for injection or infusion

בעמודים העוקבים מצויינים סעיפים בהם נעשה שינוי אשר מהווה החמרה מהיבטי בטיחות או שינוי משמעותי. למידע נוסף, יש לעיין בעלון לרופא המצורף כפי שאושר על ידי משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#!/byDrug

ניתן לקבלו מודפס על ידי פניה לחברת נוברטיס ישראל בע"מ, תוצרת הארץ 6, ת.ד. 7126, תל אביב
טל: 03-9201111, פקס: 03-9229230

בברכה,

ברוך גבריאלי
רוקח ממונה
נוברטיס ישראל בע"מ

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להלן פירוט השינויים העיקריים (טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן כטקסט אדום עם קו חוצה:)

בעלון לרופא:

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in 6.1.

Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

Patients receiving Simulect ~~should~~ **must** be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources including medications for the treatment of severe hypersensitivity reactions.

Immunosuppressive regimens involving combinations of medications increase the susceptibility to infection, including opportunistic infections, fatal infections and sepsis; the risk increased with total immunosuppressive load.

Simulect must not be administered unless it is absolutely certain that the patient will receive the graft and concomitant immunosuppression.

Hypersensitivity reactions

Severe acute (less than 24 hours) hypersensitivity reactions have been observed both on initial exposure to Simulect and on re-exposure to a subsequent course of therapy. These included anaphylactoid-type reactions such as rash, urticaria, pruritus, sneezing, wheezing, hypotension, tachycardia, dyspnoea, bronchospasm, pulmonary oedema, cardiac failure, respiratory failure and capillary leak syndrome. If a severe hypersensitivity reaction occurs, therapy with Simulect ~~should~~ **must** be permanently discontinued and no further dose be administered. Caution should be exercised when patients previously given Simulect are re-exposed to a subsequent course of therapy with this medicinal product.

There is accumulating evidence that a subgroup of patients is at an increased risk of developing hypersensitivity reactions. These are patients in whom, following the initial administration of Simulect, the concomitant immunosuppression was discontinued prematurely due, for example, to abandoned transplantation or early loss of the graft. Acute hypersensitivity reactions were observed on re-administration of Simulect for a subsequent transplantation in some of these patients.

Neoplasms and infections

Transplant patients receiving immunosuppressive regimens involving combinations with or without basiliximab are at increased risk of developing lymphoproliferative disorders (LPDs) (such as lymphoma) and opportunistic infections (such as cytomegalovirus [CMV], **BK virus**). In clinical trials, the incidence of opportunistic infections was similar in patients using immunosuppressive regimens with or without Simulect. In a pooled analysis of two five-year extension studies, no differences were found in the incidence of malignancies and LPDs between immunosuppressive regimens with or without combination of basiliximab (see section 4.8).

Vaccination

No data are available on either the effects of live and inactive vaccination or the transmission of infection by live vaccines in patients receiving Simulect. Nevertheless, live vaccines are not recommended for immunosuppressed patients. **The use of live attenuated vaccines should therefore be avoided in patients treated with Simulect.** Inactivated vaccines may be administered to immunosuppressed patients; however, response to the vaccine may depend on the degree of the immunosuppression, **therefore vaccination during treatment with Simulect may be less effective.**

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4.6 Fertility, pregnancy and lactation

Simulect is contraindicated in pregnancy and lactation (see section 4.3). Basiliximab has potentially hazardous immunosuppressive effects with respect to the course of gestation and the suckling neonate exposed to basiliximab in breast milk. Women of childbearing potential must use effective contraception during and up to 16 weeks after treatment.

~~There is no adequate information for use in pregnant women. Simulect should not be given to pregnant women except in cases where the potential benefit for the mother outweighs the potential risk for the fetus.~~

There is no animal or human data available concerning excretion of basiliximab into breast milk. However, ~~since Simulect is an immunoglobulin G (IgG1k) antibody, it may cross the human placenta and may be excreted in human milk.~~ **based on the IgG1 nature of basiliximab, excretion into milk should be expected. Breast-feeding must therefore be avoided.**

~~Women of childbearing potential should use adequate contraception to prevent pregnancy and continue its use for an additional 4 months after the last dose of Simulect.~~

~~No human data on the effect of basiliximab on fertility are available. Formal studies of the potential effect of Simulect on animal fertility have not been conducted (see section 13 Non-clinical safety data).~~

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6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

~~No known incompatibilities.~~

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