NOVARTIS

SIMULECT®

(basiliximab)

20 mg powder for solution for injection/infusion

Patient Information Leaflet

Document status: Final

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

SIMULECT® powder for solution for injection / infusion

Basiliximab 20 mg

Read all of this leaflet carefully before you are given SIMULECT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SIMULECT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT SIMULECT CONTAINS:

The active substance is basiliximab.

One vial contains 20 mg basiliximab (as protein).

The other ingredients are disodium hydrogen phosphate, anhydrous, glycine, mannitol, nitrogen, potassium dihydrogen phosphate, sodium chloride, sucrose.

Contains sugar (sucrose).

2. WHAT SIMULECT IS USED FOR:

SIMULECT is used to prevent acute organ rejection in kidney transplants in adult and paediatric patients. It is used in combination with other medicines to suppress the immune system and therefore prevent organ rejection.

3. BEFORE YOU ARE GIVEN SIMULECT:

You should not be given SIMULECT:

- If you are hypersensitive (allergic) to basiliximab or to any of the other ingredients of SIMULECT.

Take special care with SIMULECT:

- **SIMULECT** should be prescribed by experienced physicians only.
- Severe acute hypersensitivity reactions have been observed both on initial exposure and re-exposure.
- If you need to receive a vaccine, seek your doctor's advice first.

Using SIMULECT with food and drink:

SIMULECT can be taken with or without food, as it is injected directly into the body.

Pregnancy and Breastfeeding:

If you are pregnant or breast-feeding your baby while being given SIMULECT, please consult your doctor, pharmacist or other health care professional for advice before being given SIMULECT.

SIMULECT should not be used in pregnant and breastfeeding women.

Driving and using machinery:

SIMULECT is not expected to affect the ability to drive or use machines.

Important information about some of the ingredients of SIMULECT:

SIMULECT contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before being given SIMULECT.

Dosage in patients with kidney or liver impairment:

If you suffer from kidneys/liver that does not function normally, please consult your doctor or pharmacist before using **SIMULECT.**

Using other medicines with SIMULECT:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicine).

Because SIMULECT is an immunoglobulin, no metabolic medicine interactions are to be expected.

4. HOW SIMULECT IS GIVEN:

Adults:

SIMULECT will be given to you by your doctor at a suitable dose and also how you respond to the treatment.

Paediatrics:

SIMULECT will be given to the patient by the doctor at a suitable dose and also how they respond to the treatment.

If you are given more SIMULECT than you should:

In the event of overdosage, this will be determined by your medical practitioner.

When and for how long is SIMULECT given:

This will be determined by your medical practitioner.

5. POSSIBLE SIDE EFFECTS:

SIMULECT can have side effects.

Not all side effects reported for SIMULECT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SIMULECT, please consult your doctor, pharmacist or other health care professional for advice.

Check with your doctor if any of the following occur:

Nausea, diarrhoea, constipation, upper respiratory tract infection, urinary tract infection, pain, high blood pressure, headache and weight increase.

6. STORING AND DISPOSING OF SIMULECT:

Store all medicines out of reach of children.

Store under refrigerated conditions (2 to 8 °C).

Do not freeze.

SIMULECT which has been reconstituted with sterile water for injection is stable at 2 to 8 °C for 24 hours or at room temperature (25 °C or below) for 4 hours.

Discard the reconstituted solution if not used within the specified time.

KEEP OUT OF THE REACH OF CHILDREN.

7. PRESENTATION OF SIMULECT:

1 glass vial with blue flip-off cap containing 20 mg of medicinal substance.

8. IDENTIFICATION OF SIMULECT:

Glass vial containing a white, sterile freeze-dried powder for intravenous injection or infusion after reconstitution. The reconstituted solution is a clear to opalescent colourless solution.

9. REGISTRATION NUMBER:

32/30.4/0752

10. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

NOVARTIS SOUTH AFRICA (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

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2090

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11. DATE OF PUBLICATION:

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Manufacturers:

Novartis Pharma Stein AG

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