PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ORENCIA 250 mg lyophilisate for solution for infusion

Abatacept

ORENCIA contains sugar (maltose monohydrate) 525 mg per vial.

Read all of this leaflet carefully before you are given ORENCIA 250 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ORENCIA is and what it is used for
2. What you need to know before you use ORENCIA
3. How to use ORENCIA
4. Possible side effects
5. How to store ORENCIA
6. Contents of the pack and other information

1. What ORENCIA 250 mg is and what it is used for

ORENCIA contains the active substance abatacept, a protein produced in cell cultures. ORENCIA lessens the immune system's attack on normal tissues by interfering with the immune cells (called T lymphocytes) that contribute to the development of rheumatoid arthritis. ORENCIA selectively modulates the activation of T cells involved in the immune systems' inflammatory response.

ORENCIA is a medicine that is used to treat adults with active rheumatoid arthritis (RA) and for paediatric

patients 6 years of age and older with polyarticular juvenile idiopathic arthritis.

Rheumatoid Arthritis

Rheumatoid arthritis is a long-term progressive systemic disease that, if untreated, can lead to serious consequences, such as joint destruction, increased disability and impairment of daily activities. In people with rheumatoid arthritis the body's own immune system attacks normal body tissues, leading to pain and swelling of the joints. This can cause joint damage.

Polyarticular Juvenile Idiopathic Arthritis

Polyarticular juvenile idiopathic arthritis is a long-term inflammatory disease affecting one or more joints in children and adolescents.

2. What you need to know before you use ORENCIA 250 mg

ORENCIA should not be administered to you:

- if you are hypersensitive (allergic) to abatacept or any of the other ingredients of ORENCIA.
- if you have active or untreated tuberculosis (TB)
- if you are pregnant, plan to become pregnant, or are breastfeeding your baby (see **Pregnancy and breastfeeding and fertility**)

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, difficulty speaking, a change in the way you walk or problem with your balance, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be symptoms of a very rare, serious and potentially fatal brain infection called progressive multifocal leukoencephalopathy (PML).

- if you are taking a TNF blocker such as etanercept or infliximab to treat RA, as you have a greater chance of getting a serious infection if you take ORENCIA with other biologic medications for RA.
- if you are taking anakinra.
- if you have any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side-effects from ORENCIA. If you are unsure, please ask your doctor.
- if you have had tuberculosis (TB), a positive skin test for TB, or if you recently have been in close contact with someone who has had TB.
- if you develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Before you start ORENCIA, your doctor should examine you for TB and perform a skin test.
- if you have a history of chronic obstructive pulmonary (lung) disease (COPD).
- if you are scheduled to have surgery.
- if you recently received a vaccination or are scheduled for any vaccination. It is recommended that patients with polyarticular juvenile idiopathic arthritis, if possible, be brought up to date with all immunisations as per current immunisation guidelines before treatment with ORENCIA is started.
- if you have cancer, your doctor will decide if you can still be given ORENCIA.
- if you have viral hepatitis. Before you start ORENCIA, your doctor may examine you for hepatitis.
- if you have human immunodeficiency virus (HIV) infection.
- **if you have diabetes and use certain blood glucose monitors to check your blood glucose levels. ORENCIA contains maltose, which is a type of sugar that can give falsely high blood glucose readings with certain types of blood glucose monitors. Your doctor should recommend a different method for monitoring your blood glucose levels.**

Allergic reactions such as chest tightness, wheezing, severe dizziness or light-headedness, swelling or skin rash have been reported with ORENCIA.

Children and adolescents

ORENCIA is not recommended for use in patients below the age of 6 years.

Other medicines and ORENCIA 250 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ORENCIA should not be taken with biologic medications for RA, including TNF-blockers such as etanercept and infliximab. There is not enough evidence to recommend ORENCIA being given with anakinra.

ORENCIA can be used with other medicines commonly used to treat RA, such as steroids or painkillers, including non-steroidal anti-inflammatory medicines such as ibuprofen or diclofenac.

ORENCIA 250 mg with food and drink and alcohol

Not applicable

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

You should not receive ORENCIA if you are pregnant, plan to become pregnant, or are breastfeeding your baby.

Driving and using machines

Dizziness and impaired vision have been reported from patients treated with ORENCIA, therefore if a patient experiences such symptoms, driving and use of machinery should be avoided

It is not always possible to predict to what extent ORENCIA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the following activities (e.g driving, riding, flying, sailing, operating machines/equipment) until they are aware of the measure to which ORENCIA affects them.

ORENCIA 250 mg contains sugar (maltose)

ORENCIA 250 mg lyophilisate for solution for infusion contains maltose, which is a type of sugar that can give falsely high blood glucose readings with certain types of blood glucose monitors. Tell your doctor if you are diabetic.

3. How to use ORENCIA 250 mg

You will not be expected to give yourself ORENCIA. It will be given to you by a person who is qualified to do so.

The usual dose of ORENCIA is:

ORENCIA will be given to you by a healthcare professional by intravenous infusion (IV). It will take about 30 minutes to give you the full dose of medicine.

You will receive your first dose of ORENCIA followed by additional doses at 2 and 4 weeks after the first dose. You will then receive a dose every 4 weeks.

Your doctor will tell you how long your treatment with ORENCIA will last. Do not stop treatment early. If you have the impression that the effect of ORENCIA is too strong or too weak, tell your doctor or pharmacist.

If you receive more ORENCIA 250 mg than you should

Since a health care provider will administer ORENCIA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forgot to use ORENCIA 250 mg

Since a health care provider will administer ORENCIA, it is unlikely that the dose will be missed.

4. Possible side effects

ORENCIA can have side effects.

Not all side effects reported for ORENCIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ORENCIA, please consult your health care provider for advice.

If any of the following happens, stop receiving ORENCIA and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

Serious infections. Patients taking ORENCIA are at increased risk for developing infections including pneumonia, tuberculosis and other infections caused by viruses, bacteria, or fungi.

These are all very serious side effects. If you have them, you may have had a serious reaction to ORENCIA. You may need urgent medical attention or hospitalisation.

Cancer (malignancies). There have been cases of certain kinds of cancer in patients receiving ORENCIA. The role of ORENCIA in the development of cancer is not known.

The more frequent side effects with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea.

Tell your doctor or healthcare professional as soon as possible if you notice any of the following:

- feeling generally unwell, dental problems, burning sensation during urination, painful skin rash, painful skin blisters, coughing.

The symptoms described above can be signs of the side effects listed below, all of which have been observed with ORENCIA in adult clinical trials:

Frequent side effects:

- infections of the upper airway (including infections of the nose and throat)
- infections of lungs, urinary infections, painful skin blisters (herpes), rhinitis, painful sores on the lips and in the mouth
- headache, dizziness
- high blood pressure
- cough
- abdominal pain, diarrhoea, nausea, upset stomach
- rash
- fatigue, weakness
- abnormal liver function tests

Less frequent side effects:

- tooth infection, nail fungal infection, collection of pus under the skin
- skin cancer
- low blood platelet count, low white blood cells count
- depression, anxiety
- numbness
- reduced vision, eye inflammation
- palpitation, rapid heart rate, low heart rate
- low blood pressure, hot flush, flushing
- gastrointestinal infections
- increased tendency to bruise, dry skin, hair loss
- painful joints, pain in extremities

- absence of menstruation
- flu-like illness, increased weight
- ear and kidney infection

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who.umc.org) found on SAHRPA website. By reporting side effects, you can help provide more information on the safety of ORENCIA.

For reporting of side effects directly to the Holder of Certificate of Registration, please email:

pharmacovigilence@equitypharma.co.za

5. How to store ORENCIA 250 mg

Store all medicines out of reach of children.

Protect the vials from light by storing in the original package until time of use.

ORENCIA lyophilised powder must be refrigerated at 2 °C to 8 °C.

Do not use after the expiry date stated on the container.

Return unused medicine to the pharmacy.

6. Contents of the pack and other information

What ORENCIA contains

The active substance is abatacept.

The other ingredients are: maltose, monobasic sodium phosphate, sodium chloride.

What ORENCIA looks like and contents of the pack

ORENCIA 250 mg is a white to off-white, whole or fragmented cake.

Orencia 250 mg lyophilised powder for intravenous infusion is supplied as an individually packaged, single-use transparent type I glass vial with a polypropylene silicone-free disposable syringe. The product is available in a 15 ml vial providing 250 mg of abatacept.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

An electronic copy of the Professional Information (PI) is available on the Equity website http://www.equitypharmaceuticals.co.za or http://www.sahpra.org.za.