APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ACCORAN 6 mg/ml (Concentrate for solution for infusion)

Busulfan

Read all of this leaflet carefully before you are given Accoran

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

What is in this leaflet

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

1. What Accoran is and what it is used for

- Accoran contains the active substance busulfan, which belongs to a group of medicines called alkylating agents.
- Accoran is used in adults as treatment prior to transplantation in combination with cyclophosphamide.
- Accoran destroys the original bone marrow before the transplant.
- You will receive this preparative medicine before receiving a transplant of either bone marrow or haematopoietic progenitor cell.

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2. What you need to know before you use Accoran

You should not be administered Accoran

- If you are hypersensitive (allergic) to busulfan or any of the other ingredients of Accoran.
- If you are pregnant, or think you may be pregnant, or breastfeeding.
- If you have any liver problems.
- If you are a child or adolescent.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

- If you have received previous radiation therapy.
- If you have a history or you are at risk of developing seizures, or you have experienced trauma to your head.
- If you have any kidney problems.
- Inform your healthcare professional if you experience any coughing or difficulty breathing during your treatment with Accoran.

Accoran is a cytotoxic medicine that results in blood cells being decreased. You will have to have regular blood tests before and during your treatment with Accoran, to check your blood cell counts regularly. Your doctor may give you additional medicine, such as antibiotics, to prevent infections.

Children and adolescents

Do not give Accoran to children and adolescents, as it has not been studied in this population.

Other medicines and Accoran

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

- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
    - Itraconazole or metronidazole (used to treat fungal infections)
    - Ketobemidone (used to treat pain)
    - Paracetamol (used to treat pain) during the 72 hours prior to or with Accoran administration should be used with caution
    - Phenytoin (used for seizures)

Pregnancy, 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 healthcare provider for advice before taking this medicine.
- You should not use this medicine during pregnancy.
- Both men and women receiving Accoran must use effective contraception during and for up to 6 months after treatment. If, despite these measures, pregnancy occurs, tell your doctor immediately.
- You should not breast-feed while using Accoran. Discuss with your doctor when it is safe to restart breast-feeding after finishing your treatment.

Driving and using machines

- Accoran may cause dizziness.
- It is not always possible to predict to what extent Accoran may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Accoran affects them.

3. How to use Accoran

- Do not share medicines prescribed for you with any other person.
- Accoran will be given to as an intravenous injection (into a vein).

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- You will not be expected to give yourself Accoran. It will be given to you by a person who is qualified to do so.
- Your doctor will tell you how long your treatment with Accoran will last.
- If you have the impression that the effect of Accoran is too strong or too weak, tell your doctor or pharmacist.
- The dose of Accoran is calculated according to your body weight.
- The infusion is given over 2 hours.
- The dose is repeated every 6 hours for 4 consecutive days prior to transplant.
- Before you receive Accoran you will also be given anticonvulsive medicine (to prevent seizures) and antiemetics (to prevent vomiting).

If you take more Accoran than you should

Since a healthcare professional will administer Accoran, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take Accoran

Since a healthcare professional will administer Accoran, it is unlikely that the dose will be missed.

4. Possible side effects

- Accoran can have side effects.
- Not all side effects reported for Accoran are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Accoran, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Your doctor will monitor your blood counts and liver enzymes regularly to detect any serious side effects. However, tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fatigue, dizziness, shortness of breath, heart palpitations (your blood cell counts may be low)
- Fever, chills, body aches (you might have an infection)
- Stomach pain, increased stomach size, yellowing of skin (you may have a liver disorder)
- Skin rash, stomach pain or mouth ulcers (you may be experiencing a condition called Graft versus host disease, which can occur after a transplant)

These are all very serious side effects. You may need urgent medical attention.

- Tell your doctor if you notice any of the following:
  - Frequent side effects
    - Runny nose and sore throat
    - Weight loss
    - Feeling anxious, depressed and not able to sleep
    - Headache and dizziness
    - Faster heartbeat
    - High or low blood pressure
    - Difficulty breathing, cough, hiccups

- Nausea, vomiting, diarrhoea, stomach pain
- Indigestion, stomach or anal discomfort, vomiting blood
- Yellowing of skin accompanied by dark coloured urine, fever, chills (Jaundice)
- Muscle or back pain
- Pain when urinating, passing less urine, blood in urine
- Chills, fever, chest pain, pain at injection site, retention of water

o Less frequent side effects

- Confusion, feeling nervous, delirious and agitated
- Seizures
- Slowing of heartbeat
- Vomiting blood or blood in stool

- 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><or><,><pharmacist><or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Accoran.

5. How to store Accoran

- Store all medicines out of reach of children.
- This medicine is stored in the refrigerator at 2 - 8 °C.

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6. Contents of the pack and other information

What Accoran contains

- The active substance is busulfan.
- Each ml of concentrate contains 6 mg busulfan.
- Each vial contains 60 mg of busulfan.
- After dilution 1 ml of solution contains 0,5 mg busulfan.
- The other ingredients are dimethylacetamide and macrogol 400.

What Accoran looks like and contents of the pack

- Accoran is a clear, colourless solution free from visible particles.
- The solution is packed in a clear 10 ml glass vial (type I) with grey rubber stopper and sealed with aluminium purple flip-off seal packed in an outer carton.
- Pack size: 1 vial

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Building 2, Tuscany Office Park,

6 Coombe Place

Rivonia

Johannesburg

South Africa

This leaflet was last revised in

24/11/2020

Registration number

52/26/1000