1.3.2.1 Patient Information Leaflet

SCHEDULING STATUS

S4

DEFERIPRONE KEY (film-coated tablets)

Deferiprone, 500 mg

Read all of this leaflet carefully before you start taking DEFERIPRONE KEY

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

What is in this leaflet

1. What DEFERIPRONE KEY is and what it is used for

DEFERIPRONE KEY contains the active substance deferiprone. DEFERIPRONE KEY is an iron chelator, a type of medicine that removes excess iron from the body.

DEFERIPRONE KEY is used to treat iron overload caused by frequent blood transfusions in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate.

2. What you need to know before you take DEFERIPRONE KEY

Do not take DEFERIPRONE KEY:

- if you are hypersensitive (allergic) to deferiprone or any of the other ingredients of DEFERIPRONE KEY;
- if you have a history of repeated episodes of neutropenia (low white blood cell (neutrophil) count);
- if you have a history of agranulocytosis (very low white blood cell (neutrophil) count);
- if you are currently taking medicines known to cause neutropenia (a very low white blood cell count) or agranulocytosis (see *"Other medicines and DEFERIPRONE KEY"*);
- if you are pregnant or breastfeeding.

Take special care with DEFERIPRONE KEY:

- if you suffer from a condition known as neutropenia or agranulocytosis. This is a serious possible side effects that may occur while taking DEFERIPRONE KEY. Because white blood cells help to fight infection, a low neutrophil count may place you at risk of developing a serious and potentially life-threatening infection. To monitor for neutropenia, your doctor will ask you to have a blood test (to check your white blood cell count) performed regularly, as frequently as every week, while you

are being treated with DEFERIPRONE KEY. It is very important for you to keep all of these appointments. If you get any symptoms of infection such as fever, sore throat or flu-like symptoms, immediately seek medical attention. Your white blood cell count must be checked within 24 hours in order to detect potential agranulocytosis;

- if you are human immunodeficiency virus (HIV) positive, your doctor will monitor you carefully at the start of treatment;
- if your liver or kidney function is severely impaired, your doctor may recommend additional tests.

Children/ and adolescents

There are limited data available on the use of DEFERIPRONE KEY in children between 6 and 10 years of age, and no data on DEFERIPRONE KEY use in children under 6 years of age.

Other medicines and DEFERIPRONE KEY

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

Tell your doctor if you are taking any of the following medicines:

- Do not take medicines known to cause neutropenia or agranulocytosis (*see "Do not take DEFERIPRONE KEY")*.
- Do not take aluminium-based antacids at the same time as taking DEFERIPRONE KEY.

- Please consult with your doctor or pharmacist before taking vitamin C with DEFERIPRONE KEY.

DEFERIPRONE KEY with food and drink and alcohol

DEFERIPRONE KEY can be taken with or without food.

Pregnancy and breastfeeding and fertility

- You should not take DEFERIPRONE KEY if you are pregnant or breastfeeding your baby.
- DEFERIPRONE KEY could seriously harm your baby. You must use effective contraception while you are taking DEFERIPRONE KEY.
- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking DEFERIPRONE KEY.

Driving and using machinery

It is not always possible to predict to what extent DEFERIPRONE KEY 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 DEFERIPRONE KEY affects them.

3. How to take DEFERIPRONE KEY

Do not share medicines prescribed for you with any other person.

Always take DEFERIPRONE KEY exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- The amount of DEFERIPRONE KEY that you take will depend on your weight.
- The usual dose is 25 mg/kg, 3 times per day, for a total daily dose of 75 mg/kg. The total daily dose should not exceed 100 mg/kg.
- Take your first dose in the morning. Take your second dose midday. Take your third dose in the evening.
- DEFERIPRONE KEY can be taken with or without food.

Your doctor will tell you how long your treatment with DEFERIPRONE KEY will last.
If you have the impression that the effect of DEFERIPRONE KEY is too strong or too weak, tell your doctor or pharmacist.

If you take more DEFERIPRONE KEY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take DEFERIPRONE KEY

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DEFERIPRONE KEY can have side effects.

Not all side effects reported for DEFERIPRONE KEY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DEFERIPRONE KEY, please consult your healthcare professional for advice.

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

- Swelling of the 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 allergic reaction to DEFERIPRONE KEY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- The most serious side effect of DEFERIPRONE KEY is a very low white blood cell (neutrophil) count. This is a condition known as severe neutropenia or agranulocytosis. A low white blood cell count can be associated with a serious and potentially life-threatening infection. Report immediately to your healthcare professional any symptoms of infection such as: fever, sore throat or flu-like symptoms.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- abdominal pain;
- nausea;
- vomiting;
- reddish/brown discolouration of urine.
- headache;
- diarrhoea;
- increase in liver enzymes;
- fatigue;
- increase in appetite.

If you experience nausea or vomiting, it may help to take your DEFERIPRONE KEY with some food. Discoloured urine is a very common effect and is not harmful.

The following side effects have been reported but the frequency is unknown:

- allergic reactions including skin rash or hives.

Events of joint pain and swelling ranged from mild pain in one or more joints to severe disability. In most cases, the pain disappeared while patients continued taking DEFERIPRONE KEY.

Neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with movement coordination) have been reported in children who had been voluntarily prescribed more than double the maximum recommended dose of 100 mg/kg/day for several years and have also been observed in children with standard

doses of DEFERIPRONE KEY. The children recovered from these symptoms after DEFERIPRONE KEY discontinuation.

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 DEFERIPRONE KEY.

5. How to store DEFERIPRONE KEY

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package / container.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DEFERIPRONE KEY contains:

- The active substance is:

  Deferiprone

- The other ingredients are*:*

Tablet core:

Microcrystalline cellulose

Magnesium stearate

Colloidal anhydrous silica

Croscarmellose sodium

Hypromellose

Coating:

Hypromellose

Macrogol 6000

Titanium dioxide

What DEFERIPRONE KEY looks like and contents of the pack:

What DEFERIPRONE KEY looks like:

White to almost white, glossy surface oval-shaped film-coated tablets. The tablets have equal break marks on both sides. The tablet can be divided into two equal doses.

Contents of the pack:

DEFERIPRONE KEY is packed in blisters consisting of transparent, thermo-formable rigid PVC film, PVDC coated (PVC film: 250 µm/composite film: 274 µm) and aluminium foil (20 µm) with heat-sealing lacquer packed in a cardboard box.

Each blister strip contains 10 film-coated tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website www.sahpra.gov.za