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DESIDUSTAT DOSAGE

Document

OXEMIA™
Desidustat 25/50mg tablet
Let freedom flow

Desidustat - Dosing Document#

	Starting dose	Maximum dose limit	Dosage adjustment
Non-dialysis	100 mg orally thrice in a week [Dosing 2 days apart but not 4 days apart]	150 mg	According to the patient's haemoglobin (Hb) level every 4 weeks (Table 1)
Dialysis	**Erythropoiesis-stimulating Agent (ESA)-naïve patients:** 100 mg orally thrice in a week [Dosing 2 days apart but not 4 days apart] **ESA-experienced patients:** 100 mg or 125 mg or 150 mg thrice in a week [Dosing 2 days apart but not 4 days apart]	150 mg	ESA-experienced patients Based on previous Epoetin/ Darbepoetin/Methoxy polyethylene glycol-epoetin beta dose (Table 2)

- Desidustat dosing to be continued until Hb target attainment of 12 g is achieved
- In dialysis patient, Desidustat is recommended to be taken after completion of the dialysis session

Desidustat - Dose Adjustments Rules#

Change in Hb g% level every 4 weeks	Hb <10 g%	Hb 10 to <11 g%	Hb 11 to <12 g%	Hb ≥12 g%
<1.0 increase	Increase the dose	Increase the dose	Maintain the dose	Stop the treatment for 14 days, initiate one lower dose if Hb <11.5 g%
≥1.0 increase to ≤2.0 increase	Maintain the dose	Maintain the dose	Decrease the dose	
>2.0 increase	Maintain the dose	Decrease the dose	Decrease the dose	

- Change in Hb g% level was monitored every 2 weeks (first 8 weeks)
- 25 mg increase/decrease in the dose as per Hb level every 4 weeks

Desidustat - Starting Doses of Desidustat in Patients Converting from Epoetin/Darbepoetin/Methoxy Polyethylene Glycol-Epoetin Beta#

Epoetin (IU/week)	Darbepoetin (µg/week)	Methoxy polyethylene glycol-epoetin beta (µg/month)	Desidustat (mg, three times in a week)
<8000	<40	<120	100
8000 to 16000	40-80	120-200	125
>16000	>80	>200	150

Overdosage#

No incidence of overdose with Desidustat has been reported. In case of overdose with Desidustat, healthcare professional (HCP) to be consulted if symptoms deteriorate. General supportive care of the patient is indicated, including monitoring of vital signs and observation of clinical status.

Missed dose#

When a patient misses a dose of Desidustat, next scheduled dose will be administered to the subjects. However, missed dose will not be administered to the subject.

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Reference: #Desidustat package insert dated 21st Feb 2022

Abbreviated Prescribing Information: Oxemia™.

Composition: Each uncoated tablet contains Desidustat 25 mg or 50 mg. **Indication:** Treatment of Anemia in Adult Patients with Chronic Kidney Disease (CKD) not on Dialysis and on Dialysis. **Dosage and administration:** For non dialysis patients, The starting dose of Desidustat is 100 mg (4 tablets of 25mg OR 2 Tablets of 50 mg) orally thrice in a week. For dialysis patients, The Starting dose of Desidustat is 100 mg (4 tablets of 25mg OR 2 Tablets of 50 mg) or 125 mg (5 tablets of 25mg OR 2 Tablets of 50 mg and 1 tablet of 25 mg) or 150 mg (6 tablets of 25mg OR 3 Tablets of 50 mg) thrice in a week. It is recommended that Desidustat is to be taken after completion of the dialysis session. **Contraindications:** Hypersensitivity to Desidustat or any of the excipients used in the formulation. **Special warnings and precautions for use:** No drug related severe or serious adverse event or any life-threatening condition which requires special attention observed during the study. **Drug interactions:** The in vitro assays did not reveal any significant inhibition of major drug metabolizing enzymes. **Pregnancy Category: C.** Nursing mothers should not use Desidustat because it is not known whether Desidustat is excreted into the breast milk. Safety and efficacy of Desidustat in pediatric patients have not been established.Desidustat should be used with caution in geriatric patients. **Adverse events:** Most common AEs (>2%) reported from phase III includes Gastrointestinal symptoms including nausea , vomiting and abdominal pain, Headache, UTIs, Pyrexia and Peripheral edema. **Overdose:** No incidence of overdose with Desidustat has been reported. In case of overdose with Desidustat, general supportive care of the patient is indicated, including monitoring of vital signs and observation of clinical status. **Storage and handing instructions:** Store below 30°C. Keep out of reach of children. **Shelf life:** 24 months. **FOR FULL INFORMATION, PLEASE REFER TO THE FULL PRESCRIBING INFORMATION**

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