Capazi™

Vericiguat Tablet

Presentation
Capazi™ 2.5: Each film coated tablet contains Vericiguat INN 2.5 mg.
Capazi™ 5: Each film coated tablet contains Vericiguat INN 5 mg.
Capazi™10: Each film coated tablet contains Vericiguat INN 10 mg.

Description
Vericiguat is a stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) signaling pathway. When NO binds to sGC, the enzyme catalyzes the synthesis of intracellular cyclic guanosine monophosphate (cGMP), a second messenger that plays a role in the regulation of vascular tone, cardiac contractility, and cardiac remodeling. Heart failure is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, independently of and synergistically with NO, vericiguat augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation.

Indication and usage
Vericiguat is indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

Dosage & Administration
The recommended starting dose of Vericiguat is 2.5 mg orally once daily with food. The dose should be doubled approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient. For patients who are unable to swallow whole tablets, Vericiguat may be crushed and mixed with water immediately before administration.

Side-effects
The most common side effects are-hypotension, orthostatic hypotension, anemia, syncope, nausea, dyspepsia and vomiting.

Precautions
• Embryo-Fetal Toxicity: Based on data from animal reproduction studies, Vericiguat may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised about the potential risk to a fetus. A pregnancy test must be obtained before the start of treatment. Females of reproductive potential should be advised to use effective contraception during treatment with Vericiguat and for at least one month after the final dose.

Contraindications
• Vericiguat is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators.
• Vericiguat is contraindicated in pregnancy.

Use in specific population
Pregnancy
Based on data from animal reproduction studies, Vericiguat may cause fetal harm when administered to a pregnant woman and is contraindicated during pregnancy. There are no available data with Vericiguat use in pregnant women.

Nursing Mothers
There are no data on the presence of Vericiguat in human milk, the effects on the breastfed infant, or the effects on milk production. Vericiguat is present in the milk of lactating rats and it is likely that Vericiguat or its metabolites are present in human milk. Because of the potential for serious adverse reactions in breastfed infants from Vericiguat, women are not advised to breastfeed during treatment with Vericiguat.

Females and Males of Reproductive Potential
Pregnancy Testing:
Pregnancy status must be verified in females of reproductive potential prior to initiating Vericiguat.

Contraception:
Females
Vericiguat may cause fetal harm when administered to a pregnant woman. Females of reproductive potential are advised to use effective contraception during treatment and for one month after the final dose.

Pediatric Use
Safety and effectiveness of Vericiguat have not been established in pediatric patients.

Geriatric Use
No dosage adjustment of Vericiguat is required in geriatric patients. In VICTORIA, a total of 1,596 (63%) patients treated with Vericiguat were 65 years and older, and 783 (31%) patients treated with Vericiguat were 75 years and older. No overall differences in safety or efficacy of Vericiguat were observed between patients aged 65 years and older compared to younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment
No dosage adjustment of Vericiguat is recommended in patients with estimated glomerular filtration rate (eGFR) ≥15 mL/min/1.73m2 who are not on dialysis.

Hepatic Impairment
No dosage adjustment of Vericiguat is recommended in patients with mild or moderate hepatic impairment. Vericiguat has not been studied in patients with severe hepatic impairment.

Drug Interaction
• Other Soluble Guanylate Cyclase Stimulators: Vericiguat is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators.
• PDE-5 Inhibitors: Concomitant use of Vericiguat with PDE-5 inhibitors is not recommended because of the potential for hypotension.

Overdose
Limited data are available with regard to overdosage in human patients treated with Vericiguat. In VICTORIA, doses up to 10 mg have been studied. In a study of patients with preserved ejection fraction heart failure (left ventricular ejection fraction ≥45%), multiple doses of Vericiguat 15 mg have been studied and were generally well tolerated. In the event of an overdose, hypotension may result. Symptomatic treatment should be provided. Vericiguat is unlikely to be removed by hemodialysis because of high protein binding.

Storage
Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack
Capazi™ 2.5: Each box contains 3 blister strips of 10 tablets.
Capazi™ 5: Each box contains 3 blister strips of 10 tablets.
Capazi™10: Each box contains 3 blister strips of 10 tablets.

Manufactured by
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