Abridged prescribing information:

WEMBIRA DT

COMPOSITION: Each Uncoated Tablet of WEMBIRA DT contains Abiraterone dispersible tablet 250 mg for oral use. Abiraterone is an inhibitor of CYP17 (17α-hydroxylase/C17,20-lyase). Abiraterone, an androgen biosynthesis inhibitor, that inhibits 17 α-hydroxylase/C17,20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumour tissues and is required for androgen biosynthesis. INDICATIONS: In combination with Prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer (CSPC). DOSAGE: Metastatic Castration – resistant Prostate cancer: Wembira DT 1,000 mg orally once daily with prednisone 5 mg orally twice daily. Metastatic castration-sensitive prostate cancer: Wembira DT 1,000 mg orally once daily with prednisone 5 mg orally once daily. ADMINISTRATION: WEMBIRA DT is taken orally by dissolving the tablet in 100 ml of Normal water at room temperature. The complete dissolved solution to be consumed within 30 minutes. CONTRAINDICATIONS: NONE. WARNINGS AND PRECAUTIONS: Closely monitor patients with cardiovascular disease, liver function, blood glucose in patients with diabetes, for more details please refer WEMBIRA DT prescribing information. Increased fractures and mortality in combination with radium Ra 223 dichloride: Use of WEMBIRA DT plus prednisone/prednisolone in combination with radium Ra 223 dichloride is not recommended. ADVERSE REACTIONS: The most common adverse reactions (≥10%) are fatigue, arthralgia, hypertension, nausea, edema, hypokalemia, hot flush, diarrhea, vomiting, upper respiratory infection, cough, and headache. The most common laboratory abnormalities (>20%) are anemia, elevated alkaline phosphatase, hypertriglyceridemia, lymphopenia, hypercholesterolemia, hyperglycemia, and hypokalemia. DRUG INTERACTIONS: Avoid concomitant strong CYP3A4 inducers during WEMBIRA DT treatment. If a strong CYP3A4 inducer must be co-administered, increase the WEMBIRA DT dosing frequency. Avoid co-administration of WEMBIRA DT with CYP2D6 substrates that have a narrow therapeutic index. If an alternative treatment cannot be used, exercise caution and consider a dose reduction of the concomitant CYP2D6 substrate. USE IN SPECIFIC POPULATIONS: Hepatic Impairment- Do not use WEMBIRA DT in patients with baseline severe hepatic impairment (Child-Pugh Class C). Renal Impairment- No dosage adjustment is necessary for patients with renal impairment. Pregnancy and Lactation- The safety and efficacy have not been established in females. Females and Males of Reproductive Potential, advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 weeks after the final dose of WEMBIRA DT. WEMBIRA DT may impair reproductive function and fertility in males of reproductive potential. Pediatric Use- Safety and effectiveness of WEMBIRA DT in pediatric patients have not been established. Geriatric Use- No overall differences in safety or effectiveness were observed between elderly and younger patients. OVERDOSAGE: There is no specific antidote. In the event of an overdose, stop WEMBIRA DT, undertake general supportive measures, including monitoring for arrhythmias and cardiac failure and assess liver function. STORAGE: Store at below 25°C, cool and dry place. PRESENTATION: WEMBIRA DT 250 mg is available in a strip of 10 tablets in Alu-Alu pack in a single monocarton. For further information, please contact us.