**Welcome to the CAPRELSA REMS Program**

CAPRELSA® (fencampasmine) Tablets, a kinase inhibitor, is approved by the Food and Drug Administration (FDA) for the treatment of symptomatic or asymptomatic prophylactic thyroid cancer in patients with selectable locoregional or metastatic disease. Use CAPRELSA in patients with indolent, asymptomatic, or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA.

CAPRELSA can prolong the QT interval and cases of torsades de pointes and sudden death have occurred in patients receiving CAPRELSA. Because of this risk, CAPRELSA is only available through the CAPRELSA REMS Risk Evaluation and Mitigation Strategy (REMS) Program. 

The CAPRELSA REMS Program has the following specific goals:

- To educate prescribers about the risk, appropriate monitoring, and management of QT prolongation to help minimize the occurrence of torsades de pointes and sudden death
- To inform patients about the serious risks associated with CAPRELSA

Under the CAPRELSA REMS Program, only certified prescribers can prescribe CAPRELSA.

**INDICATIONS AND USAGE**

CAPRELSA is a kinase inhibitor indicated for the treatment of symptomatic or asymptomatic prophylactic thyroid cancer in patients with selectable locoregional or metastatic disease. Use CAPRELSA in patients with indolent, asymptomatic, or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA.

**IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING, FOR CAPRELSA**

- Do not use in patients with congenital long QT syndrome
- CAPRELSA can prolong the QT interval in patients with a QT interval greater than 450 milliseconds or in patients with a known QT interval abnormality. Use CAPRELSA in patients with a QT interval greater than 450 milliseconds only after careful consideration of the treatment related risks of CAPRELSA.
- Do not initiate treatment in patients whose QT interval is greater than 450 milliseconds or in patients with a known QT interval abnormality. CAPRELSA has not been studied in patients with ventricular arrhythmias or in those with a history of QTc interval prolongation or torsades de pointes.
- Do not use CAPRELSA in patients with hypokalemia, hypomagnesemia, or long QT syndrome. Correct hypokalemia, hypomagnesemia and/or hypocalcemia prior to CAPRELSA administration.
- Monitor electrolytes periodically
- Avoid drugs known to prolong the QT interval
- Only prescribers and pharmacists certified with the restricted distribution program are able to prescribe and dispense CAPRELSA.

**WARNING: QT PROLONGATION, TORSADES DE POINTES, AND SUDDEN DEATH**

- CAPRELSA can prolong the QT interval and cases of torsades de pointes and sudden death have occurred in patients receiving CAPRELSA.
- Do not use CAPRELSA in patients with hypokalemia, hypomagnesemia, or long QT syndrome. Correct hypokalemia, hypomagnesemia and/or hypocalcemia prior to CAPRELSA administration.
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