

Information for the patient

- This card contains important safety information that you should know before you are given CAPRELSA and during treatment with CAPRELSA
- Show this card to any doctor involved in your treatment. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly to:
The National Pharmacovigilance Centre -NPC- Saudi Food and Drug Authority (SFDA)
Call Center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: <https://ade.sfd.gov.sa>



- For SANOFI Pharmacovigilance center, please contact: +966-544-284-797
 - E-mail: Ksa_pharmacovigilance@sanofi.com
- By reporting side effects you can help provide more information

CAPRELSA can cause a change in the electrical activity of your heart called **QTc prolongation**, which can cause irregular heartbeats and life-threatening changes in heart rhythm.

A condition called **posterior reversible encephalopathy syndrome (PRES; also known as reversible posterior leukoencephalopathy syndrome [RPLS])** can occur while taking CAPRELSA.

During CAPRELSA treatment, telephone your doctor or tell your caregiver immediately if you:

- Feel faint, dizzy or feel your heart beating irregularly, as these may be symptoms related to QTc prolongation
- Experience headaches, seizures, convulsions, confusion, problems seeing or problems to concentrate, as these may be symptoms of PRES

Do not stop taking CAPRELSA, or change your dose, unless told to by your doctor.
If you take too many CAPRELSA tablets, telephone your doctor immediately

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Patient AlertCard: **CAPRELSA®** (vandetanib)

- See the CAPRELSA Package Leaflet for more information
- Please make sure that you have a list of your other medications with you at any visit to your doctor

Patients name:.....

Caregiver's name:

Caregiver's telephone number:.....

Doctor's name:.....

Doctor's telephone number:.....

Start date of Caprelsa Treatment :.....

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA