

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 Medicines Authority. Report Form can be downloaded from <http://www.medicinesauthority.gov.mt/adrportal> and sent to Post-licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 Malta, or by e-mail to postlicensing.medicinesauthority@gov.mt
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
 - Alternatively any suspected adverse reactions can be reported to Sanofi Srl, Viale Luigi Bodio, 37/b - 20158 Milano, Italy at PharmacovigilanceMalta@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.

Patient's name:

Caregiver's name:

Caregiver's telephone number:

Doctor's name:

Doctor's telephone number:

Start date of CAPRELSA treatment:

See the CAPRELSA Package Leaflet for more information

Please make sure that you have a list of all your other medicines with you at any visit to your doctor

Patient Alert Card: **CAPRELSA[®]** **(vandetanib)**

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