

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCAPRELSA®

Vandetanib Tablets

Read this carefully before you start taking **CAPRELSA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CAPRELSA**.

Serious Warnings and Precautions

- CAPRELSA should only be prescribed by a healthcare professional who
 - has completed the certification with the CAPRELSA Restricted Distribution Program, and
 - who is experienced in the use of anti-cancer drugs and treating medullary thyroid cancer.
- CAPRELSA may cause serious side effects, including:
 - Heart rhythm changes. This irregular heart rhythm can lead to sudden death. This change in your heart rhythm is seen on a test (electrocardiogram). This is conducted by your healthcare professional. Do not use CAPRELSA if you have:
 - low levels of potassium, magnesium and calcium in your blood
 - a heart rhythm condition (also known as “QT prolongation”) or a family history of abnormal heart rhythm
 - Fatal heart failure
 - Severe high blood pressure event

What is CAPRELSA used for?

- CAPRELSA is used to treat adults with medullary thyroid cancer. CAPRELSA is used when the:
 - tumour cannot be removed by surgery or;
 - cancer has spread from the thyroid to other parts of the body.
- CAPRELSA is only available through a controlled program referred to as the CAPRELSA Restricted Distribution Program. Under this program, only patients who are enrolled and meet all of the requirements of the CAPRELSA Restricted Distribution Program can receive CAPRELSA. For further information about the program, please call 1-800-265-7927 or visit www.caprelsa.ca/rdp.

How does CAPRELSA work?

- CAPRELSA belongs to a group of drugs that specifically target growth and spread of certain types of cancer.
- CAPRELSA works by slowing down the growth of new blood vessels in these tumours (cancers). This cuts off the supply of food and oxygen to the tumour.
- CAPRELSA also acts directly on cancer cells to kill them or slow down their rate of growth.

What are the ingredients in CAPRELSA?

Medicinal ingredients: Vandetanib

Non-medicinal ingredients: calcium hydrogen phosphate dihydrate, crospovidone, hypromellose 2910, macrogol 300, magnesium stearate, microcrystalline cellulose, povidone, and titanium dioxide E171.

CAPRELSA comes in the following dosage forms:

Tablets: 100 mg and 300 mg

Do not use CAPRELSA if you:

- if you were born with a heart condition called ‘congenital long QT syndrome’. This is a heart disorder that exists before or at birth. This is seen on an electrocardiogram test and it is conducted by your healthcare professional;
- have low levels of potassium, magnesium, or calcium in your blood;
- have uncontrolled high blood pressure;
- are allergic to vandetanib or any of the other ingredients in CAPRELSA.

If you are not sure, talk to your doctor before taking CAPRELSA.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CAPRELSA. Talk about any health conditions or problems you may have, including if you have:

- Heart disease or a family history of heart disease;
- A personal history of fainting spells;
- High blood pressure and have a history of aneurysms (enlargement and weakening of a blood vessel wall);
- Recently experienced nose bleeds. Taking CAPRELSA can cause excessive bleeding, including fatal bleeding;
- Liver or kidney problems;
- A condition in which the thyroid gland does not make enough thyroid hormone (also known as “hypothyroidism”);
- A surgery planned before starting treatment or during treatment. Your healthcare professional will advise you on when to stop taking CAPRELSA before surgery and when you may restart taking CAPRELSA again.

Other warnings you should know about:

Stroke: Treatment with CAPRELSA may cause strokes, which can be fatal.

Diarrhea: Taking CAPRELSA may cause diarrhea. Your healthcare professional may:

- prescribe you anti-diarrhea medication.
- stop your treatment with CAPRELSA until your diarrhea improves.

Neurological problems: Taking CAPRELSA may cause a brain disorder called Reversible Posterior Leukoencephalopathy Syndrome. Speak to your healthcare professional if you experience seizures, headaches, visual disturbances, confusion or difficulty thinking.

Eye problems: CAPRELSA may cause blurred vision and cornea scarring. Your healthcare professional may conduct eye examinations to monitor your eye condition.

Driving and Using Machines: CAPRELSA can cause fatigue and vision problems. Before you drive or do tasks that require special attention, wait until you know how you respond to CAPRELSA.

Lung problems: CAPRELSA can cause Interstitial lung disease (lung tissue inflamed or scarred). This can lead to death. Speak to your healthcare professional right away if you experience any new or worsening breathing problems.

Skin problems: Taking CAPRELSA may cause skin problems, such as:

- Rashes or Hand-foot syndrome
- Sensitivity to the sun. While taking CAPRELSA and for four months after the last dose you should protect yourself from sun exposure. Use sun block and wear clothes that cover your skin, including your head, arms and legs when you go outdoors.
- Stevens-Johnson Syndrome and toxic epidermal necrolysis. Both conditions can lead to death.
- delays in the time it takes for your body to heal from skin wounds. Talk to your healthcare professional if you are considering surgery, including dental surgery.

Pregnancy and breastfeeding:

Female patients:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- CAPRELSA may harm an unborn child.
- If you are able to become pregnant
 - Avoid becoming pregnant while you are taking CAPRELSA. Use effective birth control during your treatment and for at least 3 months after your last dose
 - Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with CAPRELSA
- Do not breastfeed while taking CAPRELSA. If you are considering breastfeeding, you should talk to your healthcare professional.

Male Patients:

- Avoid fathering a child while you are taking CAPRELSA
- During your treatment with CAPRELSA, use effective birth control or be surgically sterile (vasectomy). Continue using an appropriate form of contraception until 2 months after your last dose.

Testing: Your healthcare professional will conduct the following tests to monitor your liver, heart and blood:

- blood tests to check the levels of Alanine aminotransferase, potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH)
- an electrocardiogram (ECG) to monitor your heart condition
- blood pressure

Serious Drug Interactions

- Avoid taking:
 - anti-arrhythmic medicines or medicines known to cause heart rhythm changes.
 - CYP3A4 inhibitors such as itraconazole

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CAPRELSA:

- Drugs known to cause heart rhythm changes;
- Antipsychotics or antidepressants (eg. St. John's Wort);
- A specific class of pain relieving medications;
- Specific classes of antibiotics;
- Antimalarials or a specific class of antifungals;
- Specific classes of anti-nausea medications;
- Specific classes of anticancer medications; or
- A specific class of asthma and chronic obstructive pulmonary disease medications.

Avoid taking products and juices containing grapefruit, star fruit, pomegranate, Seville oranges and other similar citrus fruits.

How to take CAPRELSA:

- Take CAPRELSA exactly as your healthcare professional tells you. You should check with your healthcare professional if you are not sure.
- Take CAPRELSA at about the same time each day.
- CAPRELSA may be taken with or without food.
- Do NOT crush the tablet.
- Avoid contact with broken or crushed tablets. If they touch your skin, wash the area well.

If you have trouble swallowing the tablet, you can mix it with water as follows:

- Take half a glass (50 mL) of still (non-carbonated) water. Only use water – not any other liquids.
- Put the tablet into the water. Do NOT crush the tablet.
- Stir the water until the tablet has dispersed into the water. This may take about 10 minutes.
- Drink it right away. To make sure there is no medicine left, rinse the empty glass very well with another half of a glass of water and drink it.
- This liquid can also be given by tubes connected to the nose or stomach

Usual dose:

Recommended Adult Dose: 300 mg once a day.

Your healthcare professional may temporarily stop your treatment or reduce the dose if you:

- have moderate to severe kidney disease
- experience certain side effects

Overdose:

If you think you, or a person you are caring for, have taken too much CAPRELSA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

What you should do if you forget to take a tablet depends on the length of time until your next dose.

- **If it is 12 hours or more until your next dose:** Take the missed tablet as soon as you remember. Then take the next dose at the normal time.
- **If it is less than 12 hours until your next dose:** Skip the missed dose. Then take the next dose at the normal time.

Do not take a double dose (two doses at the same time) to make up for a forgotten tablet.

What are possible side effects from using CAPRELSA?

These are not all the possible side effects you may have when taking CAPRELSA. If you experience any side effects not listed here, tell your healthcare professional.

- Abdominal pain
- Abnormal taste or changes in taste of foods
- Anorexia (loss of appetite)
- Back pain
- Cough
- Dehydration
- Depression
- Dry eye
- Dry mouth
- Feeling tired, lack of energy and/or muscle weakness
- High blood pressure, which may be severe
- Indigestion
- Irritation of the lining of the mouth or lips or tongue
- Joint pain/pain in the extremities
- Loss of hair
- Nail problems
- Nose bleed
- Sensitivity of the skin to sunlight
- Skin issues such as dry skin, itchiness, rash or acne
- Tremor

- Trouble sleeping
- Viral infection of the upper respiratory system
- Weight loss

CAPRELSA can cause abnormal blood tests and ECG results. Your healthcare professional will do blood tests and monitor your heart during your treatment

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help*
	Only if severe	In all cases	
VERY COMMON			
Nausea (sensation of having an urge to vomit or queasy stomach)		√	
Vomiting		√	
Severe diarrhea		√	
COMMON			
Pneumonia (infection in the lungs): chest pain when you breathe or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath		√	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		√	
hand-foot syndrome: red or swollen palms, thick calluses and blisters of the hands and soles of the feet, tingling or burning, tightness of the skin		√	
Conjunctivitis (an irritation of the inner eyelid or surface of the eye)	√		
Headaches	√		
Seizures		√	
Confusion or difficulty thinking		√	
Kidney problems: decreased urination, swelling in your legs, ankles or feet, fatigue and weakness.		√	
Severe skin reactions: redness, pain, ulcers, blisters and shedding of the skin		√	
RARE			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help*
	Only if severe	In all cases	
Visual disturbances: blurred vision, visual impairment		√	
Corneal opacity (mild changes in the eye which can lead to blurred vision)		√	
Conditions where the brain may not get enough blood: weakness, numbness or paralysis in your face, arm or leg, typically on one side of your body, slurred speech or difficulty understanding others, blindness in one or both eyes or double vision, loss of balance, severe headaches, vomiting, dizziness or altered consciousness.			√
Chest pain			√
Transient ischemic attack (stroke): Sudden weakness or paralysis on one side of the body, difficulty speaking, confusion, with difficulty understanding speech and dizziness or loss of balance and coordination			√
Laryngitis (inflammation of your voice box): unnatural change of voice, throat may tickle or feel raw, sore throat, fever, difficulty swallowing		√	
Sepsis (infection of the blood): fever or dizziness, chills, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat			√
Appendicitis (inflammation of the appendix): Sudden pain that begins on the right side of the lower abdomen, pain that worsens if you cough, walk or make other jarring movements, nausea and vomiting		√	
Cholecystitis (Inflammation of the gallbladder): fever, nausea, pain that radiates to your shoulder or back, severe pain in your upper right abdomen, vomiting		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help*
	Only if severe	In all cases	
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen		√	
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat			√
Gastrointestinal problems: diarrhea, abdominal discomfort, weight loss		√	
Easy bleeding or bruising, anemia (low number of red blood cells)		√	
Kidney stones: pain when urinating, severe pain in the side and back, below the ribs		√	
Heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			√
Glaucoma: increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, and changes in vision, Hazy or blurred vision, sudden sight loss.		√	
Stevens-Johnson syndrome (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			√
Toxic Epidermal Necrolysis (severe skin reaction): redness, blistering and/or peeling of large areas of the skin			√
Fainting		√	
Dizziness		√	
Sudden or worsening shortness of breath or cough		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help*
	Only if severe	In all cases	
Artery Dissection (a tear in a blood vessel wall): sudden severe pain in the back, chest or abdomen			√
Artery Aneurysm (a bulge in the wall of any artery): cough, coughing up blood; Strong pain high in your neck or in your back when you didn't hurt yourself; Problems swallowing; Hoarse voice; Unusual pulsing in your chest or abdomen.			√
Impaired wound healing		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store CAPRELSA between 15° and 30°C.

Keep out of the reach and sight of children.

Do not use CAPRELSA after the expiry date that is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to protect the environment.

If you want more information about CAPRELSA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.sanofi.ca), or by calling 1-800-265-7927.

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