PART III:
CONSUMER INFORMATION

Pr CAPRELSA®

Vandetanib tablets

This leaflet is part III of a three-part "Product Monograph" published when CAPRELSA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CAPRELSA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

CAPRELSA (vandetanib) 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) 589-6215 or visit www.caprelsa.ca/rdp.

WHAT THE MEDICATION IS USED FOR:
CAPRELSA is used to treat medullary thyroid cancer in adult patients whose tumour cannot be removed by surgery or has spread from the thyroid to other parts of the body. Side effects you may experience related to CAPRELSA treatment may not go away as quickly after stopping treatment, given that it takes longer for the body to get rid of the drug.

WHAT IT DOES:
CAPRELSA is one of a group of drugs that specifically target the activity of a group of proteins known to be involved in the growth and spread of certain types of cancer. These proteins stimulate the development of new blood vessels that allow certain types of tumours to grow. CAPRELSA works by blocking the production of these proteins in tumour cells, which slows down the growth of new blood vessels in these tumours. This cuts off the supply of nutrients and oxygen to the tumour thereby slowing or preventing its growth. CAPRELSA also acts directly on cancer cells to kill them or slow down their rate of growth.

WHEN IT SHOULD NOT BE USED:
Do not use CAPRELSA if you:

- have congenital long QT syndrome - a heart disorder that exists before or at birth (this is seen on a test by your doctor that measures the electrical activity of your heart known as an ECG, or "electrocardiogram");
- have low calculated 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.

WHAT THE MEDICINAL INGREDIENT IS:
Vandetanib

WHAT THE NONMEDICINAL INGREDIENTS ARE:
Calcium hydrogen phosphate dihydrate, microcrystalline cellulose, crospovidone, povidone, magnesium stearate, hypromellose 2910, macrogol 300 and titanium dioxide (E171)

WHAT DOSAGE FORMS IT COMES IN:

- CAPRELSA 100 mg is a white bi-convex tablet with "Z100" imprinted on one side and the other side is plain.
- CAPRELSA 300 mg is a white oval-shaped tablet with "Z300" imprinted on one side and the other side is plain.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

CAPRELSA (vandetanib) should only be prescribed by a doctor who has completed the certification with the CAPRELSA Restricted Distribution Program and who is experienced in the use of anti-cancer drugs.

Possible serious side effects with CAPRELSA include:

- Heart rhythm changes (also known as "QT prolongation" - this is seen on a test by your doctor that measures the electrical activity of your heart known as an ECG, or "electrocardiogram")

- Heart failure (a condition where the heart cannot pump blood well and may lead to death)

- High blood pressure, which may be severe

BEFORE you use CAPRELSA talk to your doctor if any of the following conditions apply to you:

- Abnormal heart rhythm (also known as "QT prolongation") or a family history of abnormal heart rhythm;
- Heart disease or a family history of heart disease;
- A personal history of fainting spells;
- Low calculated levels of potassium, magnesium, or calcium in your blood – or a condition that could lead to lower levels such as diarrhea, vomiting, or dehydration;
- High blood pressure;
- Problems with blood clotting or excessive bleeding;
- Liver or kidney problems; or
- A condition in which the thyroid gland does not make enough thyroid hormone (also known as "hypothyroidism")

Talk to your doctor immediately if you experience seizures, headaches, visual disturbances, confusion or difficulty thinking.

CAPRELSA may harm an unborn child. Female patients who can get pregnant must use an effective birth control method while taking CAPRELSA and for at least three months after the last dose. If you are pregnant, think you may be pregnant, or plan to get pregnant while taking CAPRELSA, tell your doctor right away. Male patients must use an acceptable method of contraception, or be surgically sterile, while taking CAPRELSA and for two months after the last dose.

You should not breastfeed while taking CAPRELSA. If you are considering breastfeeding, you should talk to your doctor.

CAPRELSA is not likely to affect your ability to drive or use machines. However, if you feel weak or tired or your vision is blurred while taking this medicine, take care when you are driving or using tools or machines.

CAPRELSA can make your skin sensitive to the sun. While taking CAPRELSA and for four months after the last dose of CAPRELSA you should use sun block and wear clothes that cover your skin, including your head, arms and legs when you go outdoors to prevent sunburn.

It is possible that CAPRELSA may delay the time it takes for your body to heal from skin wounds. Talk to your doctor if you are considering surgery, including dental surgery.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that you obtain without a prescription or herbal medicines. This is because CAPRELSA can affect the way some medicines work and some medicines can have an effect on how CAPRELSA works.

Keep a list of the medicines you take and show it to your doctor and pharmacist when you get a new medicine.

Do not start, stop or change any medicine without talking to your doctor or pharmacist first.

The following list includes some, but not all, of the types of drugs that may increase the risk of heart rhythm problems while receiving CAPRELSA. You should check with your doctor before taking any other medication with CAPRELSA.

- Drugs known to cause heart rhythm changes;
- Antipsychotics or antidepressants;
- A specific class of pain relieving medications;
- Specific classes of antibiotics;
- Antimalarials or a specific class of antifungals;
- Specific classes of antinausea 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.

PROPER USE OF THIS MEDICATION

Always take CAPRELSA exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose: The usual dose is 300 mg taken by mouth each day.

Take CAPRELSA at about the same time each day.

Do not crush the tablet and avoid contact with broken or crushed tablets.

CAPRELSA may be taken with or without food.

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 disintegrated into the water. This may take about 10 minutes.
- Drink it immediately.
- To make sure there is no medicine left, rinse the empty glass very well with another half a glass of water and drink it.

While taking CAPRELSA your doctor will order certain tests to monitor your blood and heart.

OVERDOSE:

In case of drug overdose, contact a healthcare practitioner, 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 as normal.
- **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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CAPRELSA can cause side effects. Possible side effects of CAPRELSA reported in clinical trials include:

Very common (affects more than 1 in 10 patients)

- Diarrhea (your doctor may prescribe a medicine to treat this. If it gets severe, tell your doctor immediately.)
- Skin rash or acne
- Anorexia (loss of appetite)
- Feeling tired, lack of energy and/or muscle weakness
- High blood pressure, which may be severe
- Headache
- Trouble sleeping
- Sensitivity of the skin to sunlight
- Abdominal pain
- Indigestion
- Cough
- Weight loss
- Viral infection of the upper respiratory system

Common (affects less than 1 in 10 patients)

- Dehydration (your body does not have enough water and fluids as it should; this can be a result of diarrhea, vomiting or other causes)
- Weight loss
- Conditions where the brain may not get enough blood
- A type of rash that affects the hands and feet (hand-foot syndrome)
- Irritation of the lining of the mouth or lips or tongue
- Dry mouth
- Kidney stones or lower urinary tract stones
- Nose bleed
- Loss of hair
- Nail problems
- Vision blurred
- Corneal opacity (mild changes in the eye which can lead to blurred vision)
- Dry eye
- Conjunctivitis (an irritation of the inner eyelid or surface of the eye)
- Visual impairment
- Dysgeusia (abnormal taste or changes in taste of foods)
- Depression
- Back pain
- Joint pain/pain in the extremities
- Tremor

Uncommon (affects less than 1 in 100 patients):

- Heart failure (a condition where the heart cannot pump blood well); symptoms include shortness of breath and swelling of the ankles

The following side effects are only seen in tests your doctor may ask you to have done:

- Protein or blood in your urine (shown in a urine test).
- Heart rhythm changes (shown in an ECG, or "electrocardiogram"). Your doctor may tell you to take CAPRELSA at a lower dose if this happens.
- Abnormalities in your liver or pancreas (blood tests). These usually do not cause symptoms but your doctor may want to check you for them.
- Decreased levels of calcium in your blood (blood test). This may mean you need thyroid hormone treatment or a change in your current thyroid hormone treatment.

If any of the side effects get worse, or if you notice any side effects not listed in this leaflet, please contact your doctor immediately. You may need further examinations or treatment.

Your doctor will tell you if you have any of these side effects and may prescribe medication to control them.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist***
		Only if severe	**In all cases**	
Very Common	Nausea (a sensation of having an urge to vomit or queasy stomach)		√	
	Vomiting		√	
	Severe diarrhea		√	
Common	Visual disturbances		√	
	Headaches	√		
	Seizures		√	
	Confusion or difficulty thinking		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist*
		Only if severe	In all cases	
Common /Uncommon	Severe skin reactions (e.g. redness, pain, ulcers, blisters and shedding of the skin) - The frequency of these types of skin reactions may be common or uncommon depending on the type of skin reaction		√	
Uncommon	Fainting		√	
	Dizziness		√	

***If you think you have these side effects, it is important that you seek medical advice from your doctor or pharmacist immediately.**

This is not a complete list of side effects. For any unexpected effects while taking CAPRELSA, contact your doctor or pharmacist.

HOW TO STORE IT

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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:
www.genzyme.ca,

or by contacting the sponsor, Genzyme Canada at:
Customer Inquiries – 1 (800) 589-6215

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