

CAPRELSA™

vandetanib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about CAPRELSA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking CAPRELSA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CAPRELSA is used for

CAPRELSA contains a medicine called vandetanib.

CAPRELSA is used to treat a type cancer (tumour) in the thyroid gland (found in the throat near the windpipe) called medullary thyroid cancer. It is generally used when the cancer has spread to other parts of the body (metastatic).

CAPRELSA belongs to a group of medicines called antineoplastics.

CAPRELSA works by slowing down the growth of new blood vessels in tumours (cancers). This cuts off the supply of food and oxygen to the tumour. CAPRELSA may also act directly on cancer cells to kill them or slow down their growth.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

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 whilst taking this medicine, take care when you are driving or using tools or machines.

CAPRELSA may increase your chance of getting sunburnt. You should take special care to protect yourself from the sun.

There is not enough information to recommend the use of this medicine for children (under 18 years of age).

Before you take CAPRELSA

When you must not take it

Do not take CAPRELSA if you have an allergy to vandetanib or any of the other ingredients of CAPRELSA tablets listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take CAPRELSA if you have a heart disorder that you

were born with called 'congenital long QT syndrome'. This is seen on an ECG (electrocardiogram)

Do not give this medicine to a child (under 18 years).

Safety and effectiveness in children has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Heart or blood pressure problems
- Kidney problems
- Liver problems

Tell your doctor if you are pregnant or plan to become pregnant.

CAPRELSA may harm an unborn child. If you are pregnant, you should not take CAPRELSA. Women at risk of becoming pregnant must use effective contraception when they are taking CAPRELSA and for at least four months after the last dose of CAPRELSA. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding.

For the safety of your baby, you should discontinue breast-feeding during treatment with CAPRELSA. Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and CAPRELSA may interfere with each other. These include

- medicines used to treat infections such as itraconazole, ketoconazole, ritonavir, clarithromycin and rifampicin
- medicines used to control seizures such as carbamazepine and phenobarbital
- ondansetron - a medicine used to treat nausea and vomiting
- medicines used to treat mental illness such as haloperidol and chlorpromazine
- vitamin K antagonists and dabigatran often referred to as 'blood thinners'
- cyclosporin and tacrolimus - medicines used to treat transplant rejection
- digoxin - a medicine used to treat heart problems
- metformin - a medicine used to control your blood sugar
- medicines used to treat heartburn such as cisapride and proton pump inhibitors

These medicines may be affected by CAPRELSA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of the above, tell him/

her before you start taking CAPRELSA.

How to take CAPRELSA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is 300 mg once a day (as either one 300 mg tablet or three 100 mg tablets).

If you have kidney problems, your doctor may start you on a lower dose (200 mg once a day).

Your doctor may also reduce your dose down to 200 mg or 100 mg a day if you have certain side effects.

How to take it

Swallow the tablets whole. 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. Do not use any other liquid.
- Put the tablet into the water.
- Stir the tablet until it has dispersed into the water. This may take about 10 minutes.
- Then drink it straight away.
- To make sure there is no medicine left, rinse the empty glass very well with another half a glass of water and drink it.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CAPRELSA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include an increase in frequency or severity of some of the side effects listed above such as rash, diarrhoea, high blood pressure (you may have headaches, dizziness, nose bleeds etc.) and effects to your heart (including racing heart, and possible loss of consciousness).

While you are using CAPRELSA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CAPRELSA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Women at risk of becoming pregnant must use effective contraception when they are taking CAPRELSA and for at least four months after the last dose of CAPRELSA. If you become pregnant while taking this medicine, tell your doctor immediately.

To avoid exposure to the sun always protect yourself when you go outside by using sun block and wearing sun-protective clothing which covers as much skin as possible.

Some people who are taking CAPRELSA become more sensitive to the sun. This can cause sunburn.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (e.g. ECG heart test, blood tests, urine tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take CAPRELSA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Be careful driving or operating machinery until you know how CAPRELSA affects you.

This medicine may cause tiredness, feeling weak and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CAPRELSA.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Mild or moderate diarrhoea; nausea; vomiting; loss of appetite (anorexia); weight loss; dehydration
- Skin rash/acne including hand and foot rash
- Skin sensitivity to sunlight; symptoms of sunburn (redness, itching, swelling or blistering) that may occur more quickly than normal
- Tiredness; fatigue; trouble sleeping
- Muscle weakness/loss of energy

- Headache; nose bleeds
- Abdominal pain
- Blood in the urine
- Blurred vision including halos; dry eye; irritation of the inner eyelid or surface of the eye; other issues with your eye sight.
- Dry mouth; irritation or ulcers of the lining of the mouth, lips or tongue; changes in taste of food
- Unusual hair loss or thinning; nail problems
- Depression

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Severe diarrhoea
- Severe skin reactions affecting large areas of your body and may include redness or swelling of your face, hands, or soles of your feet, itching, blisters and bleeding of the lips, nose, eyes, mouth or genitals, peeling of your skin, muscle or joint aches
- Seizures, headache, confusion/difficulty concentrating
- Changes in heart rhythm, fainting or dizziness
- Cough, fever and breathlessness/chest tightness
- Shortness of breath and swelling of the feet or ankles
- Sudden onset of cramping pain in lower back and/or side, groin or abdomen.
- Stroke which may include symptoms such as loss of vision in one eye, double vision, dizziness/spinning sensation; weakness in one side of the body, or in the arms or legs; slurred speech and/or loss of co-ordination

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects for example, thyroid function, liver function, and changes in your blood, urine or heart rhythm may only be found when your doctor does tests from time to time to check your progress.

After using CAPRELSA

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store CAPRELSA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

CAPRELSA 100 mg is a white biconvex-shaped tablet with "Z100"

imprinted on one side and plain on the other.

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

CAPRELSA comes in a blister pack of 30 tablets.

Ingredients

CAPRELSA contains 100 or 300 mg of vandetanib as the active ingredient.

Other ingredients include:

- Calcium hydrogen phosphate (E341)
- Microcrystalline cellulose (E460)
- Crospovidone
- Povidone
- Magnesium stearate
- Hypromellose (E464)
- Macrogol 300
- Titanium dioxide (E171)

This medicine does not contain lactose, sucrose, tartrazine or any other azo dyes.

Supplier

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park

NSW 2113

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100 mg - 192496

300 mg - 192497