## PATIENT MEDICATION INFORMATION

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrTABRECTA®**

**Capmatinib Tablets**

Read this carefully before you start taking **TABRECTA®** 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 **TABRECTA**.

**Serious Warnings and Precautions**

- TABRECTA can harm your unborn baby if you take it while you are pregnant.
- TABRECTA can cause serious side effects, including:
  - **Interstitial lung disease / Pneumonitis (inflammation of lungs):** TABRECTA may cause inflammation or scarring of the lungs and can lead to death. Your healthcare professional will monitor you for lung problems. Tell your healthcare professional right away if you develop new or worsening symptoms of lung problems, including: cough, fever, trouble breathing, shortness of breath, or wheezing.
  - **Liver problems:** Increased liver enzymes are very common with TABRECTA. Liver problems may sometimes be serious and can lead to death. Your healthcare professional will perform blood tests to check your liver before and during treatment.

See the "Serious side effects and what to do about them" table, below, for more information on these and other serious side effects.

### What is TABRECTA used for?

For the following indication, TABRECTA has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- TABRECTA is used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC). The non-small cell lung cancer:
  - has altered mesenchymal epithelial transition (*MET*) gene, and
  - has spread to other parts of the body or is advanced and cannot be removed by surgery

Your healthcare professional will test your tumor for certain changes (alterations) in the *MET* gene. This will make sure that TABRECTA is right for you.

### What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is

reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

**How does TABRECTA work?**
Altered *MET* gene can cause your lung cancer to grow. TABRECTA belongs to a class of cancer medicines called *MET* tyrosine kinase inhibitors. It targets and inhibits this altered *MET* gene. This helps to slow down or stop the growth and spread of your lung cancer. It may also help to shrink the tumor (cancer).

**What are the ingredients in TABRECTA?**
Medicinal ingredient: Capmatinib (as capmatinib hydrochloride)
Non-medicinal ingredients: cellulose microcrystalline; crospovidone; hypromellose; iron oxide, black (for the 150 mg tablets); iron oxide, red (for the 150 mg tablets); iron oxide, yellow; macrogol 4000; magnesium stearate; mannitol; povidone; silica colloidal anhydrous; sodium laurilsulfate; talc and titanium dioxide.

**TABRECTA comes in the following dosage forms:**
Tablets; 150 mg and 200 mg capmatinib (as capmatinib hydrochloride).

**Do not use TABRECTA if you:**

- are allergic to capmatinib, or any ingredients in this medicine or container.

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

- have or have had lung or breathing problems other than your lung cancer.
- have or have had liver problems.
- have or have had pancreas problems.

**Other warnings you should know about:**

**Pregnancy and breast feeding:**

**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.
- You should not take TABRECTA if you are pregnant. It may harm your unborn baby.
- If you are able to become pregnant:
    - Your healthcare professional will do a pregnancy test before you start taking TABRECTA. This test must show that you are not pregnant.

    - Avoid becoming pregnant while you are taking TABRECTA. Use effective birth control during your treatment and for at least 7 days after your last dose of TABRECTA. Ask your healthcare professional about methods of birth control available to you.
    - Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with TABRECTA.
- Do not breastfeed while you are taking TABRECTA and for at least 7 days after your last dose. It is not known if TABRECTA passes into breast milk.

**Male patients**

- You should not father a child while you are taking TABRECTA. It may harm your unborn baby.
- During your treatment with TABRECTA, use a condom each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using condoms for at least 7 days after your last dose.
- If, during your treatment with TABRECTA, your sexual partner becomes pregnant or thinks she may be pregnant, tell your healthcare professional right away.

**Photosensitivity (sensitivity to sunlight):** TABRECTA might cause you to be more sensitive to sunlight. Limit your exposure to the sun or ultraviolet (UV) light while taking TABRECTA. Use sunscreen, wear clothes that cover your skin, and avoid sunbathing while you are taking TABRECTA.

**Driving and using machines:** Before you drive or do tasks that require special attention, wait until you know how you respond to TABRECTA.

**Children and adolescents:** TABRECTA is NOT approved for use in children and adolescents under the age of 18 years.

**Check-ups and testing:** Your healthcare professional will do blood tests before and during treatment with TABRECTA. This is to check your liver, kidney and pancreas health.

**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 TABRECTA:**

- Grapefruit products;
- Medicines used to treat seizures such as carbamazepine, phenobarbital, phenytoin;
- St. John's wort, a herbal product used to treat depression and other conditions;
- Medicines used to treat blood clots, such as dabigatran etexilate;
- Medicines used to treat gout, such as colchicine;
- Medicines used to treat diabetes, such as sitagliptin, saxagliptin;
- Medicines used to treat certain types of cancer or autoimmune diseases, such as methotrexate, mitoxantrone;
- Medicine used to treat bowel and rheumatic joint inflammation, such as sulfasalazine;
- Medicines used to treat tuberculosis, such as rifampicin;
- Antibiotics used to treat bacterial infections, such as telithromycin or clarithromycin;
- Medicines used to treat fungal infections, such as ketoconazole, itraconazole, posaconazole, voriconazole;

- Medicines used to treat HIV/AIDS, such as efavirenz, lopinavir/ritonavir, saquinavir, indinavir, or nelfinavir;
- Medicines used to treat hepatitis, such as telaprevir;
- Medicines used to treat depression, such as nefazodone;
- Medicines used to treat high blood pressure or heart problems, such as verapamil or digoxin;
- Medicines used to treat breathing problems, such as theophylline;
- Medicines used to treat muscle spasms, such as tizanidine;
- Medicines used to treat high cholesterol, such as rosuvastatin or pravastatin.

**How to take TABRECTA:**

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Do not change your dose or stop taking it unless your healthcare professional tells you to.
- Take TABRECTA for as long as your healthcare professional tells you to.
- Take TABRECTA twice a day at about the same time each day will help you to remember when to take your medicine.
- Swallow tablets whole. Do not break, chew, or crush the tablets.
- Take with or without food.

**Usual dose:**

**Maximum Recommended Adult Dose:**

- 400 mg twice a day. To make this dose, take two 200 mg tablets twice per day.

Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:

- experience serious side effects, or
- your disease gets worse.

**Usual Reduced Adult Doses:**

- 300 mg twice a day (two 150 mg tablets, twice a day), or
- 200 mg twice a day (one 200 mg tablet, twice a day)

**Overdose:**

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

**Missed Dose:**

If you miss a dose or vomit after you have taken TABRECTA:

- Do not take a double dose to make up for a forgotten dose. Instead, wait until it is time for your next dose.

**What are possible side effects from using TABRECTA?**

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

Side effects may include:

- Swollen hands, ankles, feet or face
- Nausea, vomiting
- Tiredness, weakness
- Shortness of breath
- Loss of appetite
- Diarrhea or constipation
- Cough
- Chest, stomach or back pain
- Fever
- Decreased weight
- Skin rash, hives
- Itchy skin with or without rash

TABRECTA can cause abnormal blood test results. Your healthcare professional will do blood tests before and during your treatment. These will tell your healthcare professional how TABRECTA is affecting your blood, liver, pancreas, kidneys and electrolyte levels.

| **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** | | | |
| **Liver problems:** right upper stomach area pain or swelling, nausea or vomiting, dark urine, unusual tiredness / weakness, loss of appetite, yellowing of the skin or eyes | | √ | |
| **COMMON** | | | |
| **Cellulitis** (skin infection): pain, tenderness, swelling, redness or warmth of the skin | | √ | |
| **Kidney failure, Acute Kidney Injury** (severe kidney problems)**:** Passing urine less often than usual or passing smaller amounts of urine than usual, confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles, weight gain | | √ | |

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| | **Only if severe** | **In all cases** | |
| **Severe swelling, including generalized edema** (swelling affecting the whole body) | | √ | |
| **Pneumonitis / Interstitial lung disease, Pneumonia** (lung inflammation / infection): Cough, cough which may produce phlegm, fever, chest pain when you breath or cough, trouble breathing, shortness of breath, wheezing, fatigue, weight loss, sweating and shaking, chills, nausea, vomiting or diarrhea | | √ | |
| **UNCOMMON** | | | |
| **Pancreatitis** (inflammation of the pancreas): upper abdominal pain, fever, rapid pulse, nausea, vomiting, tenderness when touching the abdomen | | √ | |
| **Hypersensitivity** (allergic reaction): fever, skin rash, blood pressure decreased, chills, itchy skin, nausea, vomiting | | √ | |

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.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- 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.

*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.*

**Storage:**

- Do not store above 25°C. Store in the original package to protect from moisture.
- Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.
- Ask your healthcare professional on how to dispose of medicines you no longer use.
- Keep out of reach and sight of children.

**If you want more information about TABRECTA:**

- 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.novartis.ca or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

TABRECTA is a registered trademark.

Last Revised

May 19, 2022