SAFETY, DOSING, AND ADMINISTRATION

TABRECTA®
(capmatinib) tablets
150 mg · 200 mg

Indication

TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

Important Safety Information

Interstitial Lung Disease (ILD)/Pneumonitis. ILD/pneumonitis, which can be fatal, occurred in patients treated with TABRECTA. ILD/pneumonitis occurred in 4.8% of patients treated with TABRECTA in the GEOMETRY mono-1 study, with 1.9% of patients experiencing grade 3 ILD/pneumonitis and 1 patient experiencing death (0.3%). Nine patients (2.4%) discontinued TABRECTA due to ILD/pneumonitis.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for TABRECTA.

USING THIS GUIDE

This brochure covers:

- The TABRECTA safety profile
- Dosing and administration
- The management of select adverse reactions, including edema
- Details about patient counseling and drug interactions

These management strategies are not intended to be medical advice or take the place of your clinical judgment based on each patient's individual presentation.

Please note: Not all adverse reactions associated with TABRECTA therapy are discussed in this brochure.

Also included as part of this guide is **HELPFUL REMINDERS FOR TAKING TABRECTA**, an informational sheet you can offer patients to help reinforce important points about administration and side effects.

TABRECTA is associated with the following Warnings and Precautions:

Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Permanently discontinue TABRECTA in patients with ILD/pneumonitis.

Hepatotoxicity: Monitor liver function tests. Withhold, dose reduce, or permanently discontinue TABRECTA based on severity.

Pancreatic Toxicity: Monitor amylase and lipase levels. Withhold, dose reduce, or permanently discontinue TABRECTA based on severity.

Hypersensitivity Reactions: Withhold or permanently discontinue TABRECTA based on severity.

Risk of Photosensitivity: May cause photosensitivity reactions. Advise patients to limit direct ultraviolet exposure.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

See full Prescribing Information for more information.

Important Safety Information (cont)
Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TABRECTA in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for TABRECTA.

SAFETY PROFILE

TABRECTA® (capmatinib) tablets 150 mg · 200 mg

ADVERSE REACTIONS

Common adverse reactions (≥10%) across all cohorts in GEOMETRY mono-1[1,2]

	TABRECTA (N=373)		
COMMON ADVERSE REACTIONS	**ALL GRADES (%)**	**GRADE 3 (%)**	**GRADE 4 (%)**
General disorders and administration-site conditions			
Edema[a]	59	13	–
Musculoskeletal pain[b]	40	4.3	–
Fatigue[c]	34	8	–
Pyrexia[d]	14	0.8	–
Weight decreased	11	0.5	–
Gastrointestinal disorders			
Nausea	46	2.4	–
Vomiting	28	2.4	–
Constipation	19	0.8	–
Diarrhea	19	0.5	–
Respiratory, thoracic, and mediastinal disorders			
Dyspnea	25	7*	0.5
Cough[e]	21	0.5	–
Pneumonia[f]	13	6*	0.5
Metabolism and nutrition disorders			
Decreased appetite	21	1.1	–
Skin and subcutaneous tissue disorders			
Rash[g]	13	0.5	–
Nervous system disorders			
Dizziness[h]	13	0.5	–

[a]Edema includes edema peripheral, generalized edema, face edema, edema, localized edema, edema genital, eyelid edema, peripheral swelling, scrotal edema, and penile edema.
[b]Musculoskeletal pain includes arthralgia, back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, myalgia, neck pain, noncardiac chest pain, pain in extremity, pain in jaw, spinal pain.
[c]Fatigue includes fatigue and asthenia.
[d]Pyrexia includes pyrexia and body temperature increased.
[e]Cough includes cough, upper airway cough syndrome, and productive cough.
[f]Pneumonia includes pneumonia aspiration, pneumonia, pneumonia influenzal, pneumonia bacterial, lower respiratory tract infection, and lung abscess.
[g]Rash includes rash, dermatitis acneiform, rash maculo-papular, eczema, erythema multiforme, rash macular, dermatitis, rash erythematous, rash pustular, dermatitis bullous, and rash vesicular.
[h]Dizziness includes dizziness, vertigo, and vertigo positional.

The majority of patients who reported adverse reactions (ARs) remained on TABRECTA.[1]

- Serious ARs occurred in 53% of patients who received TABRECTA. Serious ARs in ≥2% of patients included dyspnea, pneumonia, pleural effusion, musculoskeletal pain, general physical health deterioration, ILD/pneumonitis, edema, and vomiting[1]
- Dose reductions due to ARs occurred in 26% of patients, and dose interruptions due to ARs occurred in 57% of patients[1]
- Sixty-five patients (17%) treated with TABRECTA discontinued therapy due to ARs[1,2]
  - The most frequent ARs (≥1%) leading to permanent discontinuation of TABRECTA were ILD/pneumonitis (2.4%), edema (2.4%), fatigue (1.3%), and pneumonia (1.1%)[1]

Fatal ARs occurred in 0.5% of patients who received TABRECTA, including pneumonitis (0.3%) and death, not otherwise specified (0.3%).[1]

*Includes both grade 3 and 4.

LABORATORY ABNORMALITIES

Select laboratory abnormalities (≥20%) worsening from baseline in patients who received TABRECTA in GEOMETRY mono-1[1]

	TABRECTA[a]	
LABORATORY ABNORMALITIES	**GRADES 1 TO 4 (%)**	**GRADES 3 TO 4 (%)**
Chemistry		
Decreased albumin	72	1.9
Increased creatinine	65	0.5
Increased alanine aminotransferase	39	9
Increased amylase	34	4.7
Increased alkaline phosphatase	32	0.6
Increased gamma-glutamyltransferase	30	6
Increased lipase	29	9
Increased aspartate aminotransferase	28	6
Decreased phosphate	26	4.4
Increased potassium	25	4.1
Decreased sodium	24	6
Decreased glucose	23	0.3
Hematology		
Decreased lymphocytes	45	14
Decreased leukocytes	25	1.7
Decreased hemoglobin	24	2.8

[a]The denominator used to calculate the rate varied from 359 to 364 based on the number of patients with a baseline value and at least one post-treatment value.

Clinically relevant adverse reactions occurring in <10% of patients treated with TABRECTA included pruritus (including allergic pruritus), rash (including rash, rash macular, rash maculopapular, rash erythematous and rash vesicular), ILD/pneumonitis, cellulitis, acute kidney injury (including renal failure), urticaria, and acute pancreatitis.[1]

Serious hypersensitivity reactions and thrombocytopenia occurred in patients treated with TABRECTA in clinical trials other than GEOMETRY mono-1.[1]

Important Safety Information (cont)
Hepatotoxicity. Hepatotoxicity occurred in patients treated with TABRECTA. Increased alanine aminotransferase (ALT)/aspartate aminotransferase (AST) occurred in 15% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased ALT/AST occurred in 7% of patients. Three patients (0.8%) discontinued TABRECTA due to increased ALT/AST.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for TABRECTA.

TABRECTA® (capmatinib) tablets 150 mg · 200 mg

DOSING AND ADMINISTRATION

CONVENIENT ORAL DOSING, WITH OR WITHOUT FOOD

RECOMMENDED STARTING DOSE: 400 mg twice daily	**AM:** two 200-mg tablets	**PM:** two 200-mg tablets
	 Not actual size.	 Not actual size.

- TABRECTA can be taken with or without food[1]
- Swallow TABRECTA tablets whole. Do not break, crush, or chew the tablets[1]
- If a patient misses or vomits a dose, instruct the patient not to make up the dose, but to take the next dose at its scheduled time[1]

Dosing can be modified to manage ARs[1]

FIRST DOSE REDUCTION: 300 mg twice daily	**AM:** two 150-mg tablets	**PM:** two 150-mg tablets
SECOND DOSE REDUCTION: 200 mg twice daily	**AM:** one 200-mg tablet	**PM:** one 200-mg tablet

- Permanently discontinue TABRECTA in patients who are unable to tolerate 200 mg orally twice daily
- Patients with mild to moderate renal impairment do not require dose modifications

TABRECTA is available in 2 strengths[1]

200 mg
NDC 0078-0716-56

150 mg
NDC 0078-0709-56

Not actual size.

How to prescribe[1]

Rx

TABRECTA 200 mg
Take 2 tablets PO bid
Disp 28-day supply

Storage[1]

- Dispense in the original package with the desiccant cartridge
- Store at room temperature* and protect from moisture
- Discard any unused TABRECTA remaining after 6 weeks of first opening the bottle

*20°C to 25°C (68°F-77°F), excursions permitted between 15°C and 30°C (59°F-86°F) *[see USP Controlled Room Temperature]*.

Important Safety Information (cont)
Monitor liver function tests (including ALT, AST, and total bilirubin) prior to the start of TABRECTA, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin. Based on the severity of the adverse reaction, withhold, reduce dose, or permanently discontinue TABRECTA.

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DOSE MODIFICATIONS FOR SELECT ARs

SELECT ARS CAN BE MANAGED WITH DOSE MODIFICATIONS[1]

ADVERSE REACTION	SEVERITY	DOSE MODIFICATION
ILD/pneumonitis	Any grade	Permanently discontinue TABRECTA
Increased ALT and/or AST without increased total bilirubin	Grade 3	Withhold TABRECTA until recovery to baseline ALT/AST If recovered to baseline within 7 days, then resume TABRECTA at the same dose; otherwise, resume TABRECTA at a reduced dose
	Grade 4	Permanently discontinue TABRECTA
Increased ALT and/or AST with increased total bilirubin in the absence of cholestasis or hemolysis	ALT and/or AST greater than 3 times ULN with total bilirubin greater than 2 times ULN	Permanently discontinue TABRECTA
Increased total bilirubin without concurrent increased ALT and/or AST	Grade 2	Withhold TABRECTA until recovery to baseline bilirubin If recovered to baseline within 7 days, then resume TABRECTA at the same dose; otherwise, resume TABRECTA at a reduced dose
	Grade 3	Withhold TABRECTA until recovery to baseline bilirubin If recovered to baseline within 7 days, then resume TABRECTA at a reduced dose; otherwise, permanently discontinue TABRECTA
	Grade 4	Permanently discontinue TABRECTA
Increased lipase or amylase	Grade 3	Withhold TABRECTA until ≤grade 2 or baseline If recovered to baseline or ≤grade 2 within 14 days, resume TABRECTA at a reduced dose; otherwise, permanently discontinue TABRECTA
	Grade 4	Permanently discontinue TABRECTA
Pancreatitis	Grade 3 or grade 4	Permanently discontinue TABRECTA
Hypersensitivity	All grades	If hypersensitivity is suspected based on clinical judgment, withhold TABRECTA until resolution of the event Permanently discontinue TABRECTA in patients who develop serious hypersensitivity reactions
Other adverse reactions	Grade 2	Maintain dose level. If intolerable, consider withholding TABRECTA until resolved, then resume TABRECTA at a reduced dose
	Grade 3	Withhold TABRECTA until resolved, then resume TABRECTA at a reduced dose
	Grade 4	Permanently discontinue TABRECTA

ULN, upper limit of normal.

Important Safety Information (cont)
Pancreatic Toxicity. Elevations in amylase and lipase levels have occurred in patients treated with TABRECTA. Increased amylase/lipase occurred in 14% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased amylase/lipase occurred in 7% and 1.9% of patients, respectively. Three patients (0.8%) discontinued TABRECTA due to increased amylase/lipase. Pancreatitis (grade 3) occurred in 1 patient (0.3%); TABRECTA was permanently discontinued for this event.

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MANAGING EDEMA

Although the exact mechanism is unknown, the MET inhibitor TABRECTA may cause edema[1]

In the GEOMETRY mono-1 clinical trial, edema occurred in 59% of patients and was managed based on severity[1]

- For **grade ≤2** peripheral edema, consider measures such as[3]:

LEG ELEVATION

COMPRESSION STOCKINGS

DIETARY SALT MODIFICATION

- For **grade ≥3** peripheral edema, initiate or intensify the above measures

Edema was one of the most common ARs in GEOMETRY mono-1, leading to discontinuation in 2.4% of patients.[1]

Grading of edema[1,4]

GRADE	CTCAE v5.0 DEFINITION
1	5% to 10% interlimb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
2	>10% to 30% interlimb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental activities of daily living (ADL)
3	>30% interlimb discrepancy in volume; gross deviation from normal anatomic contour; limiting self-care ADL

CTCAE, Common Terminology Criteria for Adverse Events.

Edema is a common AR and its management may help patients remain on treatment

Important Safety Information (cont)
Monitor amylase and lipase at baseline and regularly during treatment with TABRECTA. Based on the severity of the adverse reaction, temporarily withhold, dose reduce, or permanently discontinue TABRECTA.

Hypersensitivity Reactions. Serious hypersensitivity reactions occurred in patients treated with TABRECTA in clinical trials other than GEOMETRY mono-1. Signs and symptoms of hypersensitivity included pyrexia, chills, pruritus, rash, decreased blood pressure, nausea, and vomiting. Based on the severity of the adverse reaction, temporarily withhold or permanently discontinue TABRECTA.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for TABRECTA.

Important Safety Information (cont)
Risk of Photosensitivity. Based on findings from animal studies, there is a potential risk of photosensitivity reactions with TABRECTA. In GEOMETRY mono-1, it was recommended that patients use precautionary measures against ultraviolet exposure, such as use of sunscreen or protective clothing, during treatment with TABRECTA. Advise patients to limit direct ultraviolet exposure during treatment with TABRECTA.

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PATIENT COUNSELING

Advise patients taking TABRECTA to report any signs or symptoms of potential treatment-related ARs[1]

Inform patients of the risks of severe or fatal ILD/pneumonitis. Advise patients to contact their health care provider immediately to report new or worsening respiratory symptoms	**ILD/pneumonitis**
Inform patients that they will need to undergo lab tests to monitor liver function. Advise patients to immediately contact their health care provider if they experience signs and symptoms of liver dysfunction	**Hepatotoxicity**
Inform patients that they will need to undergo lab tests to monitor pancreatic function	**Pancreatic toxicity**
Inform patients that there is a risk of hypersensitivity reactions with TABRECTA. Advise patients to stop taking TABRECTA and immediately contact their health care provider for signs and symptoms of hypersensitivity	**Hypersensitivity reactions**
Inform patients that there is a potential risk of photosensitivity reactions with TABRECTA and to limit direct ultraviolet exposure by using sunscreen or protective clothing during treatment with TABRECTA	**Photosensitivity**
Females • Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to inform their health care provider of a known or suspected pregnancy • Advise females of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose **Males** Advise males with female partners of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose	**Embryo-fetal toxicity**
Advise patients to inform their health care providers of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products	**Drug interactions**
Advise women not to breastfeed during treatment with TABRECTA and for 1 week after the last dose	**Lactation**

- The most common ARs (≥20%) were edema, nausea, musculoskeletal pain, fatigue, vomiting, dyspnea, cough, and decreased appetite

DRUG INTERACTIONS

Effect of certain drugs on TABRECTA[1]

Strong CYP3A inhibitors

- Closely monitor patients for ARs during coadministration of TABRECTA with strong CYP3A inhibitors, as they can increase capmatinib exposure, which may increase the incidence and severity of ARs of TABRECTA

Strong and moderate CYP3A inducers

- Avoid coadministration of TABRECTA with strong and moderate CYP3A inducers, as they can decrease capmatinib exposure. Decreases in capmatinib exposure may decrease TABRECTA antitumor activity

Effect of TABRECTA on other drugs[1]

CYP1A2 substrates

- Coadministration of TABRECTA increased the exposure of a CYP1A2 substrate, which may increase the ARs of these substrates. If coadministration is unavoidable between TABRECTA and CYP1A2 substrates where minimal concentration changes may lead to serious ARs, decrease the CYP1A2 substrate dosage in accordance with the approved prescribing information

P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) substrates

- Coadministration of TABRECTA increased the exposure of a P-gp substrate and a BCRP substrate, which may increase the ARs of these substrates. If coadministration is unavoidable between TABRECTA and P-gp and BCRP substrates where minimal concentration changes may lead to serious ARs, decrease the P-gp or BCRP substrate dosage in accordance with the approved prescribing information

MATE1 and MATE2K substrates

- Coadministration of TABRECTA may increase the exposure of MATE1 and MATE2K substrates, which may increase the ARs of these substrates. If coadministration is unavoidable between TABRECTA and MATE1 and MATE2K substrates where minimal concentration changes may lead to serious ARs, decrease the MATE1 or MATE2K substrate dosage in accordance with the approved prescribing information

References: 1. Tabrecta. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. Study CINC280A2201. Novartis Pharmaceuticals Corp; 2021. **3.** Data on file. Study CINC280A2201. Novartis Pharmaceuticals Corp; 2019. **4.** National Institutes of Health, National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. November 27, 2017. Accessed March 28, 2023. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf

Important Safety Information (cont)
Embryo-Fetal Toxicity. Based on findings from animal studies and its mechanism of action, TABRECTA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose.

Please see additional Important Safety Information throughout and click here for full Prescribing Information for TABRECTA.

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Indication

TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

Important Safety Information

Interstitial Lung Disease (ILD)/Pneumonitis. ILD/pneumonitis, which can be fatal, occurred in patients treated with TABRECTA. ILD/pneumonitis occurred in 4.8% of patients treated with TABRECTA in the GEOMETRY mono-1 study, with 1.9% of patients experiencing grade 3 ILD/pneumonitis and 1 patient experiencing death (0.3%). Nine patients (2.4%) discontinued TABRECTA due to ILD/pneumonitis.

Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TABRECTA in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified.

Hepatotoxicity. Hepatotoxicity occurred in patients treated with TABRECTA. Increased alanine aminotransferase (ALT)/aspartate aminotransferase (AST) occurred in 15% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased ALT/AST occurred in 7% of patients. Three patients (0.8%) discontinued TABRECTA due to increased ALT/AST.

Monitor liver function tests (including ALT, AST, and total bilirubin) prior to the start of TABRECTA, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin. Based on the severity of the adverse reaction, withhold, reduce dose, or permanently discontinue TABRECTA.

Pancreatic Toxicity. Elevations in amylase and lipase levels have occurred in patients treated with TABRECTA. Increased amylase/lipase occurred in 14% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased amylase/lipase occurred in 7% and 1.9% of patients, respectively. Three patients (0.8%) discontinued TABRECTA due to increased amylase/lipase. Pancreatitis (grade 3) occurred in 1 patient (0.3%); TABRECTA was permanently discontinued for this event.

Monitor amylase and lipase at baseline and regularly during treatment with TABRECTA. Based on the severity of the adverse reaction, temporarily withhold, dose reduce, or permanently discontinue TABRECTA.

Hypersensitivity Reactions. Serious hypersensitivity reactions occurred in patients treated with TABRECTA in clinical trials other than GEOMETRY mono-1. Signs and symptoms of hypersensitivity included pyrexia, chills, pruritus, rash, decreased blood pressure, nausea, and vomiting. Based on the severity of the adverse reaction, temporarily withhold or permanently discontinue TABRECTA

Risk of Photosensitivity. Based on findings from animal studies, there is a potential risk of photosensitivity reactions with TABRECTA. In GEOMETRY mono-1, it was recommended that patients use precautionary measures against ultraviolet exposure, such as use of sunscreen or protective clothing, during treatment with TABRECTA. Advise patients to limit direct ultraviolet exposure during treatment with TABRECTA.

Embryo-Fetal Toxicity. Based on findings from animal studies and its mechanism of action, TABRECTA can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TABRECTA and for 1 week after the last dose.

Most Common Adverse Reactions. The most common adverse reactions (≥20%) were edema (59%), nausea (46%), musculoskeletal pain (40%), fatigue (34%), vomiting (28%), dyspnea (25%), cough (21%), and decreased appetite (21%). The most common grade 3 adverse reactions (≥2%) were edema (13%), fatigue (8%), dyspnea (7%), pneumonia (6%), musculoskeletal pain (4.3%), nausea (2.4%), and vomiting (2.4%). Grade 4 dyspnea and pneumonia were reported in 0.5% of patients.

Clinically Relevant Adverse Reactions. Clinically relevant adverse reactions observed in <10% of patients were pruritus (including allergic pruritus), ILD/pneumonitis, cellulitis, acute kidney injury (including renal failure), urticaria, and acute pancreatitis.

Laboratory Abnormalities. Select laboratory abnormalities (≥20%) worsening from baseline in patients who received TABRECTA were decreased albumin (72%), increased creatinine (65%), decreased lymphocytes (45%), increased ALT (39%), increased amylase (34%), increased alkaline phosphatase (32%), increased gamma-glutamyltransferase (30%), increased lipase (29%), increased AST (28%), decreased phosphate (26%), decreased leukocytes (25%), increased potassium (25%), decreased hemoglobin (24%), decreased sodium (24%), and decreased glucose (23%).

Please click here for full Prescribing Information for TABRECTA.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

4/24 429338

HELPFUL REMINDERS FOR TAKING TABRECTA

Take TABRECTA exactly as your health care provider tells you

Take TABRECTA 2 times a day with or without food.

Swallow TABRECTA tablets whole. Do not break, chew, or crush TABRECTA tablets.

If you miss or vomit a dose of TABRECTA, **do not make up the dose**. Take your next dose at your regularly scheduled time.

- Store TABRECTA at room temperature between 68°F and 77°F (20°C and 25°C)
- Store TABRECTA in the original package with the drying agent (desiccant) cartridge
- Protect TABRECTA tablets from moisture
- Throw away (discard) any unused TABRECTA you have left after 6 weeks of first opening the bottle

Taking TABRECTA at the same times every day (for example, at breakfast and dinner) can help you remember to take your medicine

The most common side effects of TABRECTA are swelling of hands and feet, nausea, muscle or bone pain, tiredness and weakness, vomiting, trouble breathing, cough, loss of appetite, and changes in certain blood tests.

Your health care provider may change your dose, or temporarily or permanently stop treatment with TABRECTA, if you have certain side effects.

- Do not change your dose or stop taking TABRECTA without talking to your doctor

Tell your doctor right away if you have any of these serious side effects:

LUNG PROBLEMS	New or worsening cough, fever, trouble breathing, or shortness of breath
LIVER PROBLEMS	Your skin or the white part of your eyes turns yellow (jaundice); dark or "tea-colored" urine; light-colored stools (bowel movements); confusion; tiredness; loss of appetite for several days or longer; nausea and vomiting; pain, aching, or tenderness on the right side of your stomach area (abdomen); weakness; swelling in your stomach area
PANCREAS PROBLEMS	Your health care provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TABRECTA
ALLERGIC REACTIONS	Stop taking TABRECTA and tell your health care provider right away if you have fever, chills, itching, rash, dizziness or feeling faint, nausea, or vomiting

Risk of sensitivity to sunlight (photosensitivity): Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure.

Note: These are not all of the side effects that can occur with TABRECTA treatment.

Summary of Important Information for TABRECTA

What is TABRECTA?

TABRECTA is a prescription medicine used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormal mesenchymal-epithelial transition (MET) gene. Your health care provider will perform a test to make sure that TABRECTA is right for you.

It is not known if TABRECTA is safe and effective in children.

What are the possible side effects of TABRECTA?

TABRECTA may cause serious side effects. Tell your health care provider right away if you experience any of the following:

- **Lung or breathing problems.** TABRECTA may cause inflammation of the lungs that can cause death. Tell your health care provider right away if you develop any new or worsening symptoms, including:
  - cough - fever - trouble breathing or shortness of breath

Please see continued Summary of Important Information for TABRECTA, including Patient Information, on next page.

TABRECTA® (capmatinib) tablets 150 mg · 200 mg

Summary of Important Information for TABRECTA (cont)

- **Liver problems.** TABRECTA may cause abnormal liver blood test results. Your health care provider will do blood tests to check your liver function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs or symptoms of liver problems, including:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - confusion
  - loss of appetite for several days or longer
  - nausea and vomiting
  - pain, aching, or tenderness on the right side of your stomach area (abdomen)
  - weakness
  - swelling in your stomach area
- **Pancreas problems.** TABRECTA may cause changes in your blood amylase or lipase levels that may indicate a problem with your pancreas. Your health care provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs and symptoms of pancreas problems, including:
  - upper stomach (abdominal) pain that may spread to your back and get worse with eating
  - weight loss
  - nausea
  - vomiting
- **Allergic reactions.** TABRECTA can cause an allergic reaction. Stop taking TABRECTA and tell your health care provider right away if you get any signs and symptoms of an allergic reaction, including:
  - fever
  - chills
  - itching
  - rash
  - dizziness or feeling faint
  - nausea
  - vomiting
- **Risk of sensitivity to sunlight (photosensitivity).** Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure

The most common side effects of TABRECTA include:

- swelling of your hands or feet
- nausea
- muscle or bone pain
- tiredness and weakness
- vomiting
- trouble breathing
- cough
- loss of appetite
- changes in certain blood tests

Your health care provider may change your dose, or temporarily or permanently stop treatment with TABRECTA, if you develop certain side effects.

These are not all the possible side effects of TABRECTA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

What should I tell my health care provider before taking TABRECTA?

Before you take TABRECTA, tell your health care provider about all your medical conditions, 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
- are pregnant or plan to become pregnant. TABRECTA can harm your unborn baby

  Females who are able to become pregnant:
  - Your health care provider should do a pregnancy test before you start your treatment with TABRECTA
  - You should use effective birth control during treatment and for 1 week after your last dose of TABRECTA. Talk to your health care provider about birth control choices that might be right for you during this time
  - Tell your health care provider right away if you become pregnant or think you may be pregnant during treatment with TABRECTA

  Males who have female partners who can become pregnant:
  - You should use effective birth control during treatment and for 1 week after your last dose of TABRECTA
- are breastfeeding or plan to breastfeed. It is not known if TABRECTA passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of TABRECTA

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What should I avoid while taking TABRECTA?

Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure.

General information about the safe and effective use of TABRECTA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TABRECTA for a condition for which it was not prescribed. Do not give TABRECTA to other people, even if they have the same symptoms you have. It may harm them. You can ask your health care provider or pharmacist for more information about TABRECTA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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To learn more about treatment with TABRECTA, visit TABRECTA.com

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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