SAFETY, DOSING, AND ADMINISTRATION

TABRECTA™ (capmatinib) tablets
150 mg · 200 mg

Indication

TABRECTA™ (capmatinib) tablets 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.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information

Interstitial Lung Disease (ILD)/Pneumonitis. ILD/pneumonitis, which can be fatal, occurred in patients treated with TABRECTA. ILD/pneumonitis occurred in 4.5% of patients treated with TABRECTA in the GEOMETRY mono-1 study, with 1.8% of patients experiencing grade 3 ILD/pneumonitis and 1 patient experiencing death (0.3%). Eight 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 highlights the TABRECTA™ (capmatinib) tablets safety profile and offers guidance on dose modifications and adverse-reaction management. These management strategies are not intended to be medical advice or to 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 IN GEOMETRY MONO-1[1,2]

TREATMENT-NAIVE PATIENTS (n=28)

- **ORR: 68%** achieved an overall response (95% CI, 48-84; CR 4%; PR 64%)
- **mDOR: 12.6 months** (95% CI, 5.5-25.3; n=19)
  - Patients with DOR ≥12 months: 47%

PREVIOUSLY TREATED PATIENTS (n=69)

- **ORR: 41%** achieved an overall response (95% CI, 29-53; CR 0; PR 41%)
- **mDOR: 9.7 months** (95% CI, 5.5-13.0; n=28)
  - Patients with DOR ≥12 months: 32%

Trial design[1,2]:

- TABRECTA was studied in GEOMETRY mono-1, a multicenter, nonrandomized, open-label, multicohort study of patients with *EGFR* wild-type, *ALK*-negative, metastatic NSCLC
- Patients with *MET* exon 14 skipping (*MET*ex14) (n=97) comprised 2 cohorts: cohort 5b (treatment naive, n=28) and cohort 4 (treated previously with 1 or 2 prior lines of therapy, n=69)
  - Patients were enrolled in trial cohorts 4 and 5b after central confirmation of *MET*ex14 by an RNA-based clinical trial assay using RT-PCR
- Patients received TABRECTA 400 mg twice daily. Treatment was continued until disease progression, intolerance, or investigator-led discontinuation
- Evaluable patients were defined as those who completed at least 6 cycles of treatment (18 weeks) or discontinued treatment earlier
- The major efficacy outcome was overall response rate, and duration of response was an additional efficacy outcome as determined by blinded independent review committee (BIRC) according to RECIST 1.1

Warnings and Precautions: Treatment with TABRECTA may cause interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, risk of photosensitivity, and embryo-fetal toxicity.

The most common adverse reactions* for any line of treatment included[1]:

- Peripheral edema
- Fatigue
- Dyspnea
- Nausea
- Vomiting
- Decreased appetite

ALK, anaplastic lymphoma kinase; CR, complete response; *EGFR*, epidermal growth factor receptor; mDOR, median duration of response; MET, mesenchymal-epithelial transition; NSCLC, non-small cell lung cancer; ORR, overall response rate; PR, partial response; RT-PCR, reverse transcription-polymerase chain reaction.

*All grades, occurring in ≥20% of patients.

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

Adverse reactions (≥10%) in patients who received TABRECTA™ (capmatinib) tablets in GEOMETRY mono-1[1]

Common adverse reactions across all cohorts in GEOMETRY mono-1[1]	TABRECTA (N=334)		
COMMON ADVERSE REACTIONS	**ALL GRADES (%)**	**GRADE 3 (%)**	**GRADE 4 (%)**
General disorders and administration-site conditions			
Peripheral edema[a]	52	9	–
Fatigue[b]	32	8	–
Noncardiac chest pain[c]	15	2.1	–
Back pain	14	0.9	–
Pyrexia[d]	14	0.6	–
Weight decreased	10	0.6	–
Gastrointestinal disorders			
Nausea	44	2.7	–
Vomiting	28	2.4	–
Constipation	18	0.9	–
Diarrhea	18	0.3	–
Respiratory, thoracic, and mediastinal disorders			
Dyspnea	24	7	0.6
Cough	16	0.6	–
Metabolism and nutrition disorders			
Decreased appetite	21	0.9	–

[a]Peripheral edema includes peripheral swelling, peripheral edema, and fluid overload. [b]Fatigue includes fatigue and asthenia. [c]Noncardiac chest pain includes chest discomfort, musculoskeletal chest pain, noncardiac chest pain, and chest pain. [d]Pyrexia includes pyrexia and body temperature increased.

- Serious adverse reactions (ARs) occurred in 51% of patients who received TABRECTA. Serious ARs in ≥2% of patients included dyspnea, pneumonia, pleural effusion, general physical health deterioration, vomiting, and nausea[1]
- Dose reductions due to ARs occurred in 23% of patients, and dose interruptions due to ARs occurred in 54% of patients[1]
- Permanent discontinuation due to ARs occurred in 54 patients (16%)[1,2]
  - ARs leading to permanent discontinuation were peripheral edema (1.8%), pneumonitis (1.8%), fatigue (1.5%), alanine aminotransferase (ALT) increased (0.9%), aspartate aminotransferase (AST) increased (0.9%), nausea (0.9%), vomiting (0.9%), blood bilirubin increased (0.6%), blood creatinine increased (0.6%), general physical health deterioration (0.6%), ILD (0.6%), organizing pneumonia (0.6%), and pneumonia (0.6%). A fatal AR occurred in 1 patient (0.3%) due to pneumonitis

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	68	1.8
Increased creatinine	62	0.3
Increased alanine aminotransferase	37	8
Increased alkaline phosphatase	32	0.3
Increased amylase	31	4.4
Increased gamma-glutamyltransferase	29	7
Increased lipase	26	7
Increased aspartate aminotransferase	25	4.9
Decreased sodium	23	6
Decreased phosphate	23	4.6
Increased potassium	23	3.1
Decreased glucose	21	0.3
Hematology		
Decreased lymphocytes	44	14
Decreased hemoglobin	24	2.8
Decreased leukocytes	23	0.9

[a]The denominator used to calculate the rate varied from 320 to 325 based on the number of patients with a baseline value and at least one post-treatment value.

Clinically relevant ARs occurring in <10% of patients treated with TABRECTA included pruritus (allergic and generalized), ILD/pneumonitis, cellulitis, acute kidney injury (including renal failure), urticaria, and acute pancreatitis.

Important Safety Information (cont)
Hepatotoxicity. Hepatotoxicity occurred in patients treated with TABRECTA. Increased alanine aminotransferase (ALT)/aspartate aminotransferase (AST) occurred in 13% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased ALT/AST occurred in 6% of patients. Three patients (0.9%) discontinued TABRECTA due to increased ALT/AST.

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

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DOSING AND ADMINISTRATION

RECOMMENDED STARTING DOSE: 400 mg twice daily[1]

AM	PM
 Two 200-mg tablets	 Two 200-mg tablets

Not actual size.

TWICE-DAILY ORAL DOSING with or without food[1]

SHOULD BE SWALLOWED WHOLE and not broken, chewed, or crushed[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]

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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TAKING TABRECTA (cont)

TABRECTA™ (capmatinib) tablets are available in 2 strengths[1]

200 mg

NDC 0078-0716-56

150 mg

NDC 0078-0709-56

Not actual size.

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

Storage

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

Please refer to the full Prescribing Information for dose reduction, modification, and discontinuation of TABRECTA in the event of specific ARs. Management of dosing for each patient should be based on individual benefit/risk assessment.

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.

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

MANAGING SELECT ARs

TABRECTA™ (capmatinib) tablets 150 mg · 200 mg

MANAGING SELECT ARs[1]

ADVERSE REACTION	SEVERITY	DOSAGE MODIFICATION
ILD/pneumonitis	Any grade	Permanently discontinue TABRECTA™ (capmatinib) tablets
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
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.

In the GEOMETRY mono-1 clinical trial, **peripheral edema** was managed based on severity[2]:

- **Grade ≤2:** Consider measures such as leg elevation, compression stockings, and dietary salt modification
- **Grade ≥3:** Initiate or intensify the above measures

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.

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PATIENT COUNSELING

Advise patients taking TABRECTA™ (capmatinib) tablets 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 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 peripheral edema, nausea, fatigue, vomiting, dyspnea, 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

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]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020. **2.** Data on file. Study CINC280A2201. Novartis Pharmaceuticals Corp; 2019.

Important Safety Information (cont)
Most Common Adverse Reactions. The most common adverse reactions (≥20%) were peripheral edema (52%), nausea (44%), fatigue (32%), vomiting (28%), dyspnea (24%), and decreased appetite (21%). The most common grade 3 adverse reactions (≥2%) were peripheral edema (9%), fatigue (8%), dyspnea (7%), nausea (2.7%), vomiting (2.4%), and noncardiac chest pain (2.1%). Grade 4 dyspnea was reported in 0.6% of patients.

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Indication

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Important Safety Information

Interstitial Lung Disease (ILD)/Pneumonitis. ILD/pneumonitis, which can be fatal, occurred in patients treated with TABRECTA. ILD/pneumonitis occurred in 4.5% of patients treated with TABRECTA in the GEOMETRY mono-1 study, with 1.8% of patients experiencing grade 3 ILD/pneumonitis and 1 patient experiencing death (0.3%). Eight 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 13% of patients treated with TABRECTA in GEOMETRY mono-1. Grade 3 or 4 increased ALT/AST occurred in 6% of patients. Three patients (0.9%) 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.

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 peripheral edema (52%), nausea (44%), fatigue (32%), vomiting (28%), dyspnea (24%), and decreased appetite (21%). The most common grade 3 adverse reactions (≥2%) were peripheral edema (9%), fatigue (8%), dyspnea (7%), nausea (2.7%), vomiting (2.4%), and noncardiac chest pain (2.1%). Grade 4 dyspnea was reported in 0.6% of patients.

Clinically Relevant Adverse Reactions. Clinically relevant adverse reactions observed in <10% of patients were pruritus (allergic and generalized), 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 (68%), increased creatinine (62%), decreased lymphocytes (44%), increased ALT (37%), increased alkaline phosphatase (32%), increased amylase (31%), increased gamma-glutamyltransferase (29%), increased lipase (26%), increased AST (25%), decreased hemoglobin (24%), decreased leukocytes (23%), decreased sodium (23%), decreased phosphate (23%), increased potassium (23%), and decreased glucose (21%).

Please click here for full Prescribing Information for TABRECTA.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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HELPFUL REMINDERS FOR TAKING TABRECTA

Take TABRECTA™ (capmatinib) tablets 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.

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	LIVER PROBLEMS
New or worsening cough, fever, trouble breathing, or shortness of breath	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

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.

- Most common side effects include swelling of hands and feet, nausea, tiredness and weakness, vomiting, loss of appetite, changes in certain blood tests

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™ (capmatinib) tablets 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 or cannot be removed by surgery (metastatic), and
- whose tumors have an abnormal mesenchymal-epithelial transition (MET) gene

The effectiveness of TABRECTA in these patients is based on a study that measured 2 types of response to treatment (response rate and duration of response). There is no clinical information available to show if patients treated with TABRECTA live longer or if their symptoms improve. There are ongoing studies to find out how TABRECTA works over a longer period of time.

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

Your health care provider may temporarily or permanently stop treatment with TABRECTA if you develop lung or breathing problems during treatment.

Please see additional Summary of Important Information for TABRECTA on the 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

Your health care provider may change your dose, or temporarily or permanently stop treatment with TABRECTA, if you develop liver problems during treatment.

- **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
- tiredness and weakness
- vomiting
- loss of appetite
- changes in certain blood tests

These are not all of 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 of 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
- 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 or start taking, 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

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