



CANCER
DREAM
TEAM
FIGHTING

Surgeon



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Medical Oncologist



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Radiation Oncologist

Teaming

By Lori K. Baker

When your opponent is cancer, losing isn't an option.
Here's how to build a cancer-fighting dream team



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Clergy or Counselor

You could call me the cancer comeback kid. Three years shy of my 40th birthday, the age most women have their first mammogram, I discovered that I had invasive breast cancer that had spread to four lymph nodes. As a fitness buff and the mother of a 4-year-old son and 6-year-old daughter, I was so stunned by the diagnosis I felt numb.

But I was determined to do what it took to beat this disease, even though the odds were stacked perilously against me. With Stage 2 breast cancer such as mine, there was a 75 percent chance the cancer would return in five years and be incurable.

Sure, it could have been easy to throw in the towel and declare defeat—but that’s just simply not what winners do.

“To get the diagnosis of cancer or recurrent cancer is a terrible situation,” says Len Lichtenfeld, M.D., deputy chief medical officer for the American Cancer Society. “But patients need to become informed, take responsibility and take charge.”

Put Together a Game Plan

Fueled by my reporter’s instincts, I delved into research about my health condition as if I was on a hot assignment (which I was). My investigation included calling the American Cancer Society, whose national call center (800-ACS-2345) employs more than 400 people who can help newly diagnosed cancer patients learn about their disease and navigate the healthcare system.

Then I sought doctors who were not only respected experts in their field but who also would discuss my condition and medical options

as an equal—not a superior—and support me in my efforts to keep a positive attitude. “The good, caring physician by the bedside, whom you can talk to, trumps the expert who’s always flying around giving lectures,” Lichtenfeld says.

As I explored my options, I struggled against feelings of urgency—I wanted the cancer gone *now*. But Richard Wender, M.D., president of the American Cancer Society, says it best: “How many battles for your life will you face? This one is worth the extra energy, work and planning so you have a team that inspires confidence and in which you have a high level of trust.”

Fill the Positions

Who’s the captain of the cancer team? The patient, of course. But here are nine other key players on a cancer-fighting dream team:



Social Worker



Dietitian



Physical or Occupational Therapist

On Your Terms

If you were the captain of a football team, you'd know the difference between a first down and a touchdown. As the captain of your cancer team, there's also terminology you need to know:

Adjuvant therapy (A-joo-vant THAYR-uh-pee)

Treatment given after the primary treatment to increase the chances of a cure. It may include chemotherapy, radiation therapy, hormone therapy or biological therapy.

Biopsy (BY-op-see)

The removal of cells or tissues for examination by a pathologist to detect cancer.

Lymph node (limf node)

Lymph nodes are bean-shaped masses that can be found in the groin, armpit, neck or other places in the body's lymphatic system, which acts like a filter. Important for the body's immune system, they try to trap cancer cells and bacteria causing an infection.

Metastasis (meh-TAS-tuh-sis)

The spread of cancer from one part of the body to another.

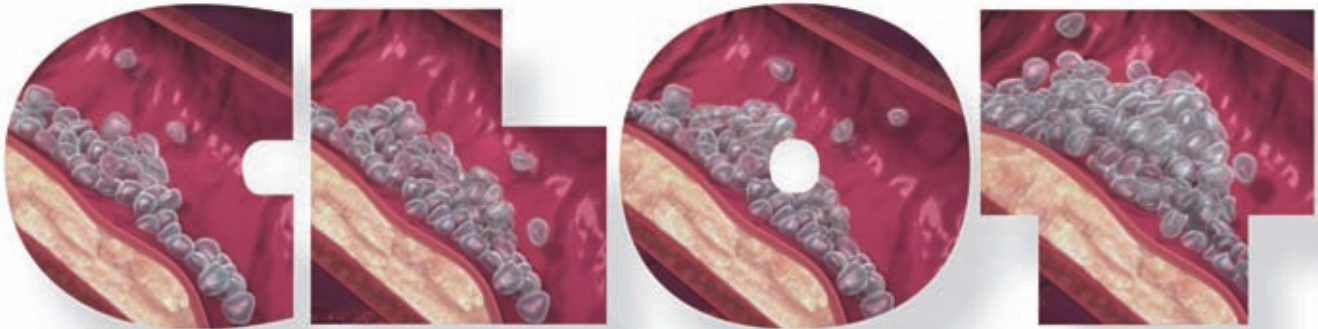
Prognosis (prog-NO-sis)

The likely outcome or course of a disease; the chance of recovery or recurrence.

Source: National Cancer Institute

1 Primary care physician. Don't wait until you receive a cancer diagnosis to sign on this key player, Wender says. "This physician is your best insurance that you won't die or suffer needlessly from cancer." That's because a primary care physician is your source for regular preventive care and early screenings. "Studies show that people with breast, cervical and colon cancer who have a primary care physician are diagnosed at earlier stages," Wender adds.

And after a frightening cancer diagnosis, it's reassuring to turn to a primary care physician whom you trust. "It's a scary time," Wender says. "It can be numbing even if the news is optimistic. Your primary care physician can become an enormous advocate for you and guide you as you assemble the rest of your cancer team." He or she can refer you to doctors specializing in cancer care, including oncologists.



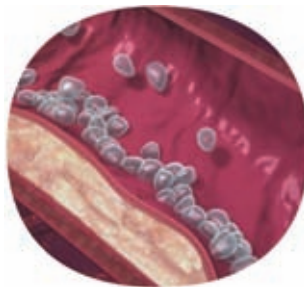
You can help protect against the formation of clots and reduce your risk of a future heart attack or stroke.

This is important information if you've been hospitalized with heart-related chest pain or had a heart attack.

That's because these conditions, known as Acute Coronary Syndrome—or ACS—are usually caused when blood platelets stick together and form clots that block blood flow to your heart. And if you've already had a clot, you're at an increased risk for a future heart attack or stroke.

PLAVIX, taken with other heart medicines, helps provide greater protection against heart attack or stroke than other heart medicines alone.

That's because prescription PLAVIX works differently than your cholesterol and blood pressure medications, focusing on your blood platelets to help keep them from sticking together and forming clots.



IMPORTANT INFORMATION: If you have a stomach ulcer or other condition that causes bleeding, you should not use PLAVIX. When taking PLAVIX alone or with some other medicines including aspirin, the risk of bleeding may increase so tell your doctor before planning surgery. And, always talk to your doctor before taking aspirin or other medicines with PLAVIX, especially if you've had a stroke. If you develop fever, unexplained weakness or confusion, tell your doctor promptly as these may be signs of a rare but potentially life-threatening condition called TTP, which has been reported rarely, sometimes in less than 2 weeks after starting therapy. Other rare but serious side effects may occur.

See important product information on the following page.

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Rx only

INDICATIONS AND USAGE

PLAVIX (clopidogrel bisulfate) is indicated for the reduction of atherothrombotic events as follows:

Recent MI, Recent Stroke or Established Peripheral Arterial Disease

For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, PLAVIX has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or non-fatal), new MI (fatal or non-fatal), and other vascular death.

Acute Coronary Syndrome

For patients with non-ST-segment elevation acute coronary syndrome (unstable anginal/non-Q-wave MI) including patients who are to be managed medically and those who are to be managed with percutaneous coronary intervention (with or without stent) or CABG, PLAVIX has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI, or stroke as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia.

For patients with ST-segment elevation acute myocardial infarction, PLAVIX has been shown to reduce the rate of stroke from any cause and the rate of a combined endpoint of death, re-infarction or death. This benefit is not known to pertain to patients who receive primary angioplasty.

CONTRAINDICATIONS

The use of PLAVIX is contraindicated in the following conditions:

- Hypersensitivity to the drug substance or any component of the product.
- Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

WARNINGS

Thrombotic thrombocytopenic purpura (TTP):

TTP has been reported rarely following use of PLAVIX, sometimes after a short exposure (<2 weeks). TTP is a serious condition that can be fatal and requires urgent treatment including plasmapheresis (plasma exchange). It is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragmented RBCs] seen on peripheral smear), neurological findings, renal dysfunction, and fever. (See **ADVERSE REACTIONS**.)

PRECAUTIONS

General

PLAVIX prolongs the bleeding time and therefore should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions (particularly gastrointestinal and intracranial). If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.

Due to the risk of bleeding and undesirable hematological effects, blood cell count determination and/or other appropriate testing should be promptly considered, whenever such suspected clinical symptoms arise during the course of treatment (see **ADVERSE REACTIONS**).

In patients with recent TIA or stroke who are at a high risk for recurrent ischemic events, the combination of aspirin and PLAVIX has not been shown to be more effective than PLAVIX alone, but the combination has been shown to increase major bleeding.

GI Bleeding: In CAPRIE, PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0% vs 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs 0.7% (PLAVIX + aspirin vs placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX.

Use in Hepatically Impaired Patients: Experience is limited in patients with severe hepatic disease, who may have bleeding diatheses. PLAVIX should be used with caution in this population.

Use in Renally-Impaired Patients: Experience is limited in patients with severe renal impairment. PLAVIX should be used with caution in this population.

Information for Patients

Patients should be told it may take them longer than usual to stop bleeding, that they may bruise and/or bleed more easily when they take PLAVIX or PLAVIX combined with aspirin, and that they should report any unusual bleeding to their physician. Patients should inform physicians and dentists that they are taking PLAVIX and/or any other product known to affect bleeding before any surgery is scheduled and before any new drug is taken.

Drug Interactions

Study of specific drug interactions yielded the following results:

Aspirin: PLAVIX did not modify the clopidogrel-mediated inhibition of ADP-induced platelet aggregation. Concomitant administration of 500 mg of aspirin twice a day for 1 day did not significantly increase the prolongation of bleeding time induced by PLAVIX. PLAVIX potentiated the effect of aspirin on collagen-induced platelet aggregation. PLAVIX and aspirin have been administered together for up to one year.

Heparin: In a study in healthy volunteers, PLAVIX did not necessitate modification of the heparin dose or alter the effect of heparin on coagulation. Coadministration of heparin had no effect on inhibition of platelet aggregation induced by PLAVIX.

Nonsteroidal Anti-inflammatory Drugs (NSAIDs): In healthy volunteers receiving naproxen, concomitant administration of PLAVIX was associated with increased occult gastrointestinal blood loss. NSAIDs and PLAVIX should be coadministered with caution.

Warfarin: Because of the increased risk of bleeding, the concomitant administration of warfarin with PLAVIX should be undertaken with caution. (See **PRECAUTIONS—General**.)

Other Concomitant Therapy: No clinically significant pharmacodynamic interactions were observed when PLAVIX was coadministered with **atenolol, nifedipine**, or both atenolol and nifedipine. The pharmacodynamic activity of PLAVIX was also not significantly influenced by the coadministration of **phenobarbital, cimetidine**, or **estrogen**.

The pharmacokinetics of **gabapentin** or **theophylline** were not modified by the coadministration of PLAVIX (clopidogrel bisulfate).

At high concentrations *in vitro*, clopidogrel inhibits P₄₅₀ (CYP₂). Accordingly, PLAVIX may interfere with the metabolism of **phenytoin, tamoxifen, tolbutamide, warfarin, torsemide, fluvastatin**, and many **non-steroidal anti-inflammatory agents**, but there are no data with which to predict the magnitude of these interactions. Caution should be used when any of these drugs is coadministered with PLAVIX.

In addition to the above specific interaction studies, patients entered into clinical trials with PLAVIX received a variety of concomitant medications including **diuretics, beta-blocking agents, angiotensin converting enzyme inhibitors, calcium antagonists, cholesterol lowering agents, coronary vasodilators, antiidiabetic agents (including insulin), thrombolytics, heparins** (unfractionated and LMWH) **GP11b/IIIa antagonists, antiepileptic agents and hormone replacement therapy** without evidence of clinically significant adverse interactions.

There are no data on the concomitant use of oral anticoagulants, non-study oral antiplatelet drugs and chronic NSAIDs with clopidogrel.

Drug/Laboratory Test Interactions

None known.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of tumorigenicity when clopidogrel was administered for 78 weeks to mice and 104 weeks to rats at dosages up to 77 mg/kg per day, which afforded plasma exposures >25 times that of humans at the recommended daily dose of 75 mg. Clopidogrel was not genotoxic in four *in vitro* tests (Ames test, DNA-repair test in rat hepatocytes, gene mutation assay in Chinese hamster fibroblasts, and metaphase chromosome analysis of human lymphocytes) and in one *in vivo* test (micronucleus test by oral route in mice). Clopidogrel was found to have no effect on fertility of male and female rats at oral doses up to 400 mg/kg per day (52 times the recommended human dose on a mg/m² basis).

Pregnancy

Pregnancy Category B. Reproduction studies performed in rats and rabbits at doses up to 500 and 300 mg/kg/day (respectively, 65 and 78 times the recommended daily human dose on a mg/m² basis), revealed no evidence of impaired fertility or fetotoxicity due to clopidogrel. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of a human response, PLAVIX should be used during pregnancy only if clearly needed.

Nursing Mothers

Studies in rats have shown that clopidogrel and/or its metabolites are excreted in the milk. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the nursing woman.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

Geriatric Use

Of the total number of subjects in CAPRIE, CURE and CLARITY controlled clinical studies, approximately 50% of patients treated with PLAVIX were 65 years of age and older and 15% were 75 years and older. In COMMIT, approximately 58% of the patients treated with PLAVIX were 60 years and older, 26% of whom were 70 years and older. The observed risk of thrombotic events with clopidogrel plus aspirin versus placebo plus aspirin by age category is provided in Figures 3 and 6 for the CURE and COMMIT trials, respectively (see **CLINICAL STUDIES**). The observed risk of bleeding events with clopidogrel plus aspirin versus placebo plus aspirin by age category is provided in Tables 5 and 6 for the CURE and COMMIT trials, respectively (see **ADVERSE REACTIONS**).

ADVERSE REACTIONS

PLAVIX has been evaluated for safety in more than 42,000 patients, including over 9,000 patients treated for 1 year or more. The clinically important adverse events observed in CAPRIE, CURE, CLARITY and COMMIT are discussed below.

The overall tolerability of PLAVIX in CAPRIE was similar to that of aspirin regardless of age, gender and race, with an approximately equal incidence (13%) of patients withdrawing from treatment because of adverse reactions.

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 5). There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage (0.1%), and fatal bleeding (0.2%), were the same in both groups.

The overall incidence of bleeding is described in Table 5 for patients receiving both PLAVIX and aspirin in CURE.

Table 5: CURE Incidence of bleeding complications (% patients)

Event	PLAVIX (+ aspirin) [†] (n=6259)	Placebo (+ aspirin) [‡] (n=6203)	P-value
Major bleeding †	3.7 ‡	2.7 §	0.001
Life-threatening bleeding	2.2	1.8	0.13
Fatal	0.2	0.2	
5 g/dL hemoglobin drop	0.9	0.9	
Requiring surgical intervention	0.7	0.7	
Hemorrhagic strokes	0.1	0.1	
Requiring intropops	0.5	0.5	
Requiring transfusion (≥4 units)	1.2	1.0	
Other major bleeding	1.6	1.0	0.005
Significantly disabling	0.4	0.3	
Intraocular bleeding with significant loss of vision	0.05	0.03	
Requiring 2-3 units of blood	1.3	0.9	
Minor bleeding †	5.1	2.4	<0.001

† Other standard therapies were used as appropriate.

‡ Life threatening and other major bleeding.

§ Major bleeding event rate for PLAVIX + aspirin was dose-dependent on aspirin:

<100 mg=2.6%; 100-200 mg=3.5%; >200 mg=4.9%

Major bleeding event rates for PLAVIX + aspirin by age were: <65 years = 2.5%, ≥65 to <75 years = 4.1%, ≥75 years 5.9%

§ Major bleeding event rate for placebo + aspirin was dose-dependent on aspirin:

<100 mg=2.0%; 100-200 mg=2.3%; >200 mg=4.0%

Major bleeding event rates for placebo + aspirin by age were: <65 years = 2.1%, ≥65 to <75 years = 3.1%, ≥75 years 3.6%

¶ † Led to interruption of study medication.

Ninety-two percent (92%) of the patients in the CURE study received heparin/LMWH, and the rate of bleeding in these patients was similar to the overall results.

There was an excess in major bleeds within seven days after coronary bypass graft surgery in patients who stopped therapy more than five days prior to surgery (event rate 4.4% PLAVIX + aspirin; 5.3% placebo + aspirin). In patients who remained on therapy within five days of bypass graft surgery, the event rate was 9.6% for PLAVIX + aspirin, and 6.3% for placebo + aspirin.

In CLARITY, the incidence of major bleeding (defined as intracranial bleeding or bleeding associated with a fall in hemoglobin > 5 g/dL) was similar between groups (1.3% versus 1.1% in the PLAVIX + aspirin and in the placebo + aspirin groups, respectively). This was consistent across subgroups of patients defined by baseline characteristics, and type of fibrinolytics or heparin therapy. The incidence of fatal bleeding (0.8% versus 0.6% in the PLAVIX + aspirin and in the placebo + aspirin groups, respectively) and intracranial hemorrhage (0.5% versus 0.7%, respectively) was low and similar in both groups.

The overall rate of noncerebral major bleeding or cerebral bleeding in COMMIT was low and similar in both groups as shown in Table 6 below.

Table 6: Number (% of Patients with Bleeding Events in COMMIT

Type of bleeding	PLAVIX (+ aspirin) (N = 22961)	Placebo (+ aspirin) (N = 22891)	P-value
Major* noncerebral or cerebral bleeding**	134 (0.6%)	125 (0.5%)	0.59
Major noncerebral	82 (0.4%)	73 (0.3%)	0.48
Fatal	36 (0.2%)	37 (0.2%)	0.90
Hemorrhagic stroke	55 (0.2%)	56 (0.2%)	0.91
Fatal	39 (0.2%)	41 (0.2%)	0.81
Other noncerebral bleeding (non-major)	831 (3.6%)	721 (3.1%)	0.005
Any noncerebral bleeding	896 (3.9%)	777 (3.4%)	0.004

* Major bleeds are cerebral bleeds or non-cerebral bleeds thought to have caused death or that required transfusion.

** The relative rate of major noncerebral or cerebral bleeding was independent of age. Event rates for PLAVIX + aspirin by age were: <60 years = 0.3%, ≥60 to <70 years = 0.7%, ≥70 years 0.8%. Event rates for placebo + aspirin by age were: <60 years = 0.4%, ≥60 to <70 years = 0.6%, ≥70 years 0.7%.

Adverse events occurring in ≥2.5% of patients in PLAVIX in the CAPRIE controlled clinical trial are shown below regardless of relationship to PLAVIX. The median duration of therapy was 20 months, with a maximum of 3 years.

Table 7: Adverse Events Occurring in ≥2.5% of PLAVIX Patients in CAPRIE

Body System Event	% Incidence (% Discontinuation)	
	PLAVIX (n=9599)	Aspirin (n=9586)
<i>Body as a Whole—general disorders</i>		
Chest Pain	8.3 (0.2)	8.3 (0.3)
Accidental/Inflicted Injury	7.9 (0.1)	7.3 (0.1)
Influenza-like symptoms	7.5 (<0.1)	7.0 (<0.1)
Pain	6.4 (0.1)	6.3 (0.1)
Fatigue	3.3 (0.1)	3.4 (0.1)
<i>Cardiovascular disorders, general</i>		
Edema	4.1 (<0.1)	4.5 (<0.1)
Hypertension	4.3 (<0.1)	5.1 (<0.1)
<i>Central & peripheral nervous system disorders</i>		
Headache	7.6 (0.3)	7.2 (0.2)
Dizziness	6.2 (0.2)	6.7 (0.3)
<i>Gastrointestinal system disorders</i>		
Any event	27.1 (3.2)	29.8 (4.0)
Abdominal pain	5.6 (0.7)	7.1 (1.0)
Dyspepsia	5.2 (0.6)	6.1 (0.7)
Diarrhea	4.5 (0.4)	3.4 (0.3)
Nausea	3.4 (0.5)	3.8 (0.4)
<i>Metabolic & nutritional disorders</i>		
Hypercholesterolemia	4.0 (0)	4.4 (<0.1)
<i>Musculo-skeletal system disorders</i>		
Arthralgia	6.3 (0.1)	6.2 (0.1)
Back Pain	5.8 (0.1)	5.3 (<0.1)
<i>Platelet, bleeding, & clotting disorders</i>		
Purpura/Bruse	5.3 (0.3)	3.7 (0.1)
Epistaxis	2.9 (0.2)	2.5 (0.1)
<i>Psychiatric disorders</i>		
Depression	3.6 (0.1)	3.9 (0.2)
<i>Respiratory system disorders</i>		
Upper resp tract infection	8.7 (<0.1)	8.3 (<0.1)
Dyspnea	4.5 (0.1)	4.7 (0.1)
Rhinitis	4.2 (0.1)	4.2 (<0.1)
Bronchitis	3.7 (0.1)	3.7 (0)
Coughing	3.1 (<0.1)	2.7 (<0.1)
<i>Skin & appendage disorders</i>		
Any event	15.8 (1.5)	13.1 (0.8)
Rash	4.2 (0.5)	3.5 (0.2)
Pruritus	3.3 (0.3)	1.6 (0.1)
<i>Urinary system disorders</i>		
Urinary tract infection	3.1 (0)	3.5 (0.1)

No additional clinically relevant events to those observed in CAPRIE with a frequency ≥2.5%, have been reported during the CURE and CLARITY controlled studies. COMMIT collected only limited safety data.

Other adverse experiences of potential importance occurring in 1% to 2.5% of patients receiving PLAVIX (clopidogrel bisulfate) in the controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in the other clinical trials).

Autonomic Nervous System Disorders: Syncope, Palpitation. **Body as a Whole-general disorders:** Asthenia, Fever, Hemia. **Cardiovascular disorders:** Cardiac failure, Central and peripheral nervous system disorders. **Cranial nerves, Hypoesthesia, Neuralgia, Parosmia, Vertigo.** **Gastrointestinal system disorders:** Constipation, Vomiting, Heart rate and rhythm disorders: Fibrillation atrial. **Liver and biliary system disorders:** Hepatic enzymes increased. **Metabolic and nutritional disorders:** Gout, hyperuricemia, non-protein nitrogen (NPN) increased. **Musculo-skeletal system disorders:** Arthritis, Arthrosis. **Platelet, bleeding & clotting disorders:** GI hemorrhage, hematoma, platelets decreased. **Psychiatric disorders:** Anxiety, Insomnia. **Red blood cell disorders:** Anemia. **Respiratory system disorders:** Pneumonia, Sinusitis. **Skin and appendage disorders:** Eczema, skin ulceration. **Urinary system disorders:** Cystitis. **Vision disorders:** Cataract, Conjunctivitis.

Other potentially serious adverse events which may be of clinical interest but were rarely reported (<1% in patients who received PLAVIX in the controlled clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in the other clinical trials).

Body as a whole: Allergic reaction, necrosis ischemic. **Cardiovascular disorders:** Edema generalized. **Gastrointestinal system disorders:** Peptic, gastric or duodenal ulcer, gastritis, gastric ulcer perforated, gastritis hemorrhagic, upper GI ulcer hemorrhagic. **Liver and Biliary system disorders:** Bilirubinemia, hepatitis infectious, liver fatty, Platelet, bleeding and clotting disorders: hemarthrosis, hematuria, hemoptysis, hemorrhage intracranial, hemorrhage retroperitoneal, hemorrhage of operative wound, ocular hemorrhage, pulmonary hemorrhage, purpura allergic, thrombocytopenia. **Red blood cell disorders:** Anemia aplastic, anemia hypochromic. **Reproductive disorders, female:** Menorrhagia. **Respiratory system disorders:** Hemothorax. **Skin and appendage disorders:** Bullous eruption, rash erythematous, rash maculopapular, urticaria. **Urinary system disorders:** Abnormal renal function, acute renal failure. **White cell and reticuloendothelial system disorders:** Agranulocytosis, granulocytopenia, leukemia, leukopenia, neutropenia.

Postmarketing Experience

The following events have been reported spontaneously from worldwide postmarketing experience:

- Body as a whole:**
 - hypersensitivity reactions, anaphylactoid reactions, serum sickness
- Central and Peripheral Nervous System disorders:**
 - confusion, hallucinations, taste disorders
- Hepato-biliary disorders:**
 - abnormal liver function test, hepatitis (non-infectious), acute liver failure
- Platelet, Bleeding and Clotting disorders:**
 - cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage)
 - thrombotic thrombocytopenic purpura (TTP) – some cases with fatal outcome (see **WARNINGS**).
 - agranulocytosis, aplastic anemia/pancytopenia
 - conjunctival, ocular and retinal bleeding
- Respiratory, thoracic and mediastinal disorders:**
 - bronchospasm, interstitial pneumonitis
- Skin and appendage tissue disorders:**
 - angioedema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, lichen planus
- Renal and urinary disorders:**
 - glomerulopathy, increased creatinine levels
- Vascular disorders:**
 - vasculitis, hypotension
- Gastrointestinal disorders:**
 - colitis (including ulcerative or lymphocytic colitis), pancreatitis, stomatitis
- Musculoskeletal, connective tissue and bone disorders:**
 - myalgia

OVERDOSAGE

Overdose following clopidogrel administration may lead to prolonged bleeding time and subsequent bleeding complications. A single oral dose of clopidogrel at 1500 or 2000 mg/kg was lethal to mice and to rats and at 3000 mg/kg to baboons. Symptoms of acute toxicity were vomiting (in baboons), prostration, difficult breathing, and gastrointestinal hemorrhage in all species.

Recommendations About Specific Treatment:

Based on biological plausibility, platelet transfusion may be appropriate to reverse the pharmacological effects of PLAVIX if quick reversal is required.

DOSAGE AND ADMINISTRATION

Recent MI, Recent Stroke, or Established Peripheral Arterial Disease

The recommended daily dose of PLAVIX is 75 mg once daily.

Acute Coronary Syndrome

For patients with non-ST-segment elevation acute coronary syndrome (unstable anginal/non-Q-wave MI), PLAVIX should be initiated with a single 300 mg loading dose and then continued at 75 mg once daily. Aspirin (75 mg-325 mg once daily) should be initiated and continued in combination with PLAVIX. In CURE, most patients with Acute Coronary Syndrome also received heparin acutely (see **CLINICAL STUDIES**).

For patients with ST-segment elevation acute myocardial infarction, the recommended dose of PLAVIX is 75 mg once daily, administered in combination with aspirin, with or without thrombolytics. PLAVIX may be initiated with or without a loading dose (300 mg) as used in CLARITY; see **CLINICAL STUDIES**.

PLAVIX can be administered with or without food.

No dosage adjustment is necessary for elderly patients or patients with renal disease. (See **Clinical Pharmacology: Special Populations**.)

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Brief Summary of Prescribing Information Revised February 2007

PLA-FEB07-B-Aa

2 Medical oncologist. Often the main healthcare provider for someone who has cancer, this physician specializes in drug therapies (chemotherapy, hormone therapy and biological therapy)—either used alone or in combination with other treatments. A medical oncologist can discuss the best treatment choices for you, whether standard therapy or clinical trials.

3 Surgeon. A surgeon is often the first cancer specialist a patient sees if he or she needs a surgical biopsy or a tumor removed. The surgeon works in conjunction with other team members to plan the best course of treatment.

4 Radiation oncologist. This physician specializes in the use of radiation to treat cancer. Because there are many types of radiation, your oncologist will work with you to find the type that will best treat your cancer.

5 Dietitian. This health professional can help cancer patients with everything from preparing menus that will meet their special nutritional needs to making certain foods more palatable when they have a loss of appetite. Most hospitals have registered dietitians on staff, and you can ask your doctor about meeting with them.

6 Physical or occupational therapists. These healthcare professionals teach exercises and physical activities that help patients gain muscle strength and movement. For example, physical therapy can help rebuild muscles in your arm and shoulder if you have chest surgery. They also can help patients avoid or minimize certain side effects of cancer surgeries, such as swelling after a mastectomy. Your primary care physician or oncologist can refer you to rehabilitation services.

7 Social worker. Social workers who specialize in working with cancer patients can anticipate problems or difficult emotions they might feel—and offer solutions. Social workers often facilitate support groups at hospitals, where cancer patients and their families can gather to share experiences and gain support from people in similar situations. If you need help finding a social worker, start by contacting your local hospital.

8 Clergy or a counselor. Because cancer patients may feel vulnerable and afraid, these professionals can help you through this emotionally difficult time. “Spiritual or mental health support can be a vital part of your treatment, depending on the stage of your cancer,” Wender says.

9 Cosmetologist. A cosmetologist knowledgeable about cancer treatments can help a patient prevent and care for the likely side effects of chemotherapy or radiation, including hair loss and dry and sensitive skin. To find a cosmetologist in your area, call **800-395-LOOK (395-5665)**, the toll-free number of Look Good ... Feel Better, a national public service program founded by the Cosmetic, Toiletry, and Fragrance Association Foundation.

Post-Game Follow-Up

It’s been more than 10 years since I received that frightening breast cancer diagnosis, and I’m classified as “cured.” Nowadays, my annual follow-up visits with my oncologist have become a ritual celebrating another year of life.

Every time I see my oncologist I think about the old TV show character Marcus Welby, M.D., a doctor who combined compassion with medical wisdom. “How long has it been since you had cancer now?” my oncologist inevitably asks with a warm smile. “You’re a survivor in every sense of the word.” ■

When to Send in a Backup

If you’ve ever thought about asking your doctor for a second opinion—then decided not to risk it—you’re not alone. No matter how many times we’ve been told doctors are professionals and won’t take it personally, lots of us struggle with challenging their recommendations.

In cancer care, though, asking for a second opinion literally can mean the difference between life and death. A study from the University of Pennsylvania illustrates the point. Cancer specialists there reviewed the medical records of 75 women with breast cancer. The specialist team discovered it disagreed with the referring doctors’ treatment recommendations in 43 percent of the cases.

What’s the take-home message? “It’s OK to get a second opinion,” says Len Lichtenfeld, M.D., deputy chief medical officer for the American Cancer Society. “After all, this is your life.”

Start Recruiting

If you or a loved one has recently been diagnosed with cancer, it’s time to start building your dream team. You’re the captain, so be sure to do your research. Start by understanding your diagnosis. Talk to your doctor or visit cancer.org.