Before treatment begins, you and your doctor need to share some key information with one another.

Things you should tell your doctor before treatment starts

Be sure to tell your doctor if you:

• **Have problems with your liver or kidneys.** Treatment with ABRAXANE can make liver problems worse. If you have liver problems, your starting dose of ABRAXANE should be lowered or withheld.

• **Are pregnant, or plan to become pregnant.** ABRAXANE can harm your unborn baby. Women who may become pregnant should use effective birth control (contraception). Talk to your doctor about the best way to prevent pregnancy while receiving ABRAXANE.

• **Are breastfeeding or plan to breastfeed.** It is not known whether ABRAXANE passes into your breast milk. Together you and your doctor must decide whether you will receive ABRAXANE or breastfeed.

• **Are a man who is planning to father a child.** You should not father a child while you are being treated with ABRAXANE. It can harm your partner’s unborn baby.

Tell your doctor about all of the medicines you take. These include:

• Prescription medicines

• Non-prescription medicines, or over-the-counter medicines

• Vitamins

• Herbal supplements

Let your doctor know how you are feeling physically and emotionally.

• Are you having symptoms now?

• How are you feeling about starting treatment with ABRAXANE? What are your concerns?

Please see Important Safety Information on pages 2–4 and accompanying Patient Information and full Prescribing Information, including Boxed WARNING.
Information your doctor should share with you

You have a right to know what to expect from treatment with ABRAXANE. There are some side effects that were reported by people who were in clinical trials for ABRAXANE. Be sure to have your doctor explain them to you.

Your doctor should let you know:
• What you can expect to happen over the course of treatment with ABRAXANE
• How, when, and where you will receive ABRAXANE
• How you will know if ABRAXANE is working
• What side effects you may experience during treatment and ways your healthcare team may help you cope with them

For more information, please speak with your healthcare professional.

ABRAXANE® is a prescription medicine used to treat advanced breast cancer in people who have already received certain other medicines for their cancer.

Important Safety Information About ABRAXANE

WARNING - LOW WHITE BLOOD CELL COUNT (NEUTROPENIA)

• Do not take ABRAXANE if your white blood cell count is below 1500 cells/mm³ (neutropenia), since you may be more likely to get a serious infection. While taking ABRAXANE, you must get regular blood tests to check for any problems that could develop
• ABRAXANE contains albumin, a substance found in human blood. Do not substitute for or with other paclitaxel formulations

WHO SHOULD NOT RECEIVE ABRAXANE?
• Do not receive ABRAXANE if:
  o your white blood cell count is below 1500 cells/mm³
  o you have had a severe allergic reaction to ABRAXANE

SERIOUS SIDE EFFECTS
ABRAXANE may cause serious side effects, including:
• Decreased blood cell counts. ABRAXANE can cause a severe decrease in neutrophils, a type of white blood cell which helps fight infections, and blood cells called platelets which help to clot blood. Your healthcare provider will check your blood cell count during your treatment with ABRAXANE

(continued)
• **Nerve problems (neuropathy).** Tell your healthcare provider if you have numbness, tingling, pain, or weakness in your hands or feet

• **Allergic reactions.** Severe allergic reactions are medical emergencies that can happen in people who receive ABRAXANE and can lead to death. You may have an increased risk of having an allergic reaction to ABRAXANE if you are allergic to other taxane medicines. Your healthcare provider will monitor you closely for allergic reactions during your infusion of ABRAXANE. Tell your healthcare provider right away if you get any of these signs of a serious allergic reaction: trouble breathing, sudden swelling of your face, lips, tongue, throat, or trouble swallowing, hives (raised bumps), rash, or redness all over your body

**OTHER RISKS**
• Treatment with ABRAXANE can make liver problems worse. If you have liver problems, your starting dose of ABRAXANE should be lowered or withheld

• ABRAXANE contains albumin (human), a product of human blood

• Do not breastfeed during your treatment and for two weeks after the last dose of ABRAXANE

**RISKS TO PREGNANCY**
• If you are pregnant or become pregnant, ABRAXANE can harm your unborn baby. Your healthcare provider should do a pregnancy test before you start treatment with ABRAXANE. Women should not become pregnant and should use effective birth control (contraception) during treatment and for at least six months after the last dose of ABRAXANE. Talk to your doctor about birth control methods you can use during this time

• ABRAXANE can harm the unborn baby of your partner

• If you are a man, you should not father a child and should use effective birth control (contraception) during treatment and for at least three months after the last dose of ABRAXANE

• ABRAXANE may cause fertility problems in males and females, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you

**OTHER POSSIBLE SIDE EFFECTS**

The most common side effects of ABRAXANE in people with breast cancer include:

- hair loss
- numbness, tingling, pain, or weakness in the hands or feet
- tiredness
- changes in your liver function tests
- nausea
- diarrhea
- infections
- decreased white blood cell count
- abnormal heartbeat
- joint and muscle pain
- low red blood cell count (anemia). Red blood cells carry oxygen to your body tissues. Tell your healthcare provider if you feel weak, tired, or short of breath

- Other side effects include vision problems, decreased appetite, kidney problems, constipation, and difficulty breathing

- In some patients receiving ABRAXANE, severe heart and blood vessel side effects have occurred. These included chest pain, heart attack, fluid under the skin, blood clots in the veins or lungs, high blood pressure, stroke, and heart failure
OTHER IMPORTANT SAFETY INFORMATION ABOUT ABRAXANE

- You should contact your doctor if you have signs or symptoms of vomiting, diarrhea, dehydration, cough, or breathing difficulties that do not go away, or signs of an allergic reaction. Tell your doctor if you have any other medical conditions.

- Treatment with ABRAXANE can cause irritation where the medicine is injected (injection site reactions). You should be monitored by your doctor or nurse during and after you receive ABRAXANE to make sure no problems occur at the injection site. In some cases, these problems occurred 7 to 10 days after the medicine was injected.

- It is not known whether ABRAXANE interacts with other drugs, so be sure to tell your doctor about any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements you are taking.

- It is not known if ABRAXANE is safe or effective in children.

- ABRAXANE has not been adequately studied in people with severe kidney problems.

These are not all the possible side effects of ABRAXANE. For more information, ask your doctor or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

Please see Patient Information and full Prescribing Information, including Boxed WARNING.