KEYTRUDA®
(pembrolizumab) Injection 100 mg



A breakthrough immunotherapy for high-risk early-stage triple-negative breast cancer

KEYTRUDA may be used as part of your treatment plan

KEYTRUDA is a prescription medicine used to treat a kind of cancer called triple-negative breast cancer (TNBC). KEYTRUDA may be used with chemotherapy medicines as treatment before surgery and then continued alone after surgery when you have early-stage breast cancer, **and** are at high risk of your breast cancer coming back.

Important Safety Information

KEYTRUDA is a medicine that may treat certain cancers by working with your immune system. KEYTRUDA can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen any time during treatment or even after your treatment has ended.

Please read the accompanying Medication Guide for KEYTRUDA and discuss it with your doctor. The physician Prescribing Information also is included. You can find additional Important Safety Information about KEYTRUDA throughout this brochure.

Getting started

Understanding your diagnosis, including what treatment options are available, can feel overwhelming at times—but you're not alone. Use this guide to help you and your care team discuss the role of treatment **before** and **after surgery** for high-risk early-stage triple-negative breast cancer **(TNBC)**—and learn if a treatment plan that includes KEYTRUDA may be right for you.

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Important Safety Information (*continued*)

Call or see your health care provider right away if you develop any signs or symptoms of the following problems or if they get worse. These are not all of the signs and symptoms of immune system problems that can happen with KEYTRUDA:

Lung problems: cough, shortness of breath, or chest pain.

Intestinal problems: diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; or severe stomach-area (abdomen) pain or tenderness.

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What is TNBC?

Triple-negative breast cancer (TNBC) is a type of breast cancer where the cancer cells don't contain estrogen or progesterone receptors and don't make any or too much HER2 protein. When the cells test "negative" on all 3 of the tests above, a diagnosis of TNBC is given.



TNBC is characterized as a cancer that can grow and spread fast.

It's important to speak with an oncologist about all options available to you for treatment.

What does "high-risk early-stage" mean?

"High-risk" refers to breast cancer that is more likely to return after having surgery to remove it. "Early-stage" means the cancer is in the breast and possibly lymph nodes, but has not spread to other parts of the body.

KEYTRUDA is an FDA-approved immunotherapy that is used as part of a treatment plan for high-risk early-stage TNBC

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What is KEYTRUDA and how does it work?

KEYTRUDA is not chemotherapy or radiation therapy—it is an immunotherapy, and it works with your immune system to help fight certain cancers.

KEYTRUDA can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen any time during treatment or even after your treatment has ended.

Watch a video that explains how **KEYTRUDA** works, featuring **Jane Arboleda**, a real oncology nurse.



Scan the QR code to open the video or visit keytruda.com/watchnow

Important Safety Information (*continued*)

Liver problems: yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); dark urine (tea colored); or bleeding or bruising more easily than normal.

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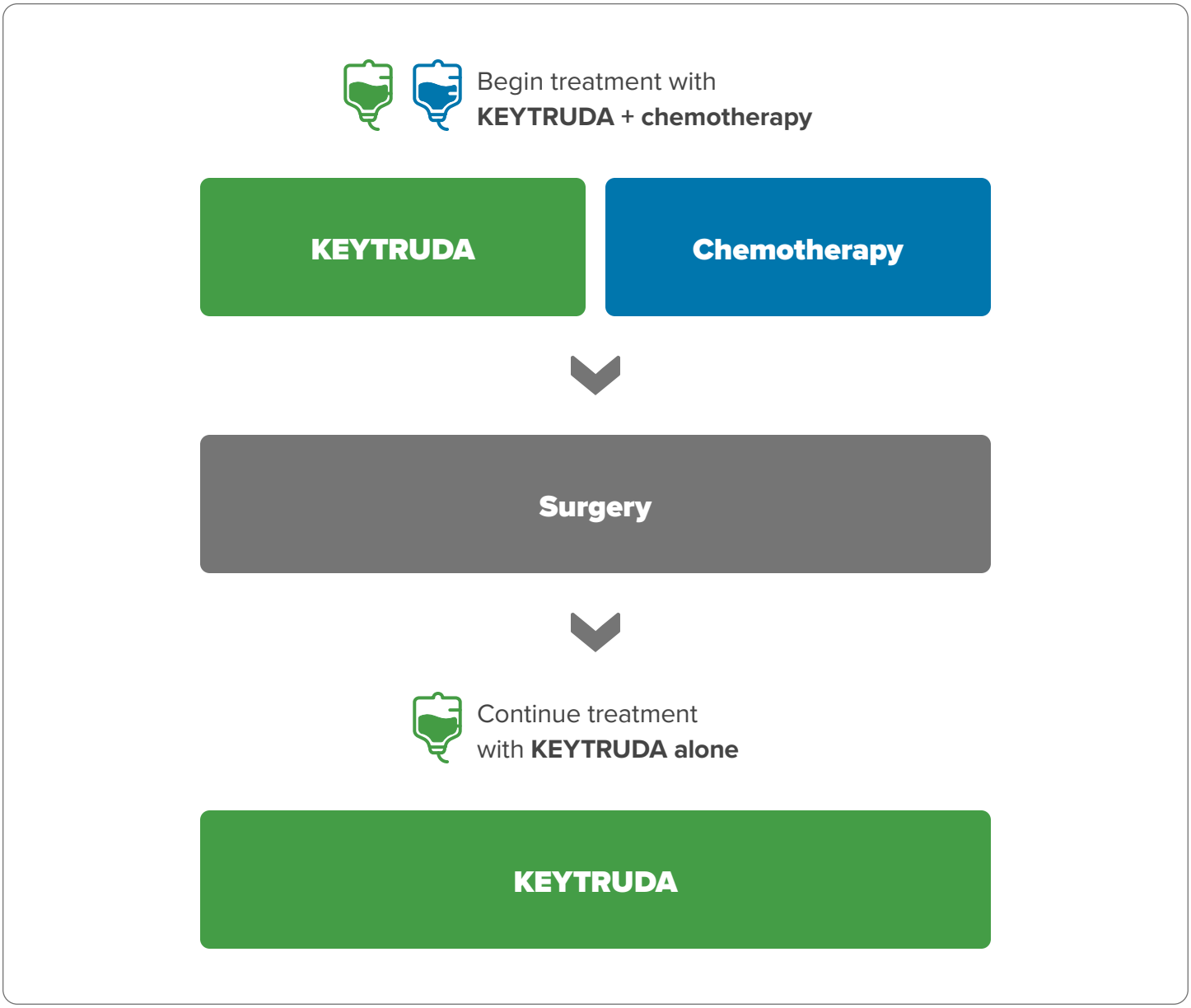
What does a treatment regimen with KEYTRUDA look like?



Read more about the treatment regimen with KEYTRUDA on the next page >

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What does a treatment regimen with KEYTRUDA look like? (*continued*)

How KEYTRUDA is used before surgery (neoadjuvant)

- KEYTRUDA is first used **with chemotherapy** before surgery. Treatment that comes before surgery is called "neoadjuvant."
- A goal of treatment before surgery is to help reduce tumor size and kill cancer cells that may have spread.
- In order to use KEYTRUDA after surgery, you need to complete treatment before your procedure as recommended by your doctor.

Surgery

- The primary goal of surgery is to remove the cancer from your body.
- Your surgeon also may remove lymph nodes in the area to determine if the cancer has spread.
- After surgery, follow the treatment plan you and your doctor created, and continue talking to your care team.

How KEYTRUDA is used after surgery (adjuvant)

- KEYTRUDA is used **alone** after surgery. Treatment after surgery is called "adjuvant."
- A goal of treatment after surgery is to help keep cancer from coming back.
- Continue treatment with KEYTRUDA alone after surgery as recommended by your doctor.

See clinical trial results for a treatment regimen with KEYTRUDA on the next page >

Important Safety Information (*continued*)

Hormone gland problems: headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.

Kidney problems: decrease in the amount of your urine; blood in your urine; swelling of your ankles; loss of appetite.

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Talk to your doctor to learn more about clinical trial results from a treatment plan with KEYTRUDA

Gathering information about treatments may help you feel ready to make decisions with your doctor. KEYTRUDA may be used with chemotherapy as treatment before surgery and then continued alone after surgery when you have early-stage TNBC and are at high risk of your breast cancer coming back.

A clinical trial of 1,174 people with high-risk early-stage TNBC compared the following 2 groups receiving different treatments.



Group 1 (KEYTRUDA + chemotherapy* followed by KEYTRUDA alone)

200 mg of KEYTRUDA every 3 weeks plus chemotherapy before surgery

Then: 200 mg of KEYTRUDA alone every 3 weeks after surgery



Group 2 (Placebo† + chemotherapy* followed by placebo alone)

Placebo every 3 weeks plus chemotherapy before surgery

Then: Placebo alone every 3 weeks after surgery

*Chemotherapy = Carboplatin plus paclitaxel followed by either doxorubicin or epirubicin along with cyclophosphamide.

†Placebo = an inactive treatment given instead of an active treatment.

Important Safety Information (*continued*)

Skin problems: rash; itching; skin blistering or peeling; painful sores or ulcers in your mouth or in your nose, throat, or genital area; fever or flu-like symptoms; swollen lymph nodes.

Problems can also happen in other organs and tissues. Signs and symptoms of these problems may include: chest pain; irregular heartbeat; shortness of breath; swelling of ankles; confusion; sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs; double vision; blurry vision; sensitivity to light; eye pain; changes in eyesight; persistent or severe muscle pain or weakness; muscle cramps; low red blood cells; bruising.

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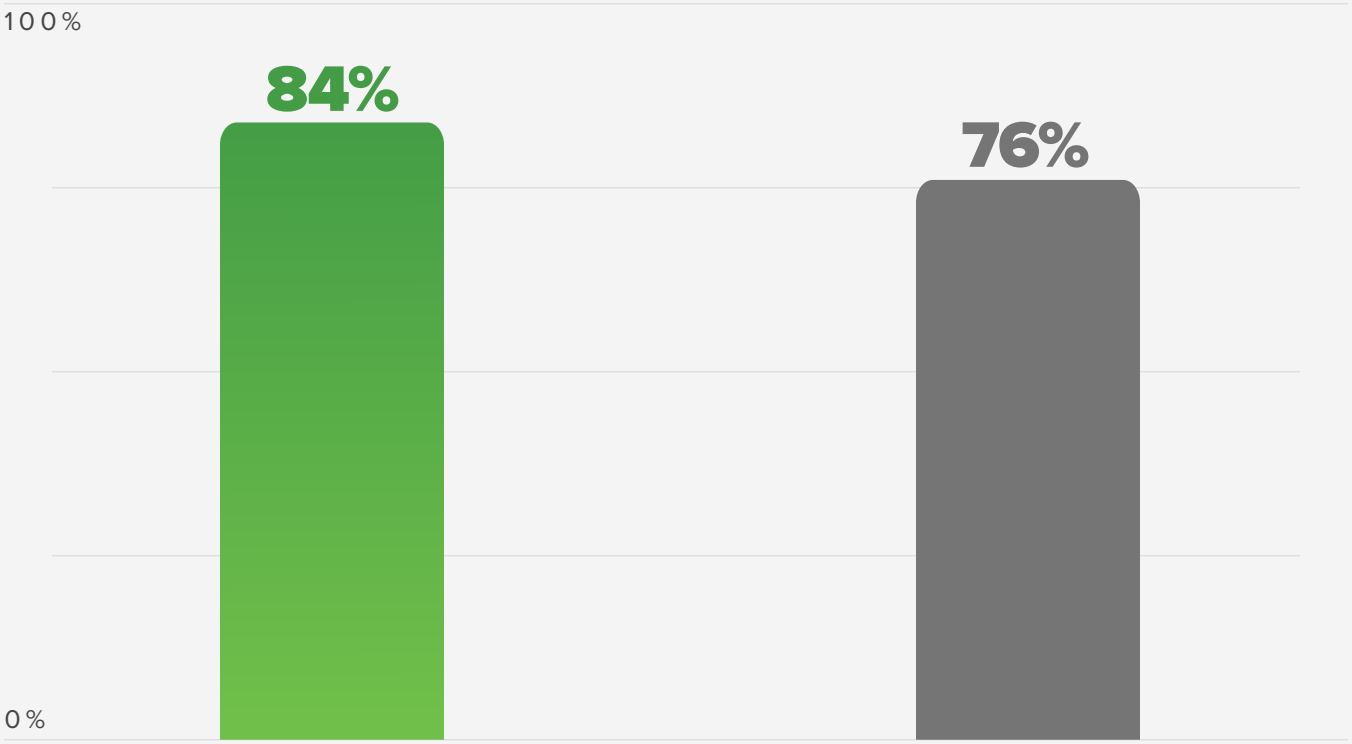
Talk to your doctor to learn more about clinical trial results from a treatment plan with KEYTRUDA (*continued*)

More people did not have their cancer get worse or come back



KEYTRUDA + chemotherapy,* then KEYTRUDA alone

661 out of 784 people did not have their cancer get worse or come back at the time of patient follow-up

Placebo† + chemotherapy,* then placebo alone

297 out of 390 people did not have their cancer get worse or come back at the time of patient follow-up

*Chemotherapy = Carboplatin plus paclitaxel followed by either doxorubicin or epirubicin along with cyclophosphamide.

†Placebo = an inactive treatment given instead of an active treatment.

The phrase "cancer did not get worse or come back" refers to event-free survival, or EFS, which is the length of time once treatment begins until a person experiences certain complications or events. These may include cancer growing or spreading that would prevent surgery, cancer growing or returning after surgery, or developing a new cancer.

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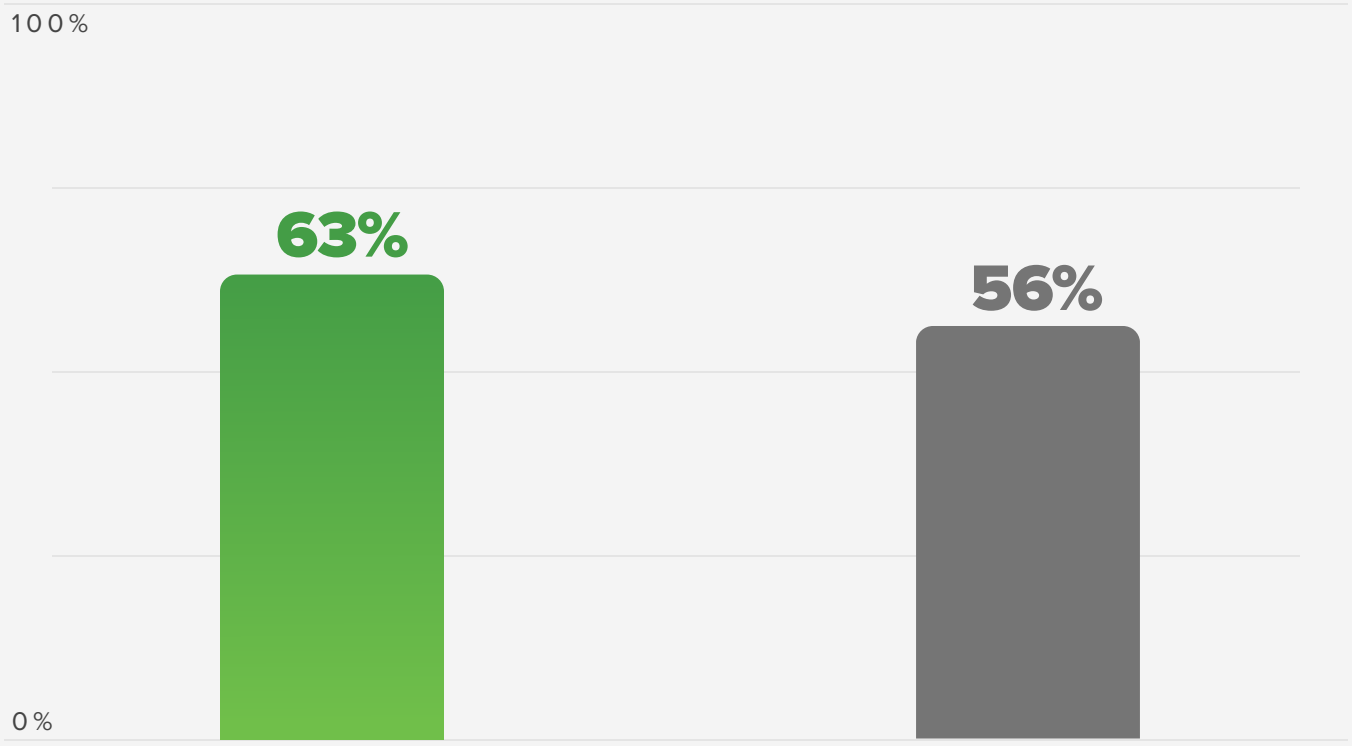
Talk to your doctor to learn more about clinical trial results from a treatment plan with KEYTRUDA (*continued*)

People who had no cancer cells found at the time of surgery



KEYTRUDA + chemotherapy*
494 out of 784 people had no cancer cells found at the time of surgery

Placebo + chemotherapy*
217 out of 390 people had no cancer cells found at the time of surgery

*Chemotherapy = Carboplatin plus paclitaxel followed by either doxorubicin or epirubicin along with cyclophosphamide.

The phrase "no cancer cells found at the time of surgery" refers to pathological complete response, or pCR, which is measured at the time of surgery. This is when the cancer could no longer be found when breast tissue and lymph nodes were examined under a microscope.

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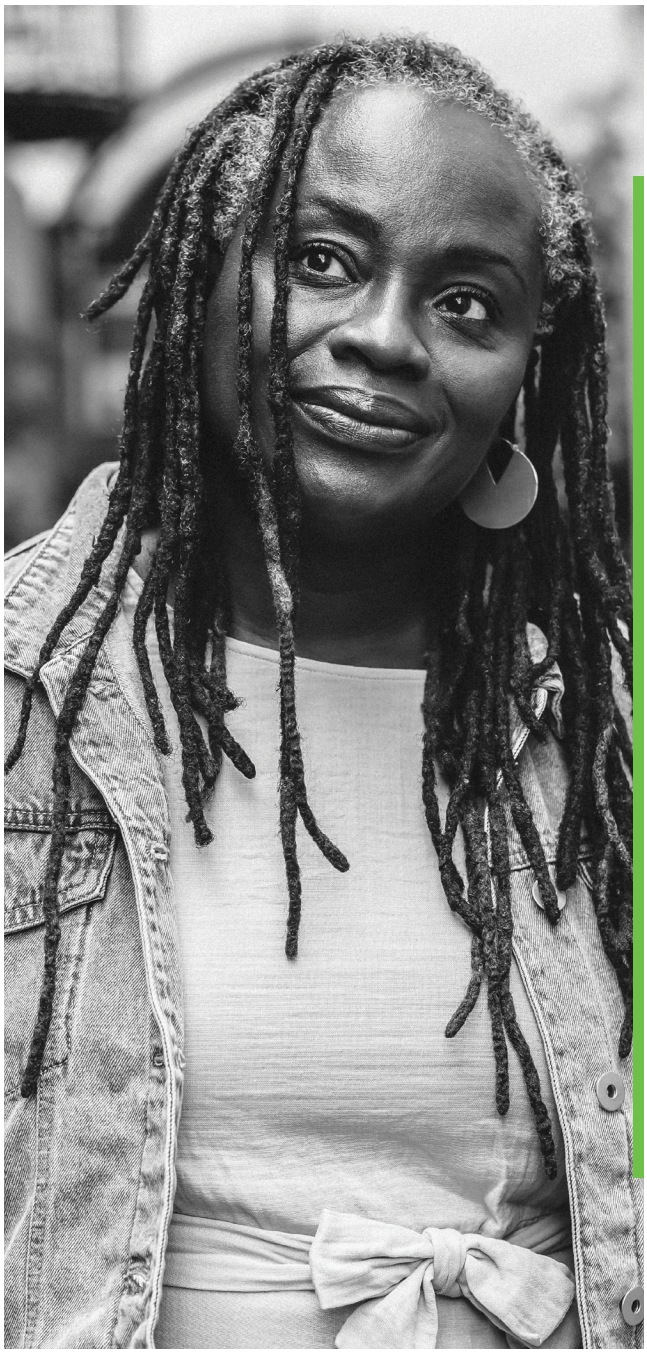
Important Safety Information (*continued*)

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feeling like passing out, fever, and back pain.

Rejection of a transplanted organ or tissue. Your health care provider should tell you what signs and symptoms you should report and they will monitor you, depending on the type of organ or tissue transplant that you have had.

Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with KEYTRUDA. Your health care provider will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your health care provider will check you for these problems during treatment with KEYTRUDA. They may treat you with corticosteroid or hormone replacement medicines. They may also need to delay or completely stop treatment with KEYTRUDA if you have severe side effects.



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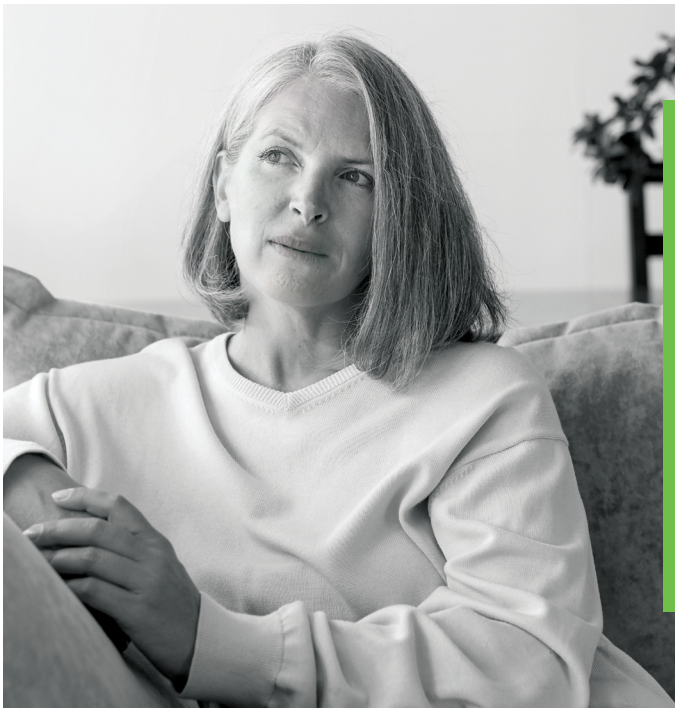
How do I take KEYTRUDA?

Your health care provider will give you KEYTRUDA into your vein through an intravenous (IV) line.

Treatments are given over 30 minutes. They usually take place at your health care provider's office or an infusion clinic.

KEYTRUDA is usually given every 3 weeks or every 6 weeks depending on the dose that you are receiving.





30 minutes per intravenous infusion of KEYTRUDA



Talk to your health care provider about the dosing schedule that is right for you and to learn more about what to expect.

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Important Safety Information (*continued*)

Before you receive KEYTRUDA, tell your health care provider if you have immune system problems such as Crohn's disease, ulcerative colitis, or lupus; have had an organ or tissue transplant, including corneal transplant, or have had or plan to have a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic); have had radiation treatment in your chest area; have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.

If you are pregnant or plan to become pregnant, tell your health care provider. KEYTRUDA can harm your unborn baby. If you are able to become pregnant, you will be given a pregnancy test before you start treatment. Use effective birth control during treatment with KEYTRUDA and for 4 months after your last dose of KEYTRUDA. Tell them right away if you think you may be pregnant or you become pregnant during treatment with KEYTRUDA.

Tell your health care provider if you are breastfeeding or plan to breastfeed. It is not known if KEYTRUDA passes into your breast milk. Do not breastfeed during treatment with KEYTRUDA and for 4 months after your last dose of KEYTRUDA.

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



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Your cancer care team is here to help

Your needs may change over the course of your treatment journey. Support may come from other health care providers, from people close to you, and even from others in the cancer community.

Your care team is available to help you with treatment decisions and answer any questions you have along the way:

- **Oncologist:**
  A doctor who has special training in diagnosing and treating cancer. Your oncologist will oversee your care and answer questions about your diagnosis and treatment plan.
- **Surgeon:**
  A doctor who is trained to perform surgical operations. A surgical oncologist specializes in performing surgery to treat cancer. Your surgeon can answer questions about your surgery to remove cancer, how to prepare for surgery, what to expect after undergoing surgery, and explain any side effects of surgery.
- **Oncology Nurse:**
  A nurse who specializes in treating and caring for people with cancer. Your oncology nurse helps coordinate care with other members of the care team, checks your physical condition, and helps you manage side effects of treatment.
- **Patient Navigator:**
  A professional who helps patients before, during, and after treatment, to help them understand and complete treatment. They can help connect you to support services and other health care professionals, and schedule appointments or tests.
- **Radiation Oncologist:**
  A doctor who specializes in using radiation to treat cancer. A radiation oncologist can help you determine if you're a candidate for radiation therapy and what to expect when undergoing radiation treatment.
- **Infusion Nurse:**
  A nurse who administers medication and fluids through an intravenous (IV) line, central line, or venous access port.

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Your cancer care team is here to help (*continued*)

Your feelings and opinions are important for decisions about your care. Ask about other support that may be available to you such as a patient or financial navigator, social worker, psychologist, physical therapist, dietitian, or community support group.

Talking with your care team can help you fully understand your diagnosis and treatment options before making a treatment decision.



Important Safety Information (*continued*)

Common side effects of KEYTRUDA when used alone include: feeling tired; pain, including pain in muscles; rash; diarrhea; fever; cough; decreased appetite; itching; shortness of breath; constipation; bones or joints and stomach-area (abdominal) pain; nausea; and low levels of thyroid hormone.

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Questions to include for the conversation with your doctor

Talking to your doctor about your treatment options for TNBC


Actor Portrayal

Use the questions below to help guide your conversation about a treatment plan before and after surgery that includes KEYTRUDA.

Questions to ask your doctor about treatment before surgery

- Have we discussed all possible treatment options before surgery?
- Could KEYTRUDA be right for me as part of a treatment plan before surgery?
- What are the possible side effects of KEYTRUDA and chemotherapy before surgery?

Questions to ask your doctor about treatment after surgery

- What is the chance my cancer could come back after surgery?
- When should I plan to restart KEYTRUDA after surgery?
- Is KEYTRUDA used alone after surgery?

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Notes

Important Safety Information (*continued*)

Common side effects of KEYTRUDA when given with certain chemotherapy medicines include: feeling tired or weak; nausea; constipation; diarrhea; decreased appetite; rash; vomiting; cough; trouble breathing; fever; hair loss; inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs; swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina; mouth sores; headache; weight loss; stomach-area (abdominal) pain; joint and muscle pain; trouble sleeping; bleeding, blisters, or rash on the palms of your hands and soles of your feet; urinary tract infection; and low levels of thyroid hormone.

These are not all the possible side effects of KEYTRUDA. Talk to your health care provider for medical advice about side effects.

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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Talk to your doctor about KEYTRUDA

Scan the QR code with your mobile device or visit **keytruda.com**

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