



KEYTRUDA[®]
(pembrolizumab) Injection 100 mg

**A breakthrough
therapy option for
advanced urothelial
bladder cancer**

**KEYTRUDA +
enfortumab vedotin (EV)**

KEYTRUDA is a prescription medicine used to treat a kind of bladder and urinary tract cancer called urothelial cancer. KEYTRUDA may be used with the medicine enfortumab vedotin in adults when your bladder or urinary tract cancer has spread or cannot be removed by surgery (advanced urothelial cancer).

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 [Medication Guide](#) for KEYTRUDA and discuss it with your doctor. The physician [Prescribing Information](#) also is available. You can find additional Important Safety Information about KEYTRUDA throughout this brochure.

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If you are considering treatment with KEYTRUDA, this digital brochure was developed with you in mind. It is designed to be a convenient resource you can turn to anytime for helpful information about KEYTRUDA when it is used in combination with a medicine called enfortumab vedotin. It's also where you'll find answers to questions, tools you can use, and tips for talking to your doctors and loved ones.

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Understanding advanced urothelial bladder cancer (UC)

► What is UC?

UC begins when normal cells in the bladder or urinary tract turn into abnormal cells and start to grow out of control.

► What is advanced UC?

As more cancer cells develop, they can spread or sometimes cannot be removed by surgery. This can be considered advanced UC. “Advanced UC” is a term used to describe both locally advanced UC and metastatic UC. Locally advanced UC is cancer that may have spread to nearby tissue or lymph nodes. Metastatic UC is cancer that has spread to other parts of the body.

► What a treatment plan with KEYTRUDA + enfortumab vedotin (EV) might look like

KEYTRUDA + enfortumab vedotin is the first FDA-approved immunotherapy and antibody-drug conjugate (ADC) combination treatment for people with advanced urothelial bladder cancer.

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► What is enfortumab vedotin?

Enfortumab vedotin is a type of medicine called an antibody-drug conjugate.

Important Safety Information (*continued*)

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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

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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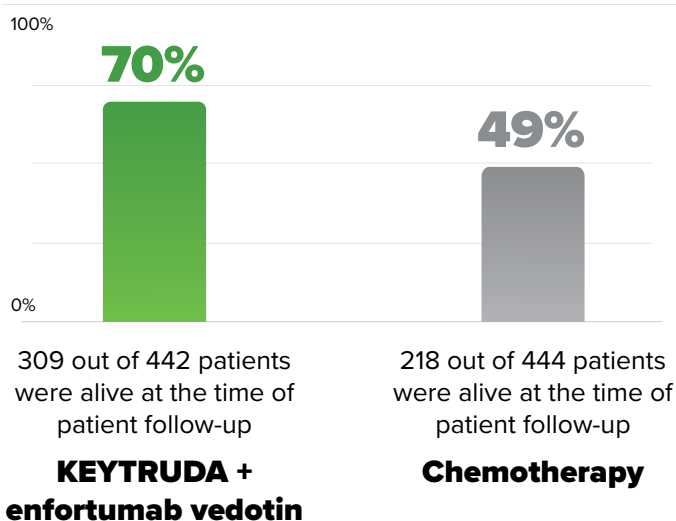
Results from a clinical trial with **KEYTRUDA** + enfortumab vedotin

KEYTRUDA + enfortumab vedotin has been proven to help people **live longer** compared to chemotherapy

Chemotherapy = gemcitabine + carboplatin or cisplatin.

A clinical trial studied patients with advanced urothelial bladder cancer who were not previously treated for their advanced disease. 442 patients received 200 mg of KEYTRUDA, an immunotherapy, intravenously on day 1 and 1.25 mg/kg of enfortumab vedotin, an antibody-drug conjugate, intravenously on days 1 and 8 of a 21-day cycle; 444 patients received carboplatin or cisplatin every 21 days and gemcitabine on days 1 and 8 of a 21-day cycle.

**More patients
lived longer**



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.

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.

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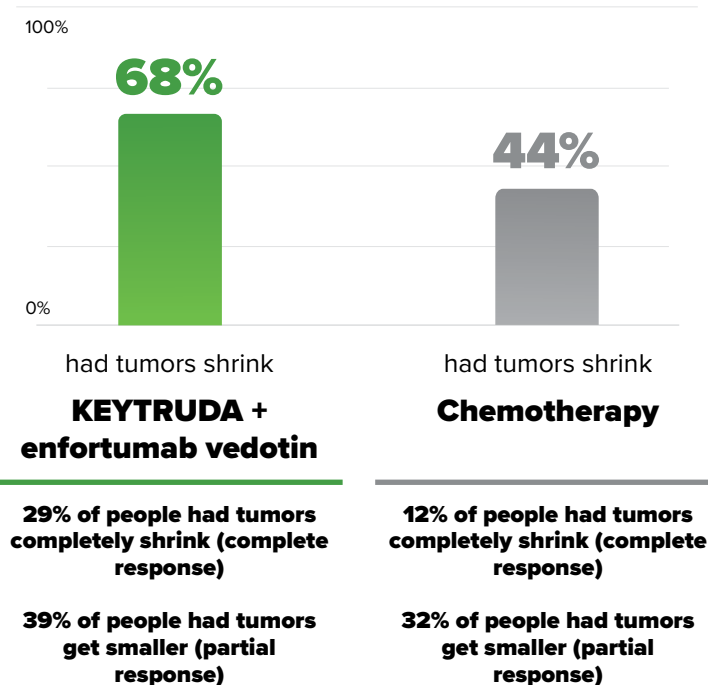
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Results from a clinical trial with **KEYTRUDA** + enfortumab vedotin (continued)

KEYTRUDA + enfortumab vedotin reduced the risk of cancer spreading, growing, or getting worse by **55%** compared to chemotherapy

Half of the patients on KEYTRUDA + enfortumab vedotin were alive without their cancer spreading, growing, or getting worse at 12.5 months, compared to 6.3 months for patients on chemotherapy. Cancer progressed in 223 of 442 patients receiving KEYTRUDA + enfortumab vedotin (50%) compared to 307 of 444 patients receiving chemotherapy (69%).

**More patients
saw tumors shrink**



Important Safety Information (continued)

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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Results from a clinical trial with **KEYTRUDA** + enfortumab vedotin (continued)

Understanding different types of results

There may be a lot to take in when learning about your diagnosis. Several terms your doctor may use to talk about your treatment goals are important to understand.

Living longer



One way your doctor may determine which medicine to choose is overall survival (OS). This is a measurement of time from the start of treatment and measures the length of time a person is alive.

Time without the cancer spreading, growing, or getting worse



Your doctor may measure the amount of time the cancer is not getting worse or spreading. This is called progression-free survival (PFS).

Getting tumors to completely shrink or get smaller



One goal is to have your tumors get smaller or completely shrink. Your doctor may refer to this as objective response rate, or ORR. When a tumor becomes smaller, it is called a partial response. When it completely shrinks, this is called a complete response.

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.

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About KEYTRUDA

KEYTRUDA in combination with enfortumab vedotin helps fight advanced urothelial bladder cancer (UC)

► What is KEYTRUDA?

KEYTRUDA is a prescription medicine used to treat a kind of bladder and urinary tract cancer called urothelial cancer. KEYTRUDA may be used with the medicine enfortumab vedotin in adults when your bladder or urinary tract cancer has spread or cannot be removed by surgery (advanced urothelial cancer).

KEYTRUDA is a type of treatment called an immunotherapy. Instead of attacking cancer cells directly, immunotherapy helps your immune system do what it is designed to do: find and fight cancer cells.

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 anytime during treatment or even after your treatment has ended.



Important Safety Information (continued)

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.

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.

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About **KEYTRUDA** (continued)



► How **KEYTRUDA** works

The immune system sends certain types of cells called T cells throughout your body to detect and fight infections and diseases—including cancer.

Cancer cells may use the PD-1 pathway to hide from T cells, allowing cancer cells to grow and spread.

PD-1 is a protein found on immune cells called T cells. It normally acts as a type of “off switch” that helps keep the T cells from attacking other cells in the body. PD-1 attaches to PD-L1, a protein found on some normal (and cancer) cells. This interaction basically tells the T cell to leave the other cell alone and not attack it. Some cancer cells have large amounts of PD-L1, which helps them hide from immune attack.

KEYTRUDA is a type of immunotherapy that works by blocking the PD-1 pathway to help prevent cancer cells from hiding so that your immune system can find and fight them.

PD-1 = programmed death receptor-1; PD-L1 = programmed death ligand 1.

Important Safety Information (continued)

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.

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What to expect from treatment with KEYTRUDA

KEYTRUDA is a prescription medicine used to treat a kind of bladder and urinary tract cancer called urothelial cancer. KEYTRUDA may be used with the medicine enfortumab vedotin in adults when your bladder or urinary tract cancer has spread or cannot be removed by surgery (advanced urothelial cancer).

The information below can help give you a better idea of how treatment with KEYTRUDA works.

How do I take KEYTRUDA?



Your doctor will give you KEYTRUDA into your vein through an intravenous (IV) line. Treatments are **given over 30 minutes**. Treatments usually take place at your doctor's office or an infusion clinic.

How long will I stay on KEYTRUDA?

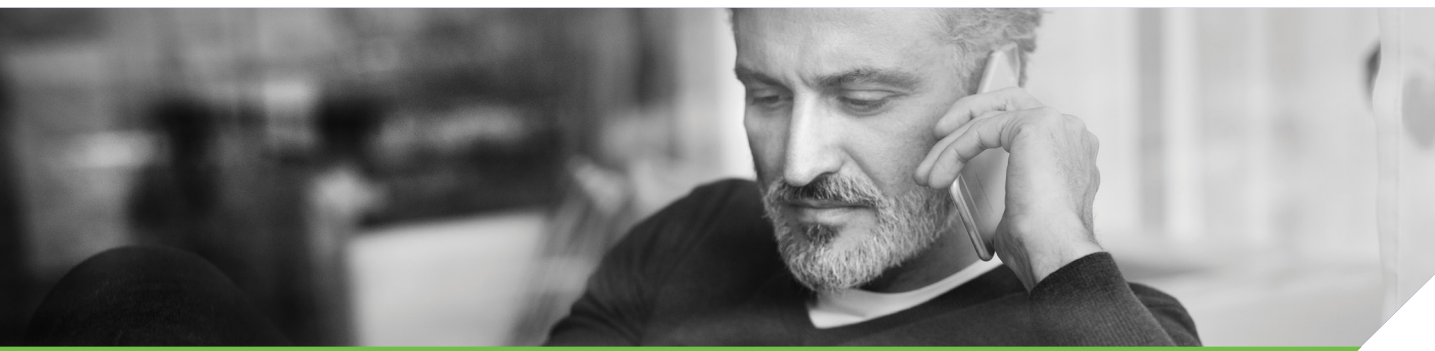


Every patient is different. For that reason, your doctor will decide how many treatments you need, based on your experience with KEYTRUDA.

How will I be monitored while on KEYTRUDA?



Your health care team will keep track of how you are responding to treatment through imaging and laboratory tests. They will also do blood tests to check you for side effects.



Important Safety Information (*continued*)

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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What to expect from treatment with KEYTRUDA (continued)



30 minutes per intravenous (IV) infusion



OR



This schedule only talks about KEYTRUDA. For questions about treatment with enfortumab vedotin, speak with your health care provider. Talk to your health care provider and discuss if your current treatment schedule is right for you. They can help answer questions. If you miss any appointments, call your health care provider as soon as possible to reschedule your appointment.



Important Safety Information (continued)

Common side effects of KEYTRUDA when given with enfortumab vedotin include rash; tingling or numbness of the arms or legs; feeling tired; itching; diarrhea; hair loss; weight loss; decreased appetite; dry eye; nausea; constipation; changes in sense of taste; and urinary tract infection.

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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Making treatment decisions together

Is **KEYTRUDA** + **EV** right for you?

Bladder cancer and treatment can be difficult to talk about, even with the people you're closest to or your doctor. Having honest, open conversations with them about your feelings is important and can help you make treatment decisions together.

Discussions with your doctor



Your doctor and health care team are the experts on cancer and treatment, but you are the expert on yourself and how you're feeling. This is valuable information for them to consider when making treatment decisions.

► Some ways to work together with your doctor:

- Tell your care team about your treatment goals so they can make suggestions that are right for you
- Ask what resources are available to help you stay on treatment, such as transportation to appointments
- Don't be afraid to speak up or ask questions
- Give a friend or family member the ability to talk to your doctor on your behalf with an advance health care directive

► Some questions to consider asking your doctor:

- This medical term is confusing. Can you explain it to us?
- What side effects of treatment should we expect?
- Do you have any suggestions for dealing with this side effect?
- Can you recommend specific organizations where I can learn more about bladder cancer?



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Making treatment decisions together (*continued*)



Discussions with your loved ones

Opening up to your loved ones can make you feel better, help them understand the support you need, and help them feel more comfortable helping you with treatment decisions.

- Talk to your loved ones about your treatment goals
- Be open and honest about your fears, concerns, and how you think they can support you
- Try to consider their suggestions about helpful resources
- Ask a family member or friend to come to appointments and take notes
- Ask a loved one if they can drive you to appointments, help you coordinate rides with others, or talk to your care team about services that provide transportation

Be sure to write down any questions you have before appointments and to take notes during appointments.



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.

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.

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.

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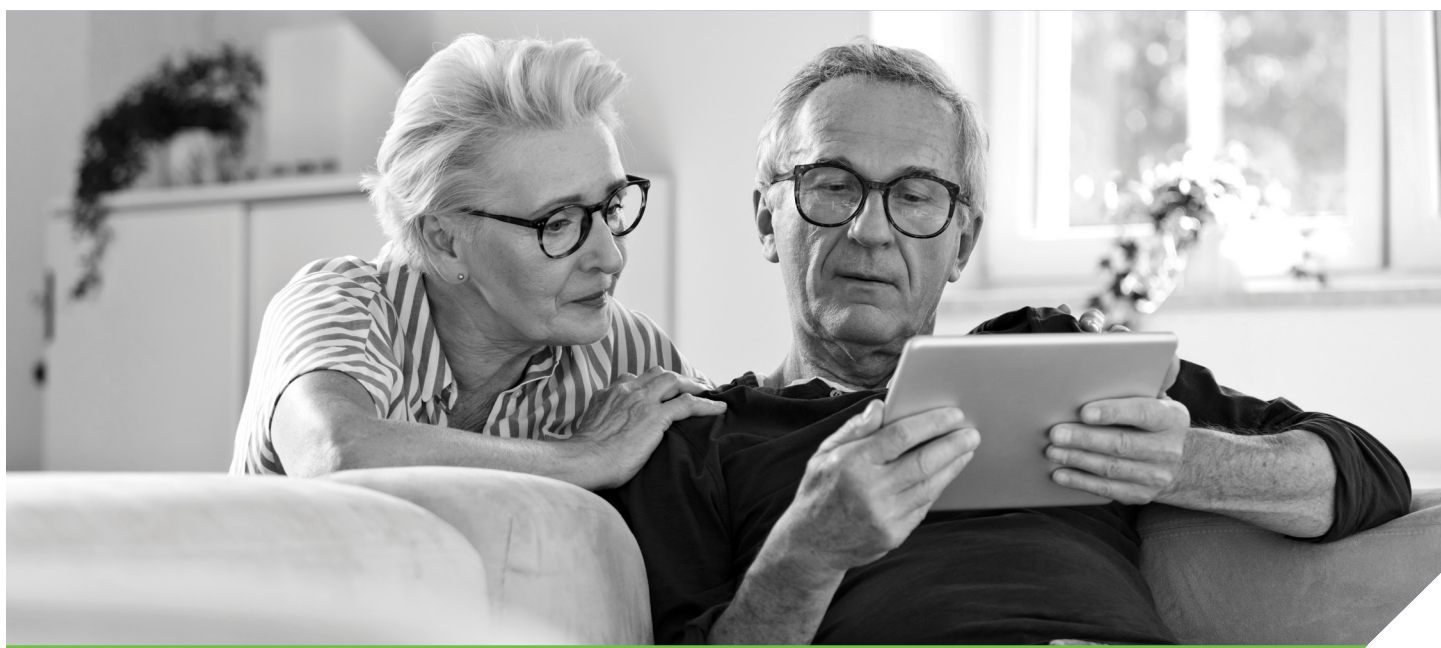
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Making treatment decisions together (*continued*)

Join a **support** group

It may be helpful to talk to people who have been touched by your type of cancer firsthand. You might be able to ask them things you feel your friends and family might not understand. Groups may help you feel less alone, catch up on treatment news, and share tips on how to cope with side effects. Depending on how you'd like to interact with others, you could meet people in support groups that are in person, over the phone, or online.

It can be hard to focus on these things sometimes, but your loved ones only want what is best for you.



Important Safety Information (*continued*)

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

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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Financial support

Need information about whether your insurance provider covers **KEYTRUDA** or about potential financial assistance options?

If you need further information or help paying for KEYTRUDA (with or without insurance coverage), Merck may be able to help. Contact The Merck Access Program at **855-257-3932**. The Merck Access Program can help answer questions like:

- ? Does my insurance cover KEYTRUDA?
- ? What are the co-pay assistance options for eligible patients?
- ? How can I find out if I'm eligible for the Merck Patient Assistance Program?

Merck provides certain of its medicines and adult vaccines for free to eligible patients who do not have prescription drug or health insurance coverage and who, without assistance, cannot afford the medicines and vaccines made by Merck. This is consistent with Merck's long-held values and tradition of putting patients first.



To speak to a Merck Access Program representative:

Call 855-257-3932



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.

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**Ask your doctor
if **KEYTRUDA** + **EV**
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US-OB-02023 06/25

