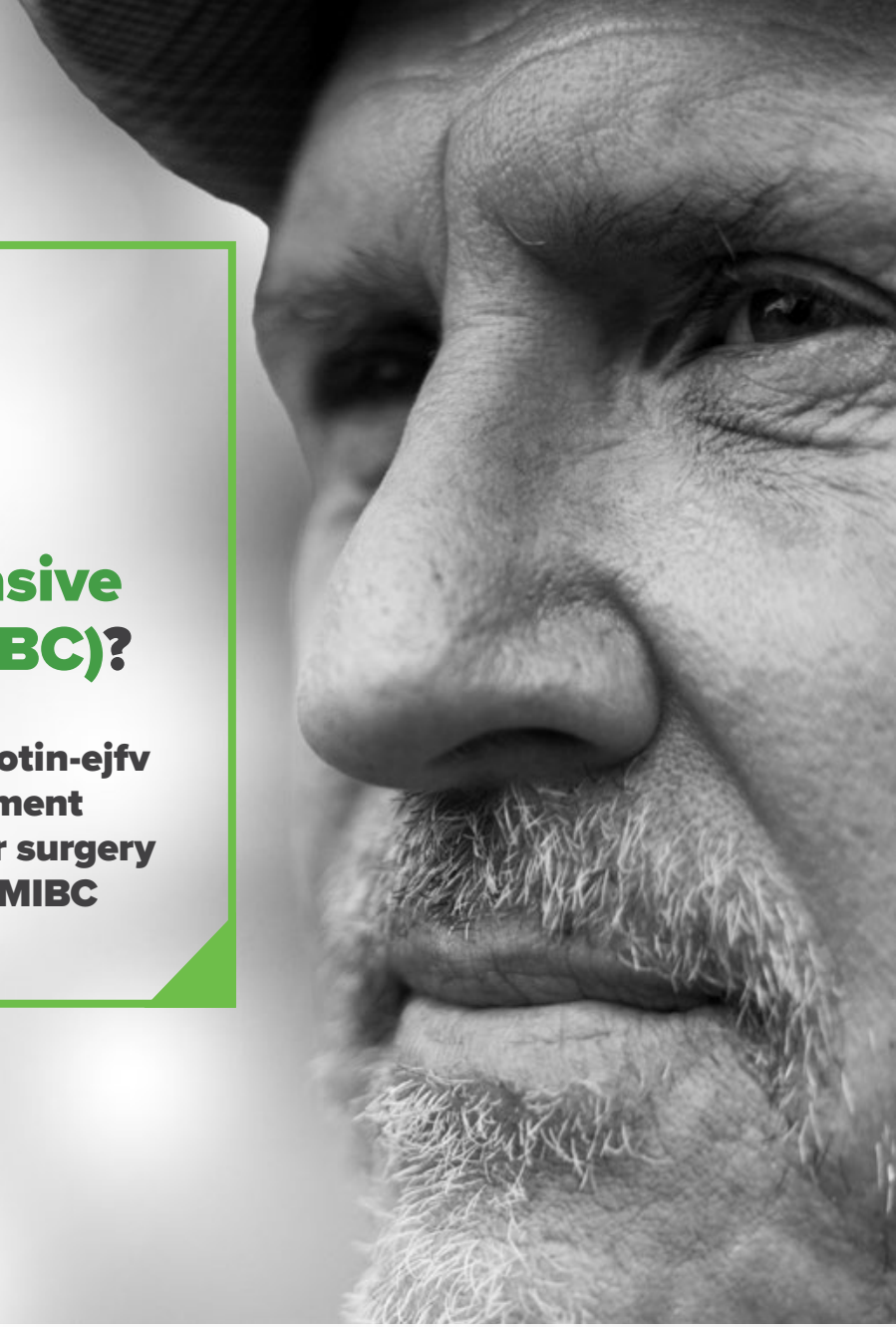




KEYTRUDA[®]
(pembrolizumab) Injection 100 mg

Facing muscle invasive bladder cancer (MIBC)?

KEYTRUDA + enfortumab vedotin-ejfv (EV) is an FDA-approved treatment regimen given before and after surgery for certain adult patients with MIBC

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-ejfv in adults before and after the surgical removal of your bladder when your bladder cancer has spread into the muscle layer of the bladder (muscle invasive bladder cancer [MIBC]) but not to other parts of the body.

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 available. You can find additional Important Safety Information about KEYTRUDA throughout this brochure.

Table of contents

This digital brochure was developed with you in mind. It is designed to be a helpful resource you can turn to anytime for information about KEYTRUDA + EV. It’s also where you’ll find clinical trial results, treatment information, tips for talking with loved ones, and questions you may want to ask your urologist, oncologist, and other members of your care team before and after surgery.

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Understanding muscle invasive bladder cancer (MIBC)

► What is urothelial bladder cancer?

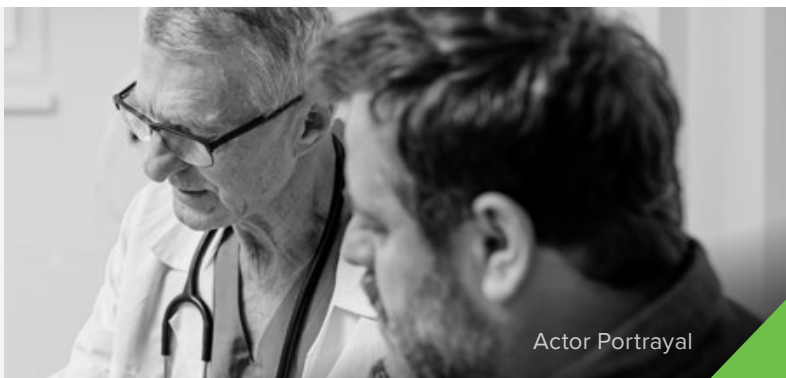
Urothelial bladder cancer is a type of cancer that begins when normal cells in the bladder or urinary tract turn into abnormal cells and start to grow out of control.

► What is MIBC?

As more cancer cells develop, they can spread from the bladder lining to the muscle layer surrounding the bladder, and into the bladder wall. This is MIBC.



Your urologist and oncologist may discuss the potential risk of your bladder cancer coming back, so it is important to discuss appropriate treatment options prior to bladder removal surgery.



Actor Portrayal

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-ejfv in adults before and after the surgical removal of your bladder when your bladder cancer has spread into the muscle layer of the bladder (muscle invasive bladder cancer [MIBC]) but not to other parts of the body.

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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About KEYTRUDA

KEYTRUDA in combination with enfortumab vedotin-ejfv (EV) helps fight muscle invasive bladder cancer (MIBC) in adult patients

► What is KEYTRUDA?

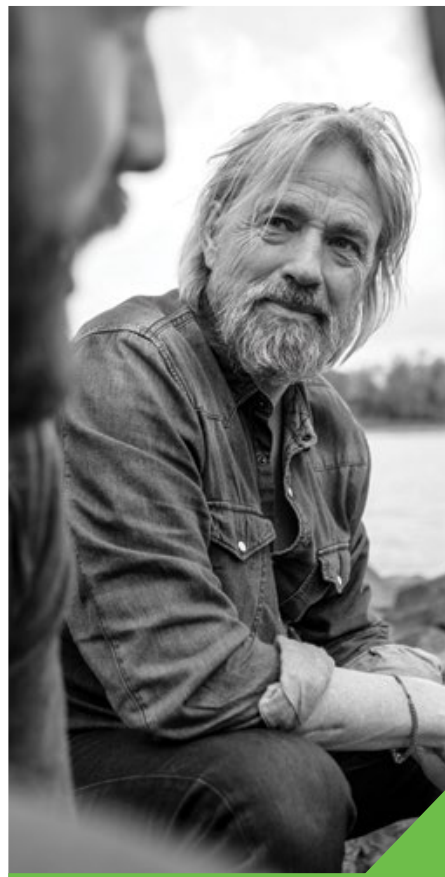
KEYTRUDA is a prescription medicine used to treat a kind of bladder and urinary tract cancer called urothelial cancer. KEYTRUDA may be used with the medicine enfortumab vedotin-ejfv in adults before and after the surgical removal of your bladder when your bladder cancer has spread into the muscle layer of the bladder (muscle invasive bladder cancer [MIBC]) but not to other parts of the body.

KEYTRUDA is not chemotherapy or radiation therapy; it's 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 any time during treatment or even after your treatment has ended.

► What is enfortumab vedotin-ejfv?

Enfortumab vedotin-ejfv is an antibody-drug conjugate.



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.

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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About **KEYTRUDA** (continued)



► How **KEYTRUDA** works with your immune system to help fight cancer cells

Cancer cells may use the PD-1 pathway to hide from T cells

The immune system is your body's natural defense against disease. 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. This stops T cells from attacking cancer cells and allows cancer cells to grow and spread.

PD-1 = programmed death receptor-1.

KEYTRUDA blocks the PD-1 pathway to help prevent cancer cells from hiding

KEYTRUDA is a type of immunotherapy that works by blocking the [PD-1 pathway](#) to help prevent cancer cells from hiding. KEYTRUDA helps the immune system do what it was meant to do: detect and fight cancer cells.

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.

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About KEYTRUDA (continued)



► Consider talking to an oncologist before surgery about your treatment options

Before surgery, talk to your doctors to determine what treatment options may be appropriate for you, and the risk of cancer coming back.

■ **If you have not been referred to an oncologist, talk to your surgeon, urologist, or another member of your care team about a referral.**

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.

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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Results from clinical trials with **KEYTRUDA** + enfortumab vedotin-ejfv (EV)

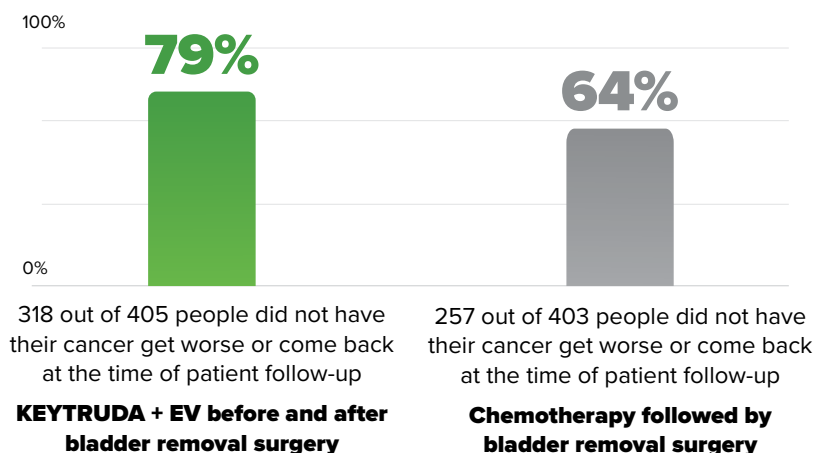
For adult patients with MIBC who were able to receive cisplatin-containing chemotherapy

A clinical trial studied 808 patients with muscle invasive bladder cancer (MIBC). 405 patients received 200 mg of KEYTRUDA intravenously over 30 minutes on day 1 and 1.25 mg/kg enfortumab vedotin-ejfv intravenously on days 1 and 8 of each 21-day cycle for 4 cycles prior to surgery, followed by adjuvant KEYTRUDA 200 mg over 30 minutes on day 1 of each 21-day cycle for 13 cycles and enfortumab vedotin-ejfv 1.25 mg/kg on days 1 and 8 of each 21-day cycle for 5 cycles. 403 patients received 1000 mg of gemcitabine on days 1 and 8 and 70 mg/m² of cisplatin on day 1 of each 21-day cycle for 4 cycles prior to surgery.

KEYTRUDA + EV before and after bladder removal surgery may help prevent MIBC from getting worse or coming back, and may help people live longer, compared to chemotherapy and bladder removal surgery

Chemotherapy = gemcitabine + cisplatin

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



Important Safety Information (*continued*)

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.

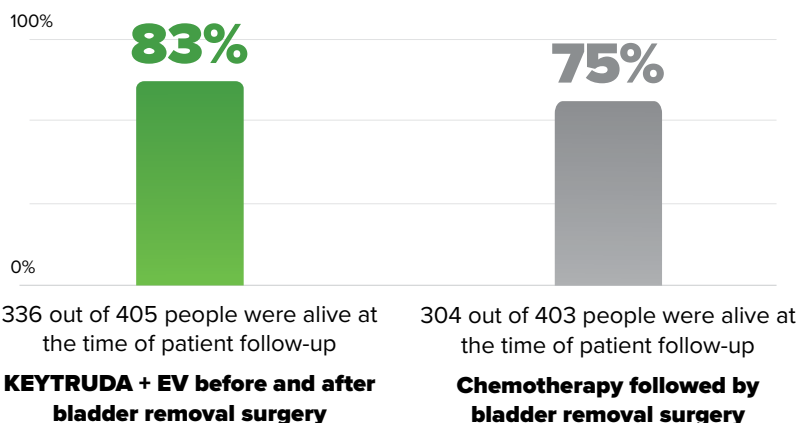
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Results from clinical trials with **KEYTRUDA** + EV (*continued*)

For adult patients with MIBC who were able to receive cisplatin-containing chemotherapy

**More people
lived longer**



More patients who received **KEYTRUDA + EV had no cancer cells found at the time of surgery compared to patients who received chemotherapy followed by bladder removal surgery.**

In the clinical trial, 55.8% (226 out of 405) of patients treated with KEYTRUDA + EV had no cancer cells found at the time of surgery compared to 32.5% (131 out of 403) of patients who received chemotherapy followed by bladder removal surgery.

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.

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.

Please read the accompanying [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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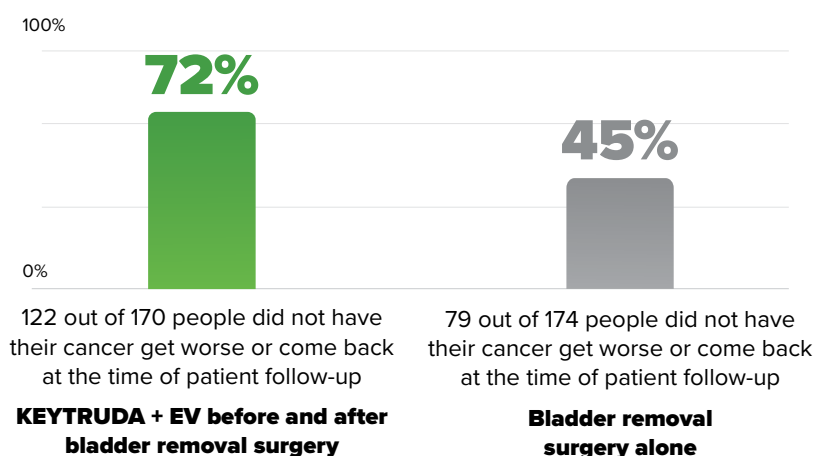
Results from clinical trials with **KEYTRUDA** + EV (*continued*)

For adult patients with MIBC who were not able to receive cisplatin-containing chemotherapy

A clinical trial studied 344 patients with muscle invasive bladder cancer (MIBC) who were not able to receive cisplatin-containing chemotherapy. 170 patients received 200 mg of KEYTRUDA intravenously over 30 minutes on day 1 and 1.25 mg/kg enfortumab vedotin-ejfv intravenously on days 1 and 8 of each 21-day cycle for 3 cycles prior to surgery, followed by KEYTRUDA 200 mg over 30 minutes on day 1 of each 21-day cycle for 14 cycles and enfortumab vedotin-ejfv 1.25 mg/kg on days 1 and 8 of each 21-day cycle for 6 cycles. 174 patients received bladder removal surgery alone.

KEYTRUDA + EV before and after bladder removal surgery may help prevent MIBC from getting worse or coming back, and may help people live longer, compared to bladder removal surgery alone

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



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.

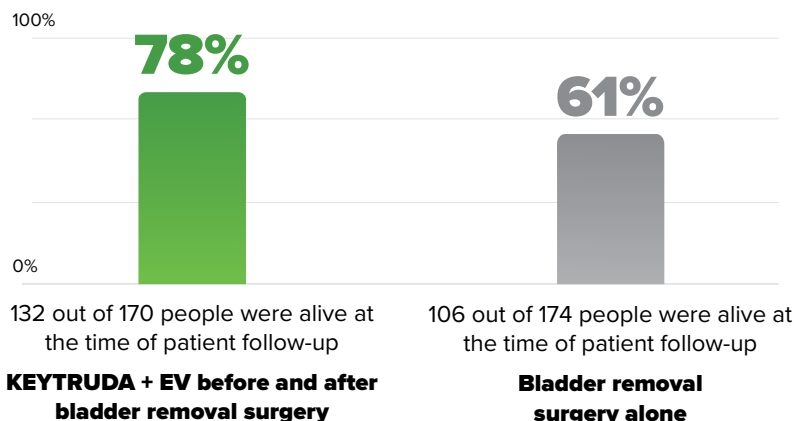
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Results from clinical trials with **KEYTRUDA** + EV (*continued*)

For adult patients with MIBC who were not able to receive cisplatin-containing chemotherapy

**More people
lived longer**



More patients who received **KEYTRUDA + EV had no cancer cells found at the time of surgery compared to patients who received bladder removal surgery alone.**

In the clinical trial, 57.1% (97 out of 170) of patients treated with KEYTRUDA + EV had no cancer cells found at the time of surgery compared to 8.6% (15 out of 174) of patients who received bladder removal surgery alone.

Important Safety Information (*continued*)

Common side effects of KEYTRUDA when given with enfortumab vedotin-ejfv include rash; tingling or numbness of the arms or legs; feeling tired or weak; 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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Understanding different types of results

There's a lot to learn about your diagnosis. Your urologist and oncologist may use several terms to talk about treatment goals, and it's important you understand them.



Time without the cancer getting worse or coming back

Your doctor may look at the length of time, once treatment begins, until a person experiences certain complications or events. This is called event-free survival (EFS). These events may include cancer growing or spreading that would prevent surgery, cancer that could not be fully removed during surgery, cancer growing or returning after surgery, or developing a new cancer.



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.



Pathological complete response

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

Important Safety Information (*continued*)

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.

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.

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What to expect from treatment

► How KEYTRUDA is given

- Before surgery, KEYTRUDA is given to adult patients with MIBC (“neoadjuvant” treatment). A goal of treatment before surgery is to help reduce tumor size.
- After surgery, KEYTRUDA is given again (“adjuvant” treatment) to complete the regimen. A goal of treatment after surgery is to help keep your cancer from coming back.
- KEYTRUDA is given in your vein through an intravenous (IV) line over 30 minutes
- Treatments usually take place at your doctor’s office or an infusion clinic
- In adults, KEYTRUDA is usually given every 3 weeks or every 6 weeks depending on the dose that you are receiving. This schedule only talks about KEYTRUDA. For questions about treatment with enfortumab vedotin-ejfv, speak with your health care provider.
- Your doctor will decide how many treatments you need based on your experience with KEYTRUDA
- Talk to your doctor about the treatment schedule that is right for you
- Your doctor 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.
- If you have questions about this treatment plan, ask your doctor. If you miss any appointments, call your health care provider as soon as possible to reschedule your appointment.

► [Explore another way to receive treatment](#)



Important Safety Information (*continued*)

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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What to expect from treatment (*continued*)



KEYTRUDA + EV is given to adult patients with MIBC both before and after bladder removal surgery

It is important to discuss appropriate treatment options with your urologist and oncologist prior to bladder removal surgery (also known as “cystectomy”).

A treatment plan with KEYTRUDA for adult patients with MIBC

Begin treatment with
KEYTRUDA + EV



**Bladder Removal
Surgery**



Continue treatment with
KEYTRUDA + EV

► **Some questions you may want to ask your urologist and oncologist before surgery:**

- Could KEYTRUDA + EV be right for me?
- How does KEYTRUDA + EV work?
- How is the treatment given?
- What side effects could I experience on treatment?
- How can I prepare for treatment?

Important Safety Information

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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Tracking your symptoms

Sharing how you are feeling early and often can help your care team understand how you're doing on treatment.

Tips for tracking your symptoms



Take pictures of any visible changes to show your health care team.



Use descriptive words to track different side effects (for example, raised, red) and how side effects make you feel (for example, itchy, dizzy).



Be sure to mention any discomfort or symptom that keeps bothering you.



Your entire care team is focused on doing what's best for you throughout treatment. You may even find there's one team member you're most comfortable talking to. If possible, let that person be your point of contact every time you report symptoms.



Keeping track of your symptoms is important. So, whether it's writing down your symptoms in a notebook or using your phone, choose something you find easy to use and stick with it.

Remember, your care team will be with you every step of the way during treatment. That's why letting them know about any symptoms you experience is important.

Be sure to tell them as soon as symptoms occur and every time they occur. This will help your doctor make recommendations for possibly managing side effects that may occur along the way.

When starting a new medication, it can be helpful to know what to expect. This downloadable [symptom tracker](#) may help you feel more prepared.

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.

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For caregivers of someone facing cancer

It can be challenging to know how to offer support to someone with MIBC. One important way you can be helpful is by guiding conversations with your loved one and their doctor:



Keep a copy of the advance health care directive and save a photo of it on your phone



Prepare questions for the care team to get clarification on treatment and side effects



Get access to paperwork and approvals



Keep in mind that sometimes your loved one may not know exactly what they need and might not feel like answering questions. Planned check-ins, listening and allowing them to express themselves, and researching their condition and treatment options all can help.

It's also important to take care of yourself. Stay connected to family and friends, exercise, meditate, continue your hobbies, or do whatever else helps you to relax and keep motivated.

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.

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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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*)

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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FDA-Approved: Ask your urologist or oncologist about another way to receive treatment, or [learn more here](#)

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