

KEYTRUDA[®]
(pembrolizumab) Injection 100 mg

Your guide while on treatment

KEYTRUDA
+ enfortumab vedotin



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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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 can find answers to questions, tools you can use, and tips for talking to your doctors and loved ones.

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KEYTRUDA + enfortumab vedotin (EV)

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

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).

► What is enfortumab vedotin?

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



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 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*)

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.

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.

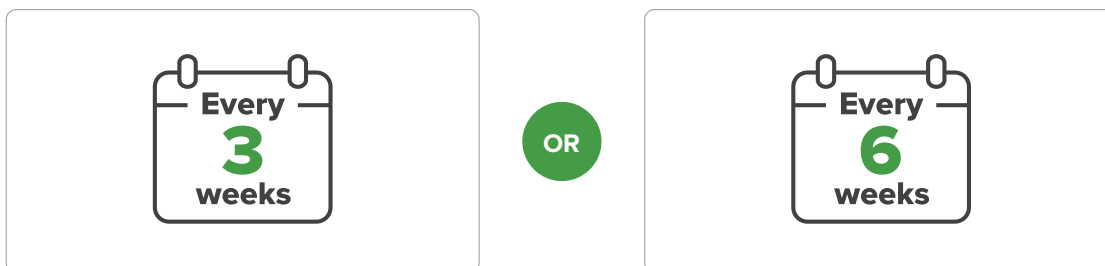
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What to expect from treatment with KEYTRUDA



30 minutes per intravenous (IV) infusion



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.

See tips for tracking symptoms on page 9

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.

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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How to approach your doctor's appointments

While on treatment with KEYTRUDA + EV, it's important to ask your doctor questions. Keep the following steps in mind when meeting with the doctor.

▶ Before your appointment, make a plan

Write questions you think may be important to bring up to the doctor during the appointment. It may be helpful to ask a family member or a friend to come with you for support.

▶ During your appointment, it's OK to ask questions

Sometimes it can feel uncomfortable asking questions or having your doctor repeat something. Don't feel embarrassed if you don't know all the answers or have to ask follow-up questions.

Here are some example questions to ask your doctor about potential side effects

- Are there side effects that I may experience?
- What should I do if I experience any side effects?
- When should I expect certain side effects to occur?
- Are there ways to help manage certain side effects?
- Who should I speak to for more information about managing side effects?



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.

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How to approach your doctor's appointments

► After your appointment, review what you learned

When you are back home, see if you can answer the following questions:

- Which side effects should I look for?
- How do I track my side effects?
- Who on my health care team should I call when I have questions or concerns?

Some doctor's offices can provide a written recap of your visit. Ask if this is available to you, so you can review it when you get home.



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.

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Helpful tips while on treatment

It's important to talk with your health care team throughout your treatment with KEYTRUDA + EV. Having honest, open conversations with them can help you stay on track with treatment.

Remember that while your doctor and health care team are the experts on cancer and treatment, you are the expert on yourself and how you're feeling. You can also rely on family, friends, and support groups for help.

Here are some tips to help you while on treatment

▶ **Reach out to your doctor about managing side effects**

If any side effects appear, call your health care provider immediately. You can learn how to track your symptoms on the next page.

▶ **Rely on family and friends for support**

Your family and friends are there to help you. There are ways they can help you during treatment, like talking to your doctor on your behalf with an advance directive. More tips on this appear later in the brochure.

▶ **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.



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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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.

Report symptoms early and often

Contact your care team as soon as symptoms occur and if they continue to happen. This will help your doctor make recommendations for possibly managing these side effects.

You may even use numbers to rate your level of discomfort. You can use a scale to rate your discomfort from 0 (no discomfort) to 5 (unbearable; not able to do any activities).

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.

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Discussions with your loved ones

Sometimes it can be difficult to ask a family member or friend for help. But your loved ones want the best for you. There are many ways other people can help you with your diagnosis.

▶ **Helping at appointments**

Whenever possible, go to the doctor with a loved one. This person can help by driving you to and from doctor's visits, taking notes, asking questions, or tracking symptoms.

▶ **Doing household chores**

There may be things around the house, like cooking and cleaning, that you feel like you can't do or get tired doing. Loved ones can help when you are not up to doing these specific chores.

▶ **Listening to your concerns**

No one needs to go through this alone. It can help to talk about your feelings with someone you can trust. Loved ones can also keep you company or give you a hug when you are feeling lonely.



If you are a caregiver, learn how you can help a loved one on the next page

Important Safety Information (continued)

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

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.

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For caregivers of someone facing cancer

It can be challenging to know what to say when caring for someone with advanced urothelial bladder cancer.

It may also be difficult to know how, when, or if it's appropriate to offer support. But caregivers can be a source of strength and stability.

Try these tips to help your loved one with bladder cancer



Approach communication positively

You can help your loved one with handling communication with the health care provider and by being another set of eyes and ears at appointments. You can keep next steps organized for the patient and assist with daily planning.



Assist the patient in managing side effects

As a caregiver, you may often learn details about how the patient is feeling before the health care team does. You can encourage your loved one to call the doctor about any side effects that may appear. You can also do day-to-day tasks, like household chores, if the patient isn't feeling well enough to do them.



Remember to take time for yourself

As important as it is to take care of the patient, it's also important to focus on yourself. Caring for someone with cancer can affect your physical and mental well-being. Practicing self-care and knowing your limits make it easier to provide the patient with the best support possible.

Important Safety Information (continued)

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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Helpful wallet card

It's important to share your treatment information with medical professionals who may not be part of your regular health care team, such as emergency room staff. Presenting this card may make it easy to inform them you're receiving treatment. It may also help ensure you don't receive medication or medical care that you shouldn't. Keep it close so these important details about your medical care don't get lost.

All you need to do is:

- 1 Print this page**
Cut out the wallet card along the dotted lines and fold it in half.
- 2 Fill it out**
Ask your health care team the name of the condition you are being treated for and what medications you should add to this card.
- 3 Keep it close**
Store your card in your wallet or any other convenient place.
- 4 Take it out**
Share this card with anyone providing you with medical care so they'll know that you're receiving treatment with certain medications.

<p>I am currently taking these medications:</p> <p>_____</p> <p>This is treatment for: _____</p> <p>My full name is: _____</p> <p>Prescribing doctor: _____</p> <p>Doctor's phone number: _____</p>	<p>Important information about my health care</p> <p>Consider calling my doctor before prescribing me any additional medications.</p> <p><small>Copyright © 2024 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved. US-OBD-01729 08/24</small></p> 
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Share this card whenever you receive medical care outside of your regular health care team.

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