

Talking to your doctor about your treatment plan for MIBC

Having open, thoughtful discussions with your doctor is an important part of deciding on a treatment for muscle-invasive bladder cancer (MIBC). This guide is designed to help you learn more about IMFINZI, an immunotherapy that is given in combination with chemotherapy* before surgery and alone after surgery to treat MIBC.



*IMFINZI may be used in combination with the chemotherapy medicines gemcitabine and cisplatin prior to surgical removal of your bladder (neoadjuvant treatment) followed by IMFINZI alone after surgery (adjuvant treatment) **to treat a type of bladder cancer called muscle invasive bladder cancer (MIBC) that has spread into the muscle layer of the bladder but not to other parts of the body.***

Download or print this guide, and bring it with you to your next appointment so that you can have an informed discussion about IMFINZI + chemotherapy* for MIBC.



Questions to help build your treatment plan



Speak to your urologist and medical oncologist.

- What are the most important things I should know about my cancer?
- What is the goal of treatment?
- What might progress look like at each step?
- What is the difference between immunotherapy and chemotherapy?
- Based on where I am with my cancer, why might IMFINZI (given with chemotherapy* before surgery and alone after surgery) be right for me?
- What are the possible side effects of IMFINZI?
- Based on the clinical trial, what were the benefits of IMFINZI and chemotherapy* before surgery and IMFINZI alone after surgery?
- How long is IMFINZI given with chemotherapy* before surgery?
- What types of support are available? How can I get in contact with support organizations?

See the next page for questions about surgery and continuing to treat MIBC with IMFINZI after surgery.

*Gemcitabine and cisplatin.

SELECT SAFETY INFORMATION

What is the most important information I should know about IMFINZI® (durvalumab)?

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI 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.

Please see additional Important Safety Information on pages 6-7 and Full Prescribing Information including Medication Guide for IMFINZI.

Talking about surgery and continuing treatment



Questions to understand surgery for MIBC



Speak to your urologist.

- What is a cystectomy? Can you tell me more about the procedure?
- What are the options for urinary diversion, and what are the pros and cons of each?
- How is each type of urinary diversion created? What is the recovery like for each?
- What urinary diversion might be the best fit for my lifestyle? What lifestyle changes will I need to make afterwards?
- What can I expect with my recovery? Is there anything I can do to make my recovery easier?
- Will I need help with daily activities after surgery? Can you tell me what kind of support I might need?
- How can my care team support me through recovery?
- What support is available if I'm having challenges?



Questions to understand continuing MIBC treatment



Speak to your medical oncologist.

- Why would I need another treatment after surgery?
- How soon after surgery would I start treatment with IMFINZI?
- How long would I receive treatment with IMFINZI after surgery? How often would I see my oncologist for treatment?
- What are the possible side effects of IMFINZI?

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Lung problems: cough, shortness of breath, and 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; and severe stomach-area (abdomen) pain or tenderness

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Key terms to know

You may come across some new or unfamiliar terms while learning more about your treatment plan. Here are **some common terms used by healthcare professionals**:

Adjuvant therapy

Treatment given after surgery

Chemotherapy (chemo)

A type of cancer treatment that attacks rapidly growing cells, including cancer cells. Chemotherapy also affects healthy cells

Continence

The ability to control bowel and bladder movements

Cystectomy

A surgery where the bladder is removed, along with nearby organs and tissues where cancer may have spread

Event-free survival (EFS)

In a clinical trial, the amount of time after treatment started that people had without their cancer coming back or getting worse

Immunotherapy

A type of treatment that works with the immune system to find and attack hidden cancer cells. Immunotherapy may also affect healthy cells

Infusion therapy

A type of medicine or treatment given through a needle or a catheter, most likely into a vein

Intravenous

A type of injection or infusion where medicine is delivered directly into a vein

Ileal conduit (also called an ostomy bag)

A type of urinary diversion where urine leaves the body through a stoma (small opening) in the stomach and collects in a bag worn on the outside of the body

Medical oncologist

A doctor who specializes in treating cancer with medicine

Muscle-invasive bladder cancer (MIBC)

A type of bladder cancer where cancer cells grow into or through the muscle that surrounds the bladder wall

Neoadjuvant therapy

Treatment given before surgery

Neobladder

A type of urinary diversion where a surgeon constructs a pouch to hold urine using a part of the small intestine. This pouch will function as an artificial bladder

Programmed cell death ligand 1 (PD-L1)

A protein that disguises cancer cells from your immune system

Placebo

A treatment that doesn't contain any medicine. Scientists use it in clinical studies to compare results with another treatment

Recurrence

When cancer comes back after a successful treatment. This can happen months or years later

Staging

The process of finding out how much cancer is in a person's body and where it is located. Different types of cancer use different staging systems

Stoma

A surgically created opening that allows urine to leave the body

Stoma nurse

A nurse who specializes in ostomy care and continence issues. Also called an ostomy or continence nurse

Urinary diversion

A new way for urine to leave the body after the bladder is removed

Urologist

A doctor who specializes in treating illnesses related to the urinary system

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

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), and bleeding or bruising more easily than normal

Please see additional Important Safety Information on pages 6-7 and Full Prescribing Information including Medication Guide for IMFINZI.

Keep in touch with your care team

You will most likely meet with a few healthcare professionals during treatment. To help keep track of the entire care team as well as their roles and responsibilities, use the space below to write down their contact information. This can be a reference whenever you need it throughout treatment.



Urologist

Name: _____

Phone/email: _____

Location: _____



Medical Oncologist

Name: _____

Phone/email: _____

Location: _____



Name: _____

Specialty/role: _____

Phone/email: _____

Location: _____



Name: _____

Specialty/role: _____

Phone/email: _____

Location: _____

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

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; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Please see additional Important Safety Information on pages 6-7 and Full Prescribing Information including Medication Guide for **IMFINZI**.

Notes

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SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Kidney problems: decrease in your amount of urine, blood in your urine, swelling of your ankles, and loss of appetite











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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMFINZI® (durvalumab)?

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI 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.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

-  **Lung problems:** cough, shortness of breath, and 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; and 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), and 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; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
-  **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, and loss of appetite
-  **Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in mouth or nose, throat, or genital area; fever or flu-like symptoms; and swollen lymph nodes
-  **Pancreas problems:** pain in your upper stomach area (abdomen), severe nausea or vomiting, and loss of appetite
-  **Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with IMFINZI. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:** Chest pain, irregular heartbeats, shortness of breath or swelling of ankles; confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems; tingling, numbness or weakness of the arms or legs; double vision, blurry vision, sensitivity to light, eye pain, changes in eye sight; persistent or severe muscle pain or weakness, muscle cramps, joint pain, joint stiffness or swelling; and low red blood cells and 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, feel like passing out, fever, and back or neck pain
-  **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 IMFINZI. Your healthcare provider will monitor you for these complications

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

IMPORTANT SAFETY INFORMATION (continued)

Before you receive IMFINZI, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. IMFINZI can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with IMFINZI.
 - You should use an effective method of birth control during your treatment and for 3 months after the last dose of IMFINZI. Talk to your healthcare provider about birth control methods that you can use during this time.
 - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with IMFINZI.
- are breastfeeding or plan to breastfeed. It is not known if IMFINZI passes into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of IMFINZI.

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

What are the possible side effects of IMFINZI?

IMFINZI can cause serious side effects (see page 6):

The most common side effects of IMFINZI when used with gemcitabine and cisplatin in adults with muscle-invasive bladder cancer (MIBC) include low red blood cells (anemia), low white blood cells, increased level of creatinine in the blood, decreased level of sodium in the blood, nausea, increased liver function tests, decreased level of calcium in the blood, decreased blood platelet counts, feeling tired, increase level of potassium in the blood, decreased lymphocyte counts, constipation, decreased level of magnesium in the blood, decreased appetite, increased level of alkaline phosphatase in the blood, rash, fever, diarrhea, vomiting and stomach (abdominal) pain.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of IMFINZI. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects related to AstraZeneca products [↗](#). If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

What is IMFINZI?

IMFINZI may be used in combination with the chemotherapy medicines gemcitabine and cisplatin prior to surgical removal of your bladder (neoadjuvant treatment) followed by IMFINZI alone after surgery (adjuvant treatment) **to treat a type of bladder cancer called muscle invasive bladder cancer (MIBC) that has spread into the muscle layer of the bladder but not to other parts of the body.**

It is not known if IMFINZI is safe and effective in children.

Please see additional Important Safety Information on [page 6](#) and Full Prescribing Information including Medication Guide for IMFINZI.

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