



MAKE SPACE

for more than cancer

IMFINZI is changing the way muscle-invasive bladder cancer (MIBC) is treated. IMFINZI is the first and only immunotherapy approved for use with chemotherapy* before surgery and alone after surgery to treat MIBC.

*Gemcitabine and cisplatin.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

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.

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 32-35 and click the following for Full Prescribing Information including Medication Guide for IMFINZI.



Getting started
with IMFINZI

A bladder cancer diagnosis can come as a shock, and finding the right information might feel overwhelming at first. But understanding your treatment plan can help you make space for more than cancer.

In this brochure, you'll learn about muscle-invasive bladder cancer (MIBC) and how adding IMFINZI to treatment with chemotherapy* and surgery may help treat it.

*Gemcitabine and cisplatin.

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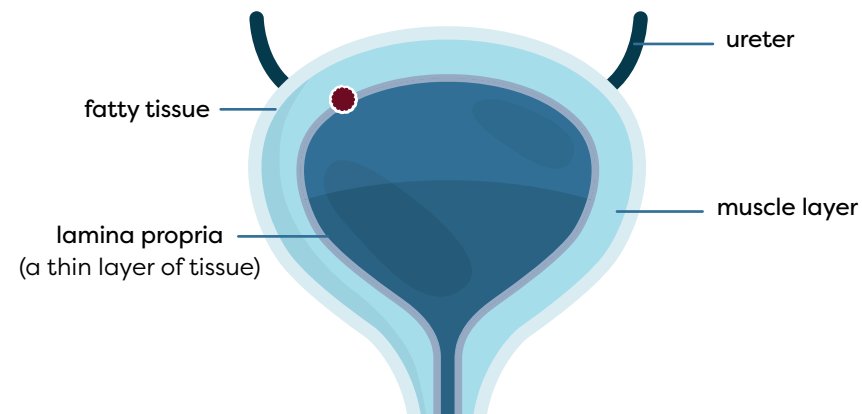
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Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:
Lung problems: cough, shortness of breath, and chest pain
For additional Important Safety Information, [click here](#).

About muscle-invasive bladder cancer

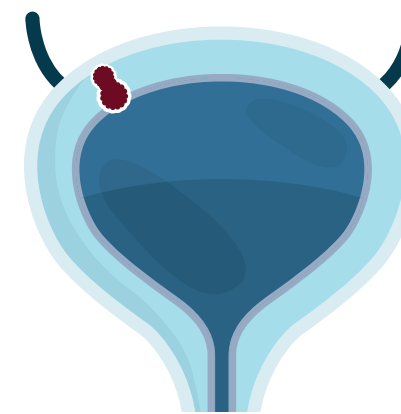
There are 2 types of bladder cancer. In non-muscle-invasive bladder cancer, cancer stays within the inner lining of the bladder. In **muscle-invasive bladder cancer (MIBC)**, cancer cells spread into or through the muscle layer of the bladder wall, and may spread to other parts of the body.

There are three main stages of MIBC:



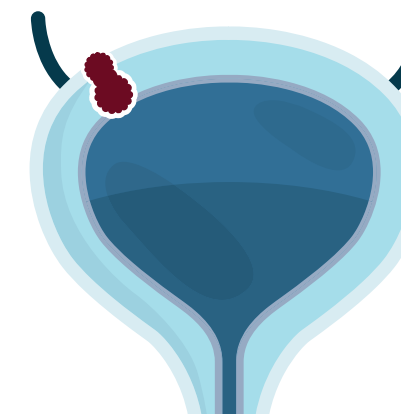
Stage T2

Cancer has grown into the muscle surrounding the bladder wall



Stage T3

Cancer has grown through the muscle around the bladder into surrounding tissues, such as nearby fatty tissues



Stage T4

Cancer has spread to other parts of the body near the bladder, such as the wall of the pelvis or abdomen, or to nearby organs



When treating cancer, doctors use a process called staging. This helps them figure out how much cancer there is and whether it has spread from where it started.



Talk to your doctor to **learn more about your stage of MIBC** and what it may mean for your treatment plan.

Treating MIBC

Chemotherapy + surgery are used to treat muscle-invasive bladder cancer



Chemotherapy



Surgery

To treat MIBC, doctors typically recommend a surgery called a radical cystectomy. This means removing the bladder, along with nearby organs and tissues where the cancer may have spread. These could include the prostate, uterus, or ovaries. But sometimes cancer cells are left behind in the body after surgery. A doctor may recommend more treatment after surgery to continue fighting cancer.



Keep reading to learn how IMFINZI, an immunotherapy, may be added to your treatment plan for MIBC.

Meet the care team members involved in your treatment plan

You will likely work with more than one type of healthcare provider to treat muscle-invasive bladder cancer.



Urologist

This is a doctor who specializes in illnesses related to the bladder. They will partner with a pathologist to determine your diagnosis and MIBC stage. A urologist may perform a procedure called a cystectomy to remove part or all of the bladder



Pathologist

A type of doctor who looks at bodies and body tissues to help diagnose illnesses, including cancer



Medical oncologist

Works with your urologist to develop a treatment plan for MIBC. They may recommend medicine to help treat cancer before and after surgery



Stoma nurse

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



Pelvic floor specialist

Treats issues related to the pelvic floor muscles, including any bladder challenges that may come up after your surgery

SELECT SAFETY INFORMATION (continued)

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

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

For additional Important Safety Information, [click here](#).

➤

IMFINZI + chemo* before surgery, followed by IMFINZI alone after surgery, is approved for MIBC

*Gemcitabine and cisplatin.

IMFINZI is the first and only immunotherapy approved for use with chemotherapy* before surgery and alone after surgery to treat MIBC

IMFINZI IS THE FIRST AND ONLY IMMUNOTHERAPY

approved for use with chemotherapy* before surgery
and alone after surgery in MIBC



IMFINZI works with the immune system to help find hidden cancer cells before and after surgery. IMFINZI may also affect healthy cells.

IMFINZI is given together with chemotherapy* **before surgery**. This is called neoadjuvant therapy.



Then, IMFINZI is given alone **after surgery**. This is called adjuvant therapy.

*Gemcitabine and cisplatin.

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

For additional Important Safety Information, [click here](#).

 **IMFINZI**[®]
durvalumab
Injection for Intravenous Use 50 mg/mL

How is IMFINZI given?

IMFINZI is given



at your
doctor's office



or at an
infusion center



as an intravenous
infusion



for about
60 minutes
per infusion

Before surgery, you'll receive IMFINZI together with chemotherapy* every 3 weeks for 4 cycles. After surgery, you'll receive IMFINZI every 4 weeks for up to 8 cycles, or as long as your doctor recommends.

Your doctor will test your blood for certain side effects.

Your healthcare provider may treat your side effects with other types of medicine. They may delay or stop treatment if you have side effects that are too difficult to manage, or they may stop treatment if your cancer gets worse.

*Gemcitabine and cisplatin.

Questions to ask your doctor

The questions here can help guide your conversation with your doctor as you learn more about MIBC and build your treatment plan together.



What is the goal of treatment before and after surgery (perioperative treatment)?



What is a urinary diversion?



How do immunotherapies like IMFINZI work?



What are the pros and cons of each urinary diversion option?



How will I receive IMFINZI?



What should I expect during my recovery?



What are the possible side effects of IMFINZI?



Scan the code to download more questions to ask your doctor.

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

For additional Important Safety Information, [click here](#).

Understanding the treatment journey for MIBC

It can be helpful to think of treatment for MIBC as a journey in 3 steps. Here's an overview about what to expect:



Pre-surgery IMFINZI + chemotherapy*



You and your care team will talk about how to prepare for surgery and your urinary diversion options (these are different ways of going to the bathroom). They will also refer you to a medical oncologist.



A medical oncologist will **recommend starting your treatment with IMFINZI + chemotherapy* as a first step before surgery.** You'll receive IMFINZI together with chemotherapy* every 3 weeks for 4 cycles.

*Gemcitabine and cisplatin.



Surgery



A urologist will perform a cystectomy. This is a procedure that **removes part or all of the bladder, and sometimes surrounding organs and tissues** if the cancer has spread.



It's common for some cancer cells to be left behind in the body after surgery. That's why you'll continue to treat MIBC with IMFINZI.



Post-surgery IMFINZI



You'll recover from surgery and adapt to your urinary diversion as you continue treating MIBC with IMFINZI. **IMFINZI will be given every 4 weeks for up to 8 cycles,** or as long as your doctor recommends.



Your care team will look after you to make sure your body is still responding to treatment.

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

For additional Important Safety Information, [click here.](#)

Types of urinary diversion

After you've had surgery to remove your bladder, you'll need a different way to go to the bathroom. Urine will be rerouted, or "diverted," using one of the methods here. This is called urinary diversion.

There are 2 common types of urinary diversion



Neobladder

- Your surgeon will create a new bladder through surgery
- This is done by creating a new pouch to hold urine using a part of the small intestine
- You'll learn to pass urine by contracting your stomach muscles
- It may feel unfamiliar, but with practice it will get easier



**Urostomy bag
(ileal conduit)**

- Your surgeon will create a small opening in the stomach called a stoma
- You'll pass urine through your stoma into a bag worn on the outside of your body called a urostomy bag
- Your urostomy bags will be designed so that you can conceal them beneath your clothing
- Instead of going to the bathroom yourself, you'll change your bag once it's full



The tips below may help as you adapt after surgery:

If you have a neobladder:

- Try emptying it more often at the beginning of your recovery to help reduce leaks
- Accidents may happen as you adjust. It can be helpful to set a schedule to empty your neobladder every 3-4 hours until you know the signs that it's full
- If you experience bladder control issues (incontinence) or other challenges, it can help to connect with a pelvic floor specialist. They can offer you more personalized guidance

If you have a urostomy bag:

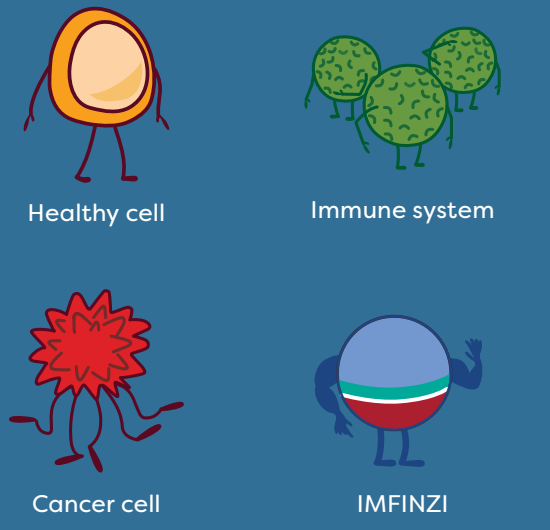
- Ask for support from a stoma nurse if you have any problems with your bag. They can provide ongoing guidance and education as you recover
- You can explore different types of bags to find the best fit. There are several types of pouching systems and designs, so don't hesitate to try a different option
- Ask your stoma nurse about wearing a smaller bag when exercising, or a waterproof dressing for swimming



Talk to your healthcare team about the pros and cons of each option before deciding on a urinary diversion.

How does IMFINZI work?

Meet the key players:



1

When cancer cells appear in your body, your immune system works to recognize and attack them.

2

PD-L1 is a protein that disguises cancer cells from the immune system.

3

IMFINZI works by binding to and blocking PD-L1 to remove the disguise...

4

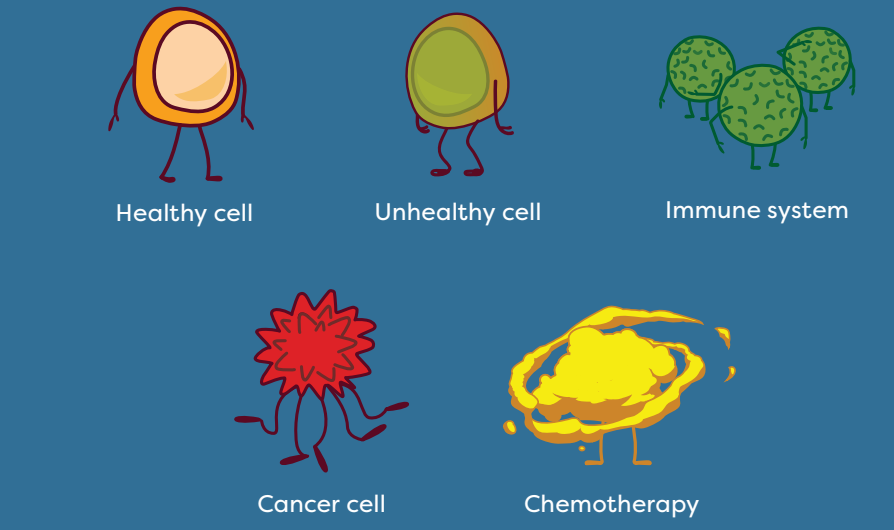
...so your immune system is better able to find and attack these cancer cells. There is a chance that IMFINZI may affect healthy cells, too.

SELECT SAFETY INFORMATION (continued)
Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:
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
For additional Important Safety Information, [click here](#).



How does chemotherapy work?

Meet the key players:



1

The immune system serves as your body's defense system against infections and diseases and can typically detect and destroy unhealthy cells.

2

Unhealthy cells, if not detected and destroyed by the immune system, may eventually turn into cancer.

3

Cancer cells grow abnormally and multiply quickly. This is where chemotherapy, a type of cancer treatment, can help.

4

Chemotherapy has the ability to destroy rapidly growing cells—such as cancer cells—throughout the body. Since chemotherapy can destroy fast-growing cells, healthy cells may also be affected.

SELECT SAFETY INFORMATION (continued)
Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:
Pancreas problems: pain in your upper stomach area (abdomen), severe nausea or vomiting, and loss of appetite
For additional Important Safety Information, [click here](#).



What were the clinical trial results with IMFINZI + chemotherapy* for MIBC?

*Gemcitabine and cisplatin.

A clinical trial compared two groups of adults with muscle-invasive bladder cancer



533

IMFINZI + chemo* group

People in the **IMFINZI + chemo* group** received IMFINZI with chemotherapy* before surgery, and IMFINZI alone after surgery.

530

Chemo* alone group

Those in the chemo* alone group received chemotherapy* before surgery and no medicine after surgery.

The clinical trial followed both groups of adults for an average of nearly 4 years (46 months).



SELECT SAFETY INFORMATION (continued)

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

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

For additional Important Safety Information, [click here](#).

➤
More people in the IMFINZI + chemo* group did not see their cancer get worse or come back

*Gemcitabine and cisplatin.

Event-free survival

An event was defined as needing to delay bladder surgery, cancer getting worse, cancer coming back, or death from any cause.

IMFINZI + chemo* group

65%

346 out of 533 people
did not see their cancer
get worse or come back

vs

Chemo* alone group

54%

284 out of 530 people
did not see their cancer
get worse or come back

Median event-free survival was not reached with IMFINZI + chemo*, then IMFINZI alone vs 46.1 months with chemo* alone. Median EFS is the length of time that half the people are living without their cancer getting worse or coming back. When more than half the people don't see their cancer get worse or come back, median EFS has not been reached. Median is the middle number in a group of numbers arranged from lowest to highest.

32%

IMFINZI + chemo*, then IMFINZI alone reduced the risk of cancer getting worse or coming back

In a clinical trial, people who received IMFINZI + chemo*, then IMFINZI alone were 32% less likely to have their cancer get worse or come back.

There were more people living who took IMFINZI + chemo* compared to those who took chemo* alone†

397

out of 533

people in the
IMFINZI + chemo* group
were still living

**COMPARED
TO**

361

out of 530

people in the
chemo* alone group
were still living

*Gemcitabine and cisplatin.

†At the end of the study period.

SELECT SAFETY INFORMATION (continued)

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

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

For additional Important Safety Information, [click here](#).



M A K E

S P A C E
for more than cancer



Support for the treatment journey

Use the next section to familiarize yourself with tips for infusion days, advice for lifestyle changes after surgery, and resources to support you.



How do I prepare for treatment?

A little planning can go a long way to help improve your treatment experience. Here are a few suggestions to help get you ready.

On infusion days, remember to



Dress comfortably in loose-fitting clothes



Take any necessary identification and insurance cards



Show up early so you don't feel rushed



Eat a small meal before your infusion



Bring a list of medications you are currently taking



Keep yourself occupied with reading materials, puzzles, and/or mobile devices



Write down any questions you may have for your care team



Drink plenty of water to stay hydrated



Schedule your next infusion before you leave

Notes

Use the space below to write down any additional questions you may have, or to jot down notes during your appointment.



What to expect after surgery

There are some important steps you'll take after surgery to get the most out of your treatment plan for MIBC.

Continuing your treatment journey after surgery



After surgery, you'll likely spend a few days recovering in the hospital, where your care team will look after you.

As you move forward in your recovery, you'll keep treating MIBC with IMFINZI.

Starting another treatment after surgery may feel overwhelming. But it's an important step to keep you on the right track.



In addition to your treatment team, other care specialists can help as you recover from surgery.

A stoma nurse specializes in ostomy care and continence issues. They can support you as you adjust to your urinary diversion.

Lean on your care team for support after surgery



If you have a neobladder, a stoma nurse can teach you how to care for it. Talking with a pelvic floor specialist can also help support your recovery.

If you are using a urostomy bag, a stoma nurse can teach you how to change your bag and help with cleaning and caring for your stoma.



Remember it's normal to have challenges as you get used to your neobladder or urostomy bag. With time, you'll build more confidence in managing daily life with a urinary diversion.

If you have questions or have difficulties with your recovery, your care team is there to help.

SELECT SAFETY INFORMATION (continued)

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

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

For additional Important Safety Information, [click here](#).

➤ Finding support



Every person living with bladder cancer has their own unique challenges and needs for different kinds of support.

The organizations here are great places to find practical resources for getting to and from treatment.

Remember that there may be local groups in your area, and you can ask your care team about these.

Finding community can help you keep moving forward.



Air Charity Network

Provides free air transportation to medical facilities for patients who are financially distressed or unable to travel on public transportation.

Visit aircharitynetwork.org



American Cancer Society Road To Recovery®

Coordinates rides with an American Cancer Society volunteer driver or with a local transportation partner to provide transportation to and from treatment for patients. Visit cancer.org

AstraZeneca wants you to have support options available



The AstraZeneca Access 360™ program can help you get started with IMFINZI. For more information, call 1-844-ASK-A360 (1-844-275-2360), Monday-Friday from 8 AM–6 PM ET, or visit MyAccess360.com.

The IMFINZI Patient Savings Program is available to assist with out-of-pocket costs for IMFINZI for eligible commercially insured patients. For more information, please visit www.azpatientsupport.com.

➤ 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

For additional Important Safety Information, [click here](#).

➤ 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 pages 32-33):

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 [pages 32-34](#) and click the following for Full Prescribing Information including Medication Guide for [IMFINZI](#).

LEARN MORE ABOUT IMFINZI

Get started at [IMFINZI.COM/MIBC](https://www.imfinzi.com/mibc)

Or call AstraZeneca at 1-800-236-9933

Monday-Friday, 8 AM–6 PM ET, excluding holidays

Please see additional Important Safety Information on pages 32-35 and click the following for Full Prescribing Information including Medication Guide for IMFINZI.



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