

A photograph of a man and a woman smiling at each other outdoors. The man is wearing a brown leather cap and a plaid shirt, and the woman has long brown hair. The photo is framed by a white line that forms a speech bubble shape.

I'M IN

because I choose hope

LOCALLY ADVANCED OR METASTATIC

BILE DUCT CANCER (CHOLANGIOCARCINOMA)
OR GALLBLADDER CANCER

IMFINZI with chemotherapy* is the first FDA approval for adults with locally advanced or metastatic bile duct cancer (cholangiocarcinoma) or gallbladder cancer to take as a first treatment

*Gemcitabine and cisplatin.

WHAT IS IMFINZI?

IMFINZI is a prescription medicine used to treat adults with **a type of cancer called biliary tract cancer (BTC)**, including cancer of the bile ducts (cholangiocarcinoma) and gallbladder cancer. IMFINZI may be used in combination with chemotherapy medicines gemcitabine and cisplatin when your BTC has spread to nearby tissues (locally advanced), **or** has spread to other parts of the body (metastatic).

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

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

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.

For additional Important Safety Information, please see pages 18-21.

A woman with dark, curly hair is shown from the chest up, playing an acoustic guitar. She is looking down at the strings of the guitar. She is wearing a light-colored, long-sleeved shirt and a patterned vest. The background is a bright, sunlit room with a window showing greenery outside. The overall mood is calm and focused.

STARTING WITH IMFINZI

Getting diagnosed with bile duct cancer (cholangiocarcinoma) or gallbladder cancer isn't something anyone can prepare for. These cancers usually don't cause symptoms in the early stages, so a diagnosis can come as a shock. Finding the information you need may be overwhelming. That's why this guide is here for you. Use it to learn more about your cancer and how treatment with IMFINZI may help, so you can plan the next step of your journey.

IMPORTANT SAFETY INFORMATION (cont'd)

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, please see pages 18-21.

TABLE OF CONTENTS

Learn about bile duct cancer (cholangiocarcinoma) and gallbladder cancer	4
What is IMFINZI?	6
How was IMFINZI studied?	7
What were the clinical trial results for IMFINZI and chemotherapy*?	8
How do IMFINZI and chemotherapy* work together?	10
How is IMFINZI given?	14
How do I prepare for treatment?	15
Resources and support	16
Important Safety Information	18

*Gemcitabine and cisplatin.

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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, please see pages 18-21.

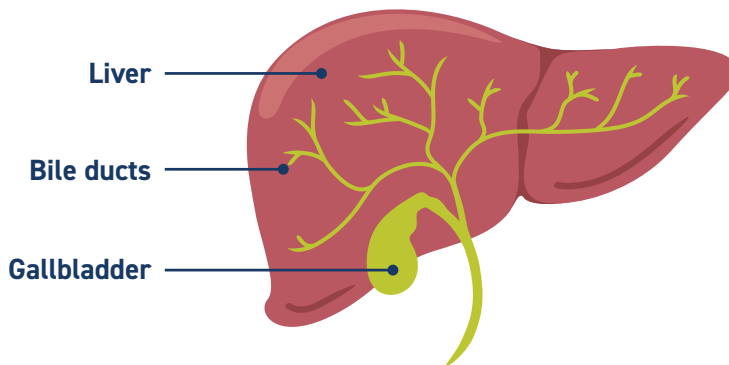
LEARN ABOUT BILE DUCT CANCER (CHOLANGIOCARCINOMA) AND GALLBLADDER CANCER

Bile duct cancer and gallbladder cancer are types of biliary tract cancers. They form in the cells of the bile duct and gallbladder.

Facts about these cancers:

- May affect the liver
- Can be caused by inflammation or blockage of the bile ducts over time
- Typically don't cause symptoms in the early stages
- Have often already spread to other parts of the body at the time of diagnosis

It's helpful to understand the anatomy of the bile ducts and the gallbladder to understand these cancers.



The **bile ducts** are a series of thin tubes that go from the **liver** to the small intestine. Their main role is to allow bile, a fluid made in the liver, to go from the liver directly into the small intestine, or into the **gallbladder** for storage. Bile helps the body digest fat in food.



Because both bile duct cancer and gallbladder cancer often don't cause symptoms in the early stages, ~80% of people are diagnosed when their cancer is in an advanced stage.

A diagnosis can feel unexpected and difficult to process. But as the treatment landscape evolves, there are reasons to be hopeful.

WHAT IS IMFINZI?

IMFINZI IS AN IMMUNOTHERAPY

There has been little progress in first-line treatment options for locally advanced or metastatic bile duct cancer (cholangiocarcinoma) or gallbladder cancer. Chemotherapy has remained the standard of care.

IMFINZI with chemotherapy (gemcitabine and cisplatin) is FDA-approved for adults with locally advanced or metastatic bile duct cancer (cholangiocarcinoma) or gallbladder cancer to take as a first treatment.

IMFINZI is a type of cancer treatment that works with your body's immune system to help fight your cancer. IMFINZI may cause the immune system to attack healthy cells.



IMFINZI with chemotherapy*
is approved to treat people with locally advanced or metastatic bile duct cancer or gallbladder cancer.

*Gemcitabine and cisplatin.



IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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, please see pages 18-21.

HOW WAS IMFINZI STUDIED?

A clinical trial compared 2 groups of adults with locally advanced or metastatic bile duct cancer or gallbladder cancer:



341 people
received IMFINZI
+ chemotherapy
(gemcitabine and cisplatin)



344 people
received placebo (no medicine)
+ chemotherapy
(gemcitabine and cisplatin)

The main goal of the study was to measure how long people lived (called overall survival). See the next page for the results of the study.

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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

For additional Important Safety Information, please see pages 18-21.

WHAT WERE THE CLINICAL TRIAL RESULTS FOR IMFINZI AND CHEMOTHERAPY*?

For people with locally advanced or metastatic bile duct cancer (cholangiocarcinoma) or gallbladder cancer:

IMFINZI + CHEMOTHERAPY* HELPED PEOPLE LIVE LONGER COMPARED TO THOSE TAKING CHEMOTHERAPY* ALONE

Median Overall Survival†



†The study measured median overall survival, which is the length of time from the start of treatment that half of the people are alive.
Data cutoff was August, 11 2021



IMFINZI with chemotherapy* lowered the risk of death by 20% compared to chemotherapy* alone.

In a follow-up analysis at 3 years‡:



‡Based on the limits of the analysis, results are descriptive and your experience may differ.

Data cutoff was October 23, 2023.

*Gemcitabine and cisplatin.

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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, please see pages 18-21.

WHAT WERE THE CLINICAL TRIAL RESULTS FOR IMFINZI AND CHEMOTHERAPY*? (cont'd)

IMFINZI + CHEMOTHERAPY* REDUCED THE CHANCE OF THE CANCER GROWING OR SPREADING COMPARED TO CHEMOTHERAPY* ALONE



In a clinical trial, **IMFINZI with chemotherapy*** lowered the risk of cancer growing or spreading by **25%** compared to chemotherapy* alone.



Within the trial, half of the people taking **IMFINZI with chemotherapy*** lived without their tumors growing or spreading for **7 months** compared to 6 months for people taking chemotherapy* alone.

*Gemcitabine and cisplatin.

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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

For additional Important Safety Information, please see pages 18-21.



HOW DO IMFINZI AND CHEMOTHERAPY* WORK TOGETHER?

MEET THE KEY PLAYERS



HEALTHY CELL



IMMUNE SYSTEM

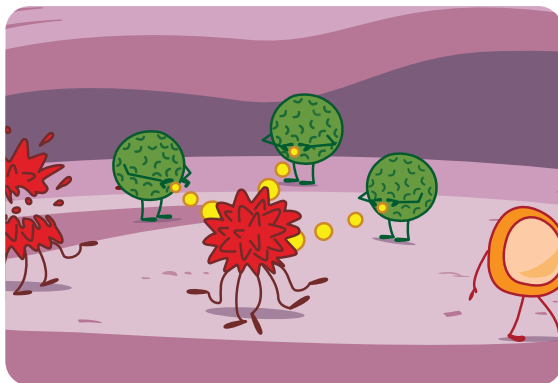


CANCER CELL



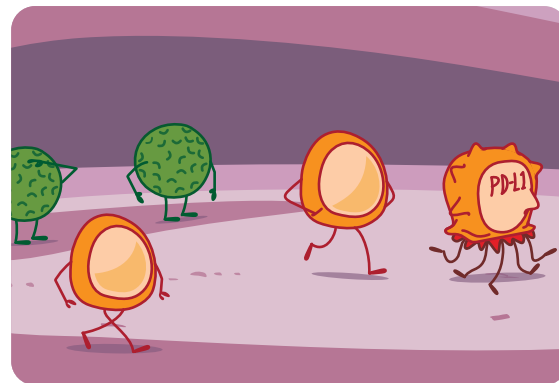
IMFINZI

HOW IMFINZI WORKS TO HELP FIGHT LOCALLY ADVANCED OR METASTATIC BILE DUCT CANCER (CHOLANGIOCARCINOMA) OR GALLBLADDER CANCER:



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.

*Gemcitabine and cisplatin.

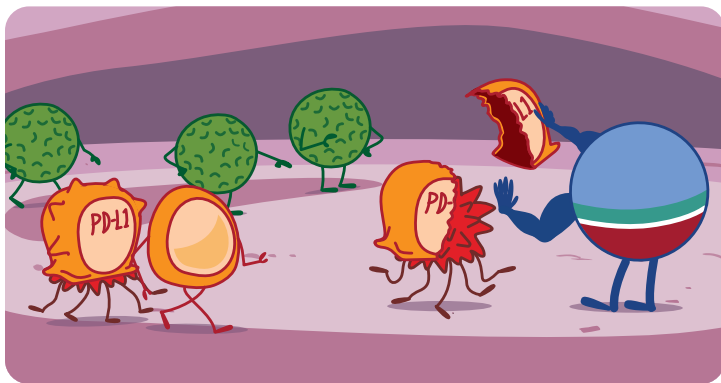
IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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

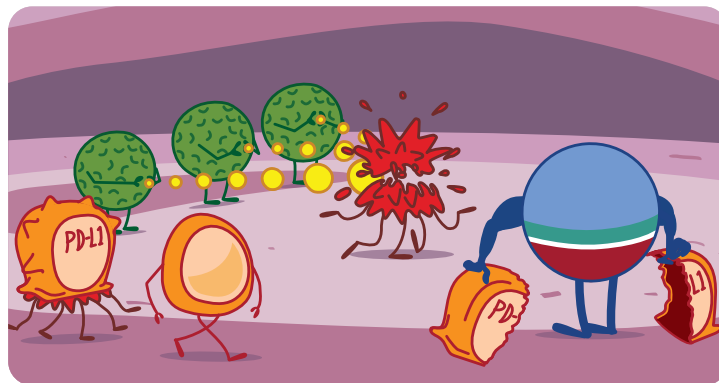
For additional Important Safety Information, please see pages 18-21.

HOW DO IMFINZI AND CHEMOTHERAPY* WORK TOGETHER? (cont'd)



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.

*Gemcitabine and cisplatin.

SELECT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ or tissue transplant that you have had

For additional Important Safety Information, please see pages 18-21.

HOW DO IMFINZI AND CHEMOTHERAPY* WORK TOGETHER? (cont'd)

MEET THE KEY PLAYERS



HEALTHY CELL



UNHEALTHY CELL



IMMUNE SYSTEM



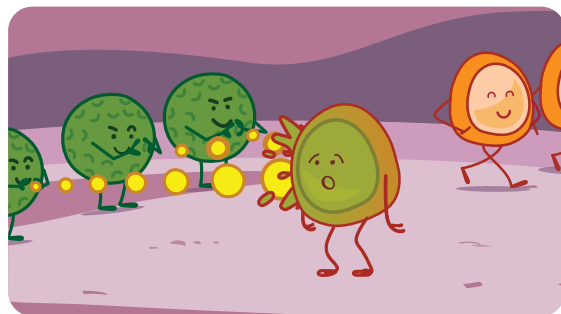
CANCER CELL



CHEMOTHERAPY

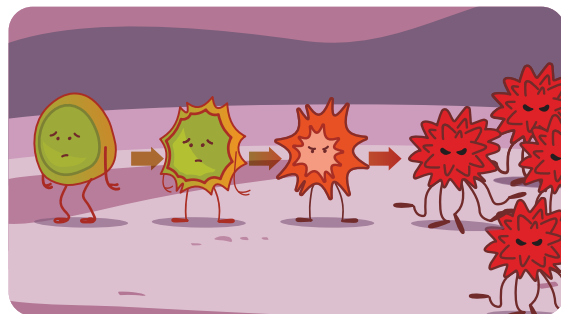
HOW CHEMOTHERAPY* WORKS TO HELP FIGHT LOCALLY ADVANCED OR METASTATIC BILE DUCT CANCER OR GALLBLADDER CANCER:

Chemotherapy is a treatment that destroys fast-growing cancer cells in the body.



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.

*Gemcitabine and cisplatin.

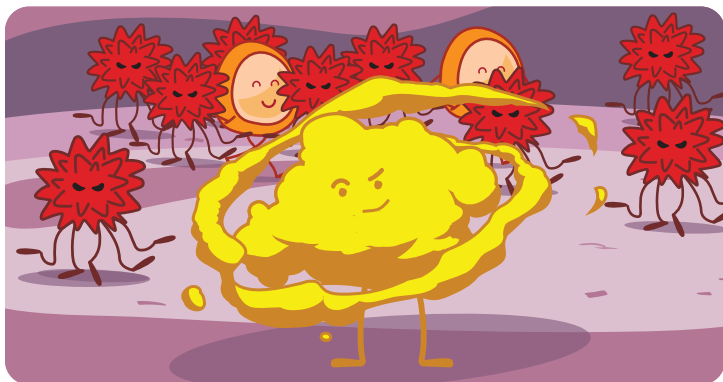
IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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

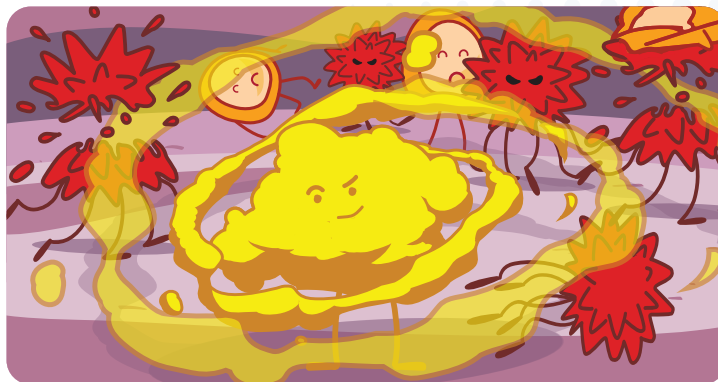
For additional Important Safety Information, please see pages 18-21.

HOW DO IMFINZI AND CHEMOTHERAPY* WORK TOGETHER? (cont'd)



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.

*Gemcitabine and cisplatin.

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):

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, please see pages 18-21.

HOW IS IMFINZI GIVEN?

IMFINZI is an intravenous (IV) infusion. It's given at your doctor's office or an infusion center. For the first part of treatment, IMFINZI is given with chemotherapy.* Then IMFINZI is given alone for the second part of treatment.

*Gemcitabine and cisplatin.



HOW LONG ARE INFUSIONS?

IMFINZI infusions last **about 60 minutes**. There may also be some extra time before or after the infusion for your doctor to run some tests. After the IMFINZI infusion, you may receive another infusion for chemotherapy.* The length of these treatments may be different.



HOW OFTEN ARE INFUSIONS?

You will be given infusions **every 3 weeks** when IMFINZI is given with chemotherapy.* Afterwards, you'll receive infusions of IMFINZI alone **every 4 weeks**.



HOW MANY CYCLES OF TREATMENT WILL I NEED?

IMFINZI is given with chemotherapy* initially. Many people are then able to continue their IMFINZI treatment without chemotherapy.* The number of treatments will be determined by your doctor, depending on the condition of your cancer. You will stop receiving IMFINZI if your cancer progresses or if side effects become intolerable.

IMPORTANT SAFETY INFORMATION (cont'd)

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

For additional Important Safety Information, please see pages 18-21.

HOW DO I PREPARE FOR TREATMENT?

IMPORTANT SAFETY INFORMATION (cont'd)

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

- have received an organ or tissue transplant, including corneal transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)

During treatment, your comfort should be a priority. A little planning can go a long way to help improve your treatment experience. Here are a few suggestions to help get you ready for infusion days:



Drink plenty of water and stay hydrated



Remember to bring your insurance card



Dress comfortably in loose-fitting clothes



Have a list of medications you are currently taking



Write down any questions you may have for your care team



Stay occupied during treatment with reading materials, puzzles, and mobile devices

For additional Important Safety Information, please see pages 18-21.

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

RESOURCES AND SUPPORT

Living with cancer comes with challenges.

But there is support available to help you on your journey. The following resources can provide:

- Additional information about your cancer
- More helpful tips for living with cancer
- Emotional support by connecting you with other people who have cancer

FOR PEOPLE WITH BILE DUCT CANCER (CHOLANGIOCARCINOMA)



Cholangiocarcinoma Foundation®

Cholangiocarcinoma Foundation (CCF)

The Cholangiocarcinoma Foundation (CCF) is a global organization dedicated to improving treatments and finding a cure for cholangiocarcinoma (bile duct cancer), while also enhancing patients' and their caregivers' quality of life. With a patient-first approach, the Foundation has become a leader in research, education, and community support. From finding the right healthcare team with the specialist map, to finding a mentor with CholangioConnect and beyond, CCF can be a valuable resource for people and caregivers. Visit [cholangiocarcinoma.org](https://www.cholangiocarcinoma.org).

FOR PEOPLE WITH GALLBLADDER CANCER



Gastrointestinal (GI) Cancers Alliance

The GI Cancers Alliance works to raise awareness and provide education and advocacy for people living with gastrointestinal cancers like gallbladder cancer. Visit [gicancersalliance.org](https://www.gicancersalliance.org).

RESOURCES AND SUPPORT (cont'd)

TRANSPORTATION ASSISTANCE



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/support-programs-and-services/road-to-recovery.



IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

HELPING YOU ACCESS THE CARE YOU NEED



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 people. 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

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):



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



Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ or tissue transplant that you have had

For additional Important Safety Information, please see pages 20-21.

IMPORTANT SAFETY INFORMATION (cont'd)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (cont'd):



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

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 or tissue transplant, including corneal 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.


IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of IMFINZI?

IMFINZI can cause serious side effects (see pages 18-19).

The most common side effects of IMFINZI when used with gemcitabine and cisplatin in adults with biliary tract cancer (BTC) include feeling tired, nausea, constipation, decreased appetite, stomach (abdominal) pain, rash, and fever.

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 is a prescription medicine used to treat adults with a **type of cancer called biliary tract cancer (BTC)**, including cancer of the bile ducts (cholangiocarcinoma) and gallbladder cancer. IMFINZI may be used in combination with chemotherapy medicines gemcitabine and cisplatin when your BTC has spread to nearby tissues (locally advanced), **or** has spread to other parts of the body (metastatic).

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

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.





VISIT [IMFINZI.COM/DISCOVER](https://www.imfinzi.com/discover) TO LEARN MORE

Or call the AstraZeneca Information Center at **1-800-236-9933**

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



IMFINZI is a registered trademark and AstraZeneca Access 360 is a trademark of the AstraZeneca group of companies.
©2025 AstraZeneca. All rights reserved. US-106826 Last Updated 12/25

