

A guide to **MONITORING SIDE EFFECTS**



**Learn why it's important
and how to keep track**

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.

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.

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



Understanding side effects

If you're starting treatment with IMFINZI, it's important for you to understand that you may experience side effects. **This guide is here to help you track signs of side effects before and after surgery for muscle-invasive bladder cancer (MIBC).**

IMFINZI is a medicine that may treat MIBC by working with your immune system when given with chemotherapy* before surgery and alone after surgery.

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 even 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.

Monitoring and reporting signs of side effects



Track how you usually feel

You can start keeping track of how you feel before treatment. Taking note of how you normally feel can help you better track any changes that may occur once treatment has started.



Respond to side effects early on

Getting medical treatment right away may help keep problems you may experience from becoming more serious. Your healthcare provider will check you for side effects during your treatment with IMFINZI. Your healthcare provider may treat you with other types of medicine. Your healthcare provider may also need to delay or completely stop treatment with IMFINZI if you have severe side effects.

*Gemcitabine and cisplatin.

Stay connected with your care team

It's important to **let your care team know** of any changes in your health. Talk to them about how you're currently feeling, new or worsening signs of side effects, or any other change. Remember, a small side effect can lead to something more serious if not treated.

Turn the page for an overview of potential urgent side effects. Use the pages in this brochure to track the signs of side effects throughout your treatment with IMFINZI and chemotherapy* before surgery and IMFINZI alone after surgery.

If you have any questions about your treatment, ask your doctor. The information in this brochure does not take the place of talking to your care team about your MIBC treatment.



Remember to fill out the wallet card on page 9 in case of an emergency.

*Gemcitabine and cisplatin.

Side effects to watch out for

Look out for the following side effects so they may be caught and managed early. **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
- 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
- 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)
- Bleeding or bruising more easily than normal



Do not attempt to treat any of the side effects without talking to your care team first.

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 your amount of 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 mouth or nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

Pancreas problems



- Pain in your upper stomach area (abdomen)
- Severe nausea or vomiting
- Loss of appetite

Side effects to watch out for (continued)

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.

Signs or symptoms 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
- 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
- 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

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

Additional safety information

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.

Additional safety information (continued)

What are the possible side effects of IMFINZI?

IMFINZI can cause serious side effects (see pages 4-6).

The most common side effects of IMFINZI when used with gemcitabine and cisplatin in adults with muscle-invasive bladder cancer (MIBC) include:

- decreased red blood cells (anemia)
- decreased 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
- increased 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.

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

Your IMFINZI wallet card

If you ever experience an emergency and need to see a doctor who's not on your regular care team, keeping this card in your wallet can let them know that you're receiving immunotherapy and help them get in touch with your doctor if they need to.



 **I am receiving immunotherapy.**

Please contact my oncologist immediately before treatment.

My Name:

Immunotherapy:

Oncologist:

Contact: -

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Tips to make sure you get the appropriate care

- 1 Fill out this card and carry it with you at all times.
- 2 Keep this card with you for at least 3 months after your last treatment, because side effects can still occur during that time.
- 3 Take a picture of this card with your phone in case you ever leave it at home.

Tracking **SIDE EFFECTS**

Experiencing side effects may be uncomfortable, but they are a normal part of cancer treatment. Remember to discuss any changes that are bothering you with your care team so you can get the support you need. That way, you can continue fighting MIBC with IMFINZI and chemotherapy* before surgery and alone after surgery. Remember that speaking up about side effects early may help you avoid complications or needing to stop treatment.

*Gemcitabine and cisplatin.

Pre-surgery side effects tracker

Track IMFINZI + chemotherapy* side effects before surgery

Below is a helpful guide you can use to track signs of side effects from treatment before surgery. Use the first row to jot down how you typically felt before beginning treatment, and then take note of any new patterns.

Take some notes about how you usually feel	 Tiredness	 Bowel Movements	 Skin Problems

Track new changes	 Tiredness	 Bowel Movements	 Skin Problems
Track dates and doctor's appointments.	Track any changes in energy levels and how many hours you slept.	Track how often bowel movements happen and how hard or soft they are.	Track where and how often you notice any rashes on your body.
Date			
Date			
Date			
Date			
Date			

*Gemcitabine and cisplatin.



Scan the QR code for a downloadable version of the side effect tracker.

 Pain	 Appetite	 Nausea	 Fever

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Track any stomach pain and how long it lasted.	Track any changes in appetite and how many meals or snacks you finished that day.	Track any feelings of queasiness or vomiting.	Track any fever symptoms and how long they lasted.

Note any other symptoms, including any new changes in blood tests:

Date	Date	Date	Date

Pre-surgery side effects tracker (continued)

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Continuing treatment with IMFINZI after surgery

Surgery is a big step in the treatment journey for MIBC, so you can feel proud for reaching this point. As you recover from surgery, you may be focused on learning to use your urinary diversion. However, the next part of your treatment plan—continuing to take IMFINZI alone after surgery—is crucial. This is because cancer cells may be left behind in the body after surgery.

You'll continue receiving IMFINZI every 4 weeks for up to 8 cycles or as long as your doctor recommends. With this tracker and your care team behind you, you can address challenges early on and get the support you need to get the most out of your treatment.



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.

Notes

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

Post-surgery side effects tracker

Track IMFINZI side effects after surgery

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