

A guide to **MONITORING SIDE EFFECTS**



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

What is IMFINZI?

IMFINZI is a prescription medicine used in combination with Bacillus Calmette-Guérin (BCG) to treat **a type of bladder cancer called high-risk non-muscle invasive bladder cancer (NMIBC) that has not spread into the muscle layer of the bladder**, when you have not had prior treatment with BCG.

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 and Bacillus Calmette-Guérin (BCG) for high-risk non-muscle-invasive bladder cancer (NMIBC), it's important to understand that you may experience side effects. Side effects may happen anytime during treatment, or even after your treatment has ended.

Use the pages in this booklet to track any signs of side effects throughout your treatment journey.

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Understanding IMFINZI + BCG

IMFINZI is a medicine that may treat high-risk non-muscle-invasive bladder cancer (NMIBC) by working with your immune system when given with BCG. IMFINZI is used together with BCG to treat a type of bladder cancer called high-risk non-muscle-invasive bladder cancer (NMIBC).

There are 2 stages of treatment with IMFINZI + BCG for high-risk NMIBC:



+



1 year of IMFINZI + BCG



1 additional year of BCG alone

Your doctor will determine how often and how long you will receive treatment. You will stop if your side effects are too difficult to manage. Remember, side effects may happen during any of these stages or even after your treatment has ended.

- IMFINZI works with your immune system to treat cancer, which can also affect the way normal organs and tissues 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 or symptoms of side effects



Track how you usually feel

It can help to start tracking how you feel before treatment starts. That way, you'll have a better sense of what's normal for you and can spot any changes.



Report side effects as soon as possible

Getting medical treatment right away could help keep problems you may experience from getting worse. Your healthcare provider will check you for side effects during your treatment with IMFINZI. They may also need to delay or completely stop treatment with IMFINZI if you have severe side effects.

Stay connected with your care team

It's important to let your care team know of any changes in your health, like new or worsening signs of side effects. Keep in mind, a small side effect may lead to something more serious if not treated.

If you have any questions about your treatment, ask your doctor. The information in this booklet does not take the place of talking to your care team about your high-risk NMIBC.



Remember to fill out the wallet card on page 11 in case of an emergency.

Turn the page for an overview of potential urgent side effects.

Side effects to watch out for

Look out for the following side effects during treatment so they can 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 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
- 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 6-9).

The most common side effects of IMFINZI when used with Bacillus Calmette-Guérin (BCG) in adults with high-risk NMIBC include:

- increased liver function tests
- urinary tract infection
- increased level of potassium in blood
- pain or discomfort with urination
- decreased red blood cells (anemia)
- blood in urine
- increased level of creatinine in the blood
- muscle or bone pain
- decreased lymphocyte counts
- urinate more often
- decreased level of sodium in the blood
- feeling tired
- rash
- 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.

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 with you can let them know that you're receiving IMFINZI and help them get in touch with your care team 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

- Keep this card with you after your last treatment, because side effects can still occur during that time
- 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. Talk about any changes that are bothering you with your care team so you can get the support you need as you treat high-risk NMIBC.

Although treatment for high-risk NMIBC involves IMFINZI + BCG, the side effects on the following pages are linked to IMFINZI treatment, not BCG. Talk to your doctor about side effects you may experience during BCG treatment.

Remember that speaking up about side effects early may help keep these problems from becoming more serious.

IMFINZI side effects tracker

Track IMFINZI side effects during your treatment alongside BCG.

Use the first row of this guide to note how you typically felt before beginning treatment, and then take note of any new patterns.

Take some notes about how you usually feel	 Urination	 Muscle or bone pain

Track new changes	 Urination	 Muscle or bone pain
Track dates and doctor's appointments.	Track any blood in the urine, pain while urinating, urinating more often, or urinary infection.	Track any muscle or bone pain and how long it lasted.
Date		
Date		
Date		
Date		
Date		

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

Flip the page for more tracking slots.

 Skin Problems	 Tiredness	 Fever

 Skin Problems	 Tiredness	 Fever
Track where and how often you notice any rashes on your body.	Track any changes in energy levels and how many hours you slept.	Track any fever symptoms and how long they lasted.

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

IMFINZI side effects tracker (continued)

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➤ Continuing treatment with BCG

The second year of treatment means treating high-risk non-muscle-invasive bladder cancer (NMIBC) with BCG alone. This allows BCG treatment to keep targeting cancer cells.



Connecting with support groups

Being able to lean on other people affected by bladder cancer, either in-person, online, or through the phone, may help you feel supported through your journey. By talking through your treatment experience, you may stay more connected to your community and feel better about treatment. Ask your care team about bladder cancer support groups.



Your care team can help explain and respond to any side effects you may have from BCG treatment.

Be sure to contact them if you notice new changes in how you are feeling.





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



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