

A guide to **MONITORING SIDE EFFECTS**



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

What is IMFINZI?

IMFINZI is used in combination with FLOT prior to and after surgery followed by IMFINZI alone to treat adults with **a type of stomach cancer called GC or GEJC that can be removed by surgery.**

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.

FLOT stands for fluorouracil, leucovorin, oxaliplatin, and docetaxel.

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 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 stomach (gastric) cancer or gastroesophageal junction cancer that can be removed with surgery.**

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI is used together with chemotherapy* before and after surgery, followed by IMFINZI alone, to treat a type of stomach cancer called gastric cancer (GC) or gastroesophageal junction adenocarcinoma (GEJC) that can be removed with surgery.

There are 3 important steps to treatment: pre-surgery (IMFINZI + chemotherapy*), surgery, and post-surgery (IMFINZI + chemotherapy,* followed by IMFINZI alone). Side effects may happen during any of these 3 steps or even after your treatment has ended.

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

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 during treatment, after surgery, or while continuing on treatment.



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.

*Fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT).

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 may 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 and chemotherapy,* followed by 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 stomach (gastric) cancer or gastroesophageal junction cancer that can be removed with surgery.



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

*Fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT).

Side effects to watch out for

Look out for the following side effects, which can happen before or after surgery, 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 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
- 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.

What are the possible side effects of IMFINZI?

IMFINZI can cause serious side effects (see pages 4-7).

The most common side effects of IMFINZI when used with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) in adults with gastric cancer (GC) or gastroesophageal junction adenocarcinoma (GEJC) that can be removed by surgery include:

- diarrhea
- nausea
- inflammation of the nerves causing numbness, weakness, tingling, or burning pain of the arms and legs
- feeling tired
- hair loss
- decreased appetite
- rash
- stomach (abdominal) pain
- vomiting
- muscle and joint pain
- fever
- pain and sores in the mouth


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 [\[7\]](#). 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.

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 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. Talk about any changes that are bothering you with your care team so you can get the support you need as you treat gastric (stomach) cancer or gastroesophageal junction cancer that can be removed with surgery.

Remember that speaking up about side effects early, whether it's before or after surgery, may help keep these problems from becoming more serious.

Side effects before surgery

IMFINZI is given with chemotherapy* at this step to help find and attack cancer cells before surgery. IMFINZI and chemotherapy* may also affect healthy cells.

	Cycle 1	Cycle 2
IMFINZI		
		
Chemotherapy*		



You'll get up to 2 cycles of IMFINZI with chemotherapy.*
The treatment period before surgery is about 8 weeks.



IMFINZI and chemotherapy* infusions are given in cycles. A treatment cycle is typically equal to 4 weeks.

*Fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT).







Notes

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

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	 Bowel Movements	 Nausea/Vomiting	 Pain
Track new changes	 Bowel Movements	 Nausea/Vomiting	 Pain
Track dates and doctor's appointments.	Track how often bowel movements happen and how hard or soft they are.	Track any feelings of queasiness or vomiting.	Track any stomach pain and how long it lasted.
Date			
Date			
Date			
Date			
Date			

*Fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT).




 Skin Problems	 Tiredness	 Appetite	 Fever
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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 changes in appetite and how many meals or snacks you finished that day.	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 after surgery

Surgery is a big step in the treatment journey for stomach (gastric) cancer or gastroesophageal junction cancer that can be removed with surgery, so you can feel proud for reaching this point. Continuing treatment after surgery is a crucial next step. This is because cancer cells may be left behind in the body after surgery.



Post-surgery



Your doctor will give you IMFINZI and chemotherapy* infusions again for up to 2 cycles. After 2 cycles, your doctor will treat with IMFINZI alone for up to 10 cycles. As a reminder, IMFINZI and chemotherapy* infusions are given as cycles.

A treatment cycle is typically equal to 4 weeks. Your doctor will decide how many treatments you need.



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

*Fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT).







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Post-surgery side effects tracker

Track side effects after surgery

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