

A GUIDE TO MONITORING FOR SIGNS AND SYMPTOMS

LEARN WHY IT'S IMPORTANT
AND HOW TO DO IT

WHAT ARE IMFINZI® (DURVALUMAB) AND IMJUDO® (TREMELIMUMAB-ACTL)?

IMFINZI is a prescription medicine used in combination with IMJUDO to treat adults with **a type of liver cancer that cannot be removed by surgery (unresectable hepatocellular carcinoma or uHCC)**.

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

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMFINZI and IMJUDO?

IMFINZI and IMJUDO are medicines that may treat certain cancers by working with your immune system. IMFINZI and IMJUDO 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 accompanying Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.



UNDERSTANDING SIDE EFFECTS

IMFINZI and IMJUDO are medicines that may treat certain cancers by working with your immune system. If you're starting treatment with IMFINZI and IMJUDO, it's important for you to understand that you may experience side effects. IMFINZI and IMJUDO may cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. There is a possibility that 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. That's why tracking your side effects is such an important part of your treatment.

MONITORING AND REPORTING SIGNS OF SIDE EFFECTS



TRACK HOW YOU FEEL NORMALLY

There's a chance you may already be feeling side effects from your cancer, previous treatments, or even other medications. So it's important to write down how you feel before treatment to help you monitor any changes.



CATCH YOUR SIDE EFFECTS EARLY

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 and IMJUDO. Your healthcare provider may also need to delay or completely stop treatment with IMFINZI and IMJUDO 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 body. Talk to them about how you're currently feeling, new 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.

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 unresectable hepatocellular carcinoma (uHCC) treatment.

URGENT SIDE EFFECTS

Look out for the following side effects so they may be caught and managed early.



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

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

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

URGENT SIDE EFFECTS (cont'd)

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 and IMJUDO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

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

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 and IMJUDO. 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 and IMJUDO if you have severe side effects

Before you receive IMFINZI and IMJUDO, 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 and IMJUDO 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 and IMJUDO.
- You should use an effective method of birth control during your treatment and for 3 months after the last dose of IMFINZI and IMJUDO. 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 and IMJUDO.
- are breastfeeding or plan to breastfeed. It is not known if IMFINZI and IMJUDO pass into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of IMFINZI and IMJUDO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ADDITIONAL SAFETY INFORMATION (cont'd)

WHAT ARE THE POSSIBLE SIDE EFFECTS OF IMFINZI AND IMJUDO?

IMFINZI and IMJUDO can cause serious side effects (see pages 4-6):

The most common side effects of IMFINZI and IMJUDO in adults with unresectable hepatocellular carcinoma (uHCC) include:

- Rash
- Diarrhea
- Feeling tired
- Itchiness
- Muscle or bone pain
- 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 and IMJUDO. Ask your healthcare provider or pharmacist for more information.




Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. 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 accompanying Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

HOW TO TRACK SIGNS OF SIDE EFFECTS

SIDE EFFECTS TRACKER


Below is a helpful guide you can use to track signs of side effects during a single day.

	 BOWEL MOVEMENTS	 SKIN PROBLEMS	 PAIN
What's normal for me	I usually have <u>3</u> bowel movements a day	My skin problems flare up: <input checked="" type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	On a scale of 1 to 10 (10 = severe), my pain is usually: <u>4</u> and lasts: <u>3-5</u> hours
Date, appointments, etc	Write down how many bowel movements you've had today and any other details	Note any other details <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	How painful? How long? Describe your pain
January 12 infusion at Dr. White	2	Skin rash and itchiness <input type="radio"/> <input checked="" type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	- Morning stomach pain - 4 in intensity - Lasted 3 hrs
		<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	
		<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	
		<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	
		<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> NEVER OFTEN	













It's important to write down how you normally feel before your first infusion, so you can notice any changes that may occur during treatment.



NAME:

 TIREDNESS	 OTHER SIGNS OF SIDE EFFECTS	WHAT ACTIVITIES DID YOU DO?
I usually sleep: 8 hours a day	I usually experience:	
Write down how many hours you've slept today	Write down how many times you felt this today	
5		went to the park today.











SIDE EFFECTS TRACKER

	 BOWEL MOVEMENTS	 SKIN PROBLEMS	 PAIN
What's normal for me	I usually have _____ bowel movements a day	My skin problems flare up:  NEVER OFTEN	On a scale of 1 to 10 (10 = severe), my pain is usually: _____ and lasts: _____ hours
Date, appointments, etc	Write down how many bowel movements you've had today and any other details	Note any other details  NEVER OFTEN	How painful? How long? Describe your pain
		 NEVER OFTEN	
		 NEVER OFTEN	
		 NEVER OFTEN	
		 NEVER OFTEN	
		 NEVER OFTEN	

NAME:

 TIREDNESS	 OTHER SIGNS OF SIDE EFFECTS	WHAT ACTIVITIES DID YOU DO?
I usually sleep: _____ hours a day	I usually experience:	
Write down how many hours you've slept today	Write down how many times you felt this today	



SIDE EFFECTS TRACKER

	 BOWEL MOVEMENTS	 SKIN PROBLEMS	 PAIN
What's normal for me	I usually have _____ bowel movements a day	My skin problems flare up:  NEVER OFTEN	On a scale of 1 to 10 (10 = severe), my pain is usually: _____ and lasts: _____ hours
Date, appointments, etc	Write down how many bowel movements you've had today and any other details	Note any other details  NEVER OFTEN	How painful? How long? Describe your pain
		 NEVER OFTEN	
		 NEVER OFTEN	
		 NEVER OFTEN	
		 NEVER OFTEN	
		 NEVER OFTEN	



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

NAME:



 TIREDNESS	 OTHER SIGNS OF SIDE EFFECTS	WHAT ACTIVITIES DID YOU DO?
I usually sleep: _____ hours a day	I usually experience:	
Write down how many hours you've slept today	Write down how many times you felt this today	

INFORMATION IN YOUR POCKET

THE 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 an 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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3 TIPS TO MAKE SURE YOU GET THE APPROPRIATE CARE

- 1 Once you've started treatment: Fill out this card and carry it with you at all times.
- 2 Even after you stop treatment: Keep this card with you for at least 3 months, because side effects can still occur during that time.
- 3 Take a picture: If you have a phone with a camera, take a picture of this card just in case you leave it at home.





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



IMJUDO[®]
tremelimumab-actl
Injection for Intravenous Use 20 mg/mL



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