

IMFINZI®

(durvalumab)

PATIENT MEDICATION GUIDE

1. WHAT IMFINZI IS AND WHAT IT IS USED FOR

IMFINZI (durvalumab) is used to treat two types of lung cancer called extensive-stage small cell lung cancer (ES-SCLC) and locally advanced, non-small cell lung cancer (NSCLC), biliary tract cancer (BTC), endometrial cancer, as well as a type of liver cancer called unresectable hepatocellular carcinoma (uHCC) in adults.

IMFINZI in combination with chemotherapy is used when your ES-SCLC:

- has spread extensively within your lungs and cannot be removed by surgery and radiation therapy, or
- has spread to other parts of your body

IMFINZI in combination with chemotherapy before surgery, followed by IMFINZI alone after surgery, is used when your NSCLC can be removed by surgery and is at high risk of recurrence, and you have no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

IMFINZI may also be used alone if your NSCLC:

- has spread within your lungs and cannot be removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

IMFINZI in combination with chemotherapy is used when your BTC, such as cancer of the bile ducts (cholangiocarcinoma) and gallbladder:

- has spread within these regions (or to other parts of the body).

IMFINZI in combination with tremelimumab is used if your uHCC:

- cannot be removed by surgery (unresectable), and
- you have not received prior oral or injectable medicines for it.

IMFINZI in combination with chemotherapy is used when your endometrial cancer has spread to other parts of your body or has reappeared, followed by treatment with:

- IMFINZI alone if your endometrial cancer is mismatch repair deficient (dMMR).
- IMFINZI in combination with olaparib if your endometrial cancer is mismatch repair proficient (pMMR).

IMFINZI may be given in combination with other anti-cancer medicines. If you have any questions about these medicines, ask your doctor.

IMFINZI works by helping your immune system fight your cancer.

2. WARNINGS AND PRECAUTIONS

Tell your doctor before you are given IMFINZI if you have:

- an autoimmune disease (an illness where the body's immune system attacks its own cells);
- an organ transplant;
- lung problems or breathing problems;
- liver problems.

3. MONITORING AND REPORTING SIGNS OF SIDE EFFECTS

In some patients, IMFINZI can cause the immune system to attack normal organs and tissues and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death if left untreated.

While you are on IMFINZI, you will need to look out for any signs of side effects. However, keep in mind that you may have been experiencing side effects from your cancer or previous treatments before you started treatment with durvalumab.

CATCH YOUR SIDE EFFECTS EARLY

If a side effect is identified early, it may be managed before becoming more serious and possibly causing treatment to be stopped.

It is important to let your doctor know of any changes in your body. Talk to him/her about how you are 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.

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 cancer or treatment.

Do not attempt to treat side effects yourself before talking to your doctor.

4. POSSIBLE SIDE EFFECTS AND IMPORTANT SIGNS/SYMPTOMS TO LOOK OUT FOR

Like all medicines, IMFINZI can cause side effects, although not everybody gets them.

Frequency	SCLC	NSCLC	BTC
Very common (may affect more than 1 in 10 people)	<ul style="list-style-type: none"> • Decrease in white blood cells – susceptibility to infection • Decrease in red blood cells – early tiredness or difficulty in breathing • Decrease in platelets – easy bruising • Cough • Nausea • Constipation • Vomiting • Hair loss • Fatigue • Decreased appetite 	<ul style="list-style-type: none"> • Decrease in red blood cells – early tiredness or difficulty in breathing • Decrease in white blood cells – susceptibility to infection • Decrease in platelets – easy bruising • Underactive thyroid gland that can cause tiredness or weight gain • Nausea • Constipation • Diarrhoea • Vomiting • Fatigue • Increase in liver enzymes (aspartate aminotransferase, alanine aminotransferase) • Decreased appetite • Peripheral neuropathy • Cough • Rash • Hair loss • Pruritus 	<ul style="list-style-type: none"> • Decrease in red blood cells – early tiredness or difficulty in breathing • Decrease in white blood cells – susceptibility to infection • Decrease in platelets – easy bruising • Diarrhoea • Stomach pain • Constipation • Nausea • Vomiting • Fatigue • Fever • Increase in liver enzymes (aspartate aminotransferase, alanine aminotransferase) • Decreased appetite • Skin rash • Pruritus

<p>Common (may affect up to 1 in 10 people)</p>	<ul style="list-style-type: none"> • Decrease in white blood cells with fever • Decrease in whole blood cells • Severe inflammation of lung • Increase in liver enzymes • Inflammation of liver • Diarrhoea • Stomach pain • Inflammation in the mouth • Underactive thyroid gland that can cause tiredness or weight gain • Overactive thyroid gland that can cause increase in heart rate or weight loss • Inflammation or infection of thyroid gland • Decrease in adrenal gland secretions – lethargy, low BP, salt imbalance • Blood creatinine increased • Painful urination • Rash and itchiness • Skin inflammation • Fever • Swollen hands or legs • Upper respiratory tract infection • Pneumonia • Dental and oral infections • Muscle pain 	<ul style="list-style-type: none"> • Severe inflammation of lung • Hoarseness of voice • Overactive thyroid gland that can cause increase in heart rate or weight loss • Blood creatinine increased • Painful urination • Swollen hands or legs • Pneumonia • Muscle pain • Infusion related reactions • Fever • Decrease in adrenal gland secretions – lethargy, low BP, salt imbalance • Abdominal pain • Inflammation in the mouth • Inflammation of liver • Upper respiratory tract infection • Skin inflammation 	<ul style="list-style-type: none"> • Decrease in white blood cells with fever • Ringing in the ears • Underactive thyroid gland that can cause tiredness or weight gain • Overactive thyroid gland that can cause increase in heart rate or weight loss • Decrease in adrenal gland secretions – lethargy, low BP, salt imbalance • Inflammation in the mouth • Amylase increased • Swollen hands or legs • Chills • Swelling • Malaise • Blood bilirubin increase • Increase in liver enzyme (gamma-glutamyltransferase) • Inflammation of liver • Upper respiratory tract infections • Pneumonia • Bacteria entering the blood stream • Oral infection • Infusion related reaction • Decreased electrolytes (calcium, magnesium,
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	<ul style="list-style-type: none"> • Infusion related reactions 		<p>sodium, phosphate, potassium)</p> <ul style="list-style-type: none"> • Dehydration • Back Pain • Muscle pain • Muscle Spasms • Headache • Numbness and pain in hands and legs • Insomnia • Acute Kidney Injury • Blood creatinine increased • Painful urination • Cough/ Productive cough • Shortness of breath • Blockage of blood vessel in lung • Hiccups • Hair loss • Skin inflammation • Low blood pressure
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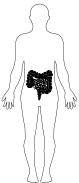


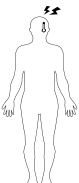


Frequency	Endometrial Cancer	uHCC
Very common (may affect more than 1 in 10 people)	<ul style="list-style-type: none"> • Decrease in red blood cells – early tiredness or difficulty in breathing • Decrease in white blood cells – susceptibility to infection • Decrease in platelets – easy bruising • Underactive thyroid gland that can cause tiredness or weight gain • Nausea • Constipation • Diarrhoea • Vomiting • Stomach pain • Inflammation in the mouth • Fatigue • Swollen hands and legs • Fever • Increase in liver enzymes (aspartate aminotransferase, alanine aminotransferase) • Upper respiratory tract infection • Decreased appetite • Muscle pain • Neuropathy peripheral • Dizziness • Headache • Altered sense of taste • Blood creatinine increased • Cough/ productive cough • Shortness of breath • Hair loss • Skin rash 	<ul style="list-style-type: none"> • Underactive thyroid gland that can cause tiredness or weight gain • Stomach pain • Diarrhoea • Abnormal pancreas test • Swollen hands and legs • Fever • Increase in liver enzymes • Cough • Itchiness • Skin rash

	<ul style="list-style-type: none"> • Pruritis 	
Common (may affect up to 1 in 10 people)	<ul style="list-style-type: none"> • Decrease in white blood cells with fever • Disorder in which the bone marrow does not make enough red blood cells • Hypersensitivity • Blood clots in veins • Overactive thyroid gland that can cause increase in heart rate or weight loss • Indigestion • Inflammation or infection of thyroid gland • Pneumonia • Fungal infection in mouth • Dental and oral soft tissue infections • Infusion related reactions • Painful urination • Severe inflammation of lung • Hoarseness of voice • Skin inflammation 	<ul style="list-style-type: none"> • Decrease in adrenal gland secretions – lethargy, low BP, salt imbalance • Overactive thyroid gland that can cause increase in heart rate or weight loss • Inflammation or infection of thyroid gland • Amylase increased • Inflammation of the lining of the colon • Lipase increased • Inflammation of the pancreas • Inflammation of the liver • Dental and oral infections • Flu • Pneumonia • Upper respiratory tract infections • Infusion-related reaction • Muscle pain • Blood creatinine increased • Painful urination • Severe inflammation of lung • Skin inflammation • Skin rash and itchiness • Night sweats

IMPORTANT SIGNS AND SYMPTOMS TO LOOK OUT FOR

Look out for the following signs and symptoms so they may be caught and managed early.
Call or see your doctor as soon as it is possible if you develop any of the following signs and symptoms or if they get worse.
Do not attempt to treat any of the symptoms without talking to your doctor first.

INFLAMMATION OF LUNGS		HORMONE GLAND PROBLEMS (ESPECIALLY THE THYROID, ADRENALS, PITUITARY AND PANCREAS)		INFLAMMATION OF KIDNEYS	
	<ul style="list-style-type: none">• New or worsening cough• Shortness of breath• Chest pain		<ul style="list-style-type: none">• Fast heart rate• Extreme tiredness• Weight gain or weight loss• Dizziness or fainting• Feeling more hungry or thirsty than usual• Headaches that will not go away or unusual headaches• Hair loss• Feeling cold• Constipation• Changes in mood or behaviour, such as decreased sex drive, irritability or forgetfulness• High blood sugar• Passing urine more often than usual• Fast and deep breathing• Confusion• A sweet smell to your breath• A sweet or metallic taste in your mouth• A different odour to your urine or sweat		<ul style="list-style-type: none">• Producing less urine than normal• Blood in urine• Swollen hands or legs• Painful urination
INFLAMMATION OF LIVER				SKIN PROBLEMS (RASH or DERMATITIS)	
	<ul style="list-style-type: none">• Yellowing of your skin or the whites of your eyes• Severe nausea or vomiting• Pain on the right side of your stomach• Drowsiness• Dark urine (tea coloured)• Bleeding or bruising more easily than usual• Feeling less hungry than usual				<ul style="list-style-type: none">• Rash• Itching• Skin blistering• Ulcers in mouth or other mucous membrane• Easy bruising

INFLAMMATION OF INTESTINE		INFLAMMATION OF HEART		INFLAMMATION OF MUSCLES	
	<ul style="list-style-type: none"> • Diarrhoea • More bowel movements than usual • Stools that are black, tarry, sticky, or have blood or mucus • Severe stomach pain or tenderness 		<ul style="list-style-type: none"> • Shortness of breath during exercise or exertion • Tiredness • Heart palpitations • Chest pain 		<ul style="list-style-type: none"> • Muscle pain or stiffness
OTHER SYMPTOMS		INFUSION-RELATED REACTIONS		INFLAMMATION OF BRAIN	
	<ul style="list-style-type: none"> • Neck stiffness • Fever • Confusion • Changes in mood or behaviour • Blurry or double vision • Eye pain or redness • Other vision problems • Hoarseness of voice • Night sweats • Dental infection 		<ul style="list-style-type: none"> • Chills or shaking • Itching or rash • Flushing • Shortness of breath or wheezing • Dizziness • Fever 		<ul style="list-style-type: none"> • Seizures • Headache • Fever • Chills • Vomiting • Confusion • Sleepiness

5. ADDITIONAL SAFETY INFORMATION

- If you get any side effects, talk to your doctor.
- 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 delay or completely stop treatment with IMFINZI if you have severe side effects.
- If you visit the emergency room or doctor who is not your regular care team, it is important to tell them that you are getting an immunotherapy.

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