

MEDICATION GUIDE

IMFINZI® (im-FIN-zee)
(durvalumab)
injection

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

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.

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
- increase 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

• 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, 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.
- 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.

What is IMFINZI?

IMFINZI is a prescription medicine used to treat adults with:

- **a type of lung cancer called non-small cell lung cancer (NSCLC).**
 - IMFINZI may be used in combination with chemotherapy that contains platinum prior to surgery and alone after surgery when your NSCLC:
 - can be removed by surgery, **and**
 - is not known to have an abnormal “EGFR” or “ALK” gene.
 - IMFINZI may be used alone when your NSCLC:
 - has not spread outside your chest
 - cannot be removed by surgery, **and**
 - has responded or stabilized with initial treatment with chemotherapy that contains platinum, given at the same time as radiation therapy.
 - IMFINZI may be used in combination with tremelimumab-actl and chemotherapy that contains platinum when your NSCLC:
 - has spread to other parts of your body (metastatic), **and**
 - does not have an abnormal “EGFR” or “ALK” gene.
- **a type of lung cancer called small cell lung cancer (SCLC).**
 - for limited-stage small cell lung cancer (LS-SCLC), IMFINZI may be used alone when your LS-SCLC cannot be removed by surgery, **and**
 - has responded or stabilized after initial treatment with chemotherapy that contains platinum, given at the same time as radiation therapy.
 - for extensive-stage small cell lung cancer (ES-SCLC), IMFINZI may be used with the chemotherapy medicines etoposide and either carboplatin or cisplatin as your first treatment when your ES-SCLC has spread within your lungs or to other parts of the body.
- **a type of cancer called biliary tract cancer (BTC),** including cancer of the bile ducts (cholangiocarcinoma) and gallbladder cancer. IMFINZI may be used in combination with chemotherapy medicines gemcitabine and cisplatin when your BTC:
 - has spread to nearby tissues (locally advanced), or
 - has spread to other parts of the body (metastatic).
- **a type of liver cancer that cannot be removed by surgery (unresectable hepatocellular carcinoma or uHCC).** IMFINZI is used in combination with tremelimumab-actl to treat uHCC.
- **a type of uterine cancer called endometrial cancer.** IMFINZI may be used in combination with chemotherapy medicines carboplatin and paclitaxel followed by IMFINZI alone when your endometrial cancer:
 - has spread (advanced) or has come back (recurrent), **and**
 - a laboratory test shows that your tumor is mismatch repair deficient (dMMR).
- **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.** IMFINZI may be used in combination with gemcitabine and cisplatin (neoadjuvant treatment) prior to the surgical removal of your bladder followed by IMFINZI alone after surgery (adjuvant treatment).
- **a type of stomach cancer called gastric cancer (GC) or gastro-esophageal junction adenocarcinoma (GEJC) that can be removed by surgery.** IMFINZI is used in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) prior to and after surgery followed by IMFINZI alone.

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

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.

How will I receive IMFINZI?

- Your healthcare provider will give you IMFINZI into your vein through an intravenous (IV) line over 60 minutes.
- IMFINZI is usually given every 2, 3 or 4 weeks.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will test your blood to check you for certain side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of IMFINZI?

IMFINZI can cause serious side effects, including:

See "What is the most important information I should know about IMFINZI?"**The most common side effects of IMFINZI when used with platinum-containing chemotherapy in adults with NSCLC that can be removed by surgery include:**

- | | |
|--------------------------------|-----------------------|
| • low red blood cells (anemia) | • feeling tired |
| • nausea | • muscle or bone pain |
| • constipation | • rash |

The most common side effects of IMFINZI when used alone in adults with NSCLC that cannot be removed by surgery include:

- | | |
|-----------------------------|--------------------------------------|
| • cough | • upper respiratory tract infections |
| • feeling tired | • shortness of breath |
| • inflammation in the lungs | • rash |

The most common side effects of IMFINZI when used with tremelimumab-actl and platinum-containing chemotherapy in adults with metastatic NSCLC include:

- | | |
|-------------------------|----------------------|
| • nausea | • decreased appetite |
| • feeling tired or weak | • rash |
| • muscle or bone pain | • diarrhea |

The most common side effects of IMFINZI when used alone in adults with LS-SCLC include:

- | | |
|-----------------------------|-------------------------|
| • inflammation in the lungs | • feeling tired or weak |
|-----------------------------|-------------------------|

The most common side effects of IMFINZI when used with etoposide and either carboplatin or cisplatin in adults with ES-SCLC include:

- nausea
- feeling tired or weak
- hair loss

The most common side effects of IMFINZI when used with gemcitabine and cisplatin in adults with BTC include:

- feeling tired
- nausea
- constipation
- decreased appetite
- stomach (abdominal) pain
- rash
- fever

The most common side effects of IMFINZI when used with tremelimumab-actl in adults with uHCC include:

- rash
- diarrhea
- feeling tired
- itchiness
- muscle or bone pain
- stomach (abdominal) pain

The most common side effects of IMFINZI when used with carboplatin and paclitaxel in adults with endometrial cancer include:

- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs
- muscle or bone pain
- nausea
- hair loss
- feeling tired
- stomach (abdominal) pain
- constipation
- rash
- decreased level of magnesium in the blood
- increased liver function tests
- diarrhea
- vomiting
- cough
- decreased level of potassium in the blood
- shortness of breath
- headache
- increased level of alkaline phosphatase in the blood

The most common side effects of IMFINZI when used with gemcitabine and cisplatin in adults with 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
- stomach (abdominal) pain

The most common side effects of IMFINZI when used with FLOT in adults with GC or GEJC 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 of 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 to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMFINZI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about IMFINZI, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about IMFINZI that is written for health professionals.

What are the ingredients in IMFINZI?**Active ingredient:** durvalumab**Inactive ingredients:** L-histidine, L-histidine hydrochloride monohydrate, α,α -trehalose dihydrate, polysorbate 80, Water for Injection, USP.

Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

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For more information, call 1-800-236-9933 or go to www.IMFINZI.com

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