

**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 a type of cancer in the bladder and urinary tract or certain types of lung cancer by working with your immune system.

IMFINZI can cause your 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.

**Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse:**

**Lung problems (pneumonitis).** Signs and symptoms of pneumonitis may include:

- new or worsening cough
- shortness of breath
- chest pain

**Liver problems (hepatitis).** Signs and symptoms of hepatitis may include:

- yellowing of your skin or the whites of your eyes
- dark urine (tea colored)
- severe nausea or vomiting
- bleeding or bruising more easily than normal
- pain on the right side of your stomach area (abdomen)
- feeling less hungry than usual
- drowsiness

**Intestinal problems (colitis).** Signs and symptoms of colitis may include:

- diarrhea or more bowel movements than usual
- severe stomach area (abdomen) pain or tenderness
- stools that are black, tarry, sticky, or have blood or mucus

**Hormone gland problems (especially the thyroid, adrenals, pituitary, and pancreas).** Signs and symptoms that your hormone glands are not working properly may include:

- headaches that will not go away or unusual headaches
- feeling cold
- extreme tiredness
- constipation
- weight gain or weight loss
- your voice gets deeper
- dizziness or fainting
- urinating more often than usual
- feeling more hungry or thirsty than usual
- nausea or vomiting
- hair loss
- stomach area (abdomen) pain
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

**Kidney problems, including nephritis and kidney failure.** Signs of kidney problems may include:

- decrease in the amount of urine
- swelling of your ankles
- blood in your urine
- loss of appetite

**Skin problems.** Signs of these problems may include:

- rash
- skin blistering
- itching

**Problems in other organs.** Signs and symptoms may include:

- neck stiffness
- headache
- confusion
- fever
- chest pain, shortness of breath, or irregular heartbeat (myocarditis)
- severe or persistent muscle pain
- severe muscle weakness
- changes in mood or behavior
- low red blood cells (anemia)
- excessive bleeding or bruising
- blurry vision, double vision, or other vision problem
- eye pain or redness

**Severe Infections.** Signs and symptoms may include:

- fever
- cough
- frequent urination
- pain when urinating
- flu-like symptoms

**Severe infusion reactions.** Signs and symptoms of severe infusion reactions may include:

- chills or shaking
- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- fever
- feel like passing out
- back or neck pain
- facial swelling

**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 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 cancer in the bladder and urinary tract called urothelial carcinoma. IMFINZI may be used when your urothelial carcinoma:
  - has spread or cannot be removed by surgery, **and**
  - you have tried chemotherapy that contains platinum, and it did not work or is no longer working.
- a type of lung cancer called non-small cell lung cancer (NSCLC). IMFINZI may be used 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.
- **a type of lung cancer called small cell lung cancer (SCLC). IMFINZI may be used with the chemotherapy medicines etoposide and carboplatin or cisplatin as your first treatment when your SCLC:**
  - has spread within your lungs or to other parts of the body, (extensive-stage small cell lung cancer, or ES-SCLC).

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 had an organ transplant.
- have lung or breathing problems.
- have liver problems.
- are being treated for an infection.
- are pregnant or plan to become pregnant. IMFINZI can harm your unborn baby. If you are able to become pregnant, you should use an effective method of birth control during your treatment and for at least 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 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 at least 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 in people with urothelial carcinoma include:

- feeling tired
- muscle or bone pain
- constipation
- decreased appetite
- nausea
- swelling of your arms and legs
- urinary tract infection

The most common side effects of IMFINZI in people with NSCLC include:

- cough
- feeling tired
- inflammation in the lungs (pneumonitis)
- upper respiratory tract infections
- shortness of breath
- rash

The most common side effects of IMFINZI when used with other anticancer medicines in people with ES-SCLC include:

- nausea
- hair loss
- feeling tired or weak

Tell your doctor 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 healthcare provider 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 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,  $\alpha,\alpha$ -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](http://www.IMFINZI.com)

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