IMFINZI® (durvalumab) **Patient Alert Card**

I AM RECEIVING IMMUNOTHERAPY

Fill out the information inside and carry this card with you at all times to share with healthcare professionals (including your GP, Accident and Emergency team or other specialist doctor).

INFORMATION FOR PATIENTS

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. You can let your doctor know about any side effects you may experience and the doctor can report them via https://pophealth.my.site.com/carmreportnz/s/

IMPORTANT: Notify your oncologist/Cancer Care Team as soon as possible if you notice any change in your wellbeing or health that is different or worse than before you started your treatment with IMFINZI.

- Alerting your oncologist/Cancer Care Team early means they can start managing your side effects sooner, which may prevent these side effects from becoming more serious.
- Do not attempt to treat side effects yourself.

IMFINZI® durvalumab

AstraZeneca

References: 1. IMFINZI® Consumer Medicine Information. **2.** IMFINZI® Data Sheet. **3.** Champiat S, et al. *Ann Oncol* 2016;559-574. IMFINZI® is a registered trademark of the AstraZeneca group of companies. Registered user AstraZeneca Limited, PO Box 87453, Meadowbank, Auckland 1742. For Medical Information enquiries or to report an adverse event or product quality complaint: Telephone 0800 684 432 or (09) 306 5650 or via https://contactazmedical.astrazeneca.com

NZ-2283. TAPS MR10298. IMFS0127/EMBC. Date of preparation: May 2024.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Signs and symptoms of some side effects that require urgent medical attention[1]

INFLAMMATION OF THE LUNGS (pneumonitis)

- New or worsening cough
- Shortness of breath
- Chest pain

LUNG INFECTION (pneumonia, influenza)

- Coughing of phlegm
- Fever
- Chills
- Difficulty breathing

INFLAMMATION OF THE LIVER (hepatitis)

- Yellowing of your skin or the whites of your eyes
- Nausea or vomiting
- Pain on the right side of stomach
- Feeling less hungry
- Drowsiness
- Dark urine
- Bleeding or bruising more easily than normal

HORMONE GLAND PROBLEMS (especially the thyroid, adrenals and pituitary)

- Headaches that will not go away or unusual headaches
- Extreme tiredness
- Weight gain or weight loss
- Dizziness or fainting
- Feeling more hungry or thirsty than usual
- Hair loss
- Feeling cold
- Constipation
- Changes in your voice
- Urinating more often than usual
- Nausea or vomiting
- Stomach area (abdomen) pain
- Changes in mood or behaviour, such as decreased sex drive, increased anxiety, irritability or forgetfulness
- Fast and deep breathing, confusion, or a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat

INFUSION RELATED REACTIONS

- Chills or shaking
- Itching or rash
- Flushing
- Shortness of breath or wheezing
- Dizziness
- Fever
- Feeling like passing out
- Back or neck pain
- Facial swelling

INFLAMMATION OF THE INTESTINES (colitis)

- Diarrhoea
- More bowel movements than usual
- Black, tarry, sticky stools
- Stools with blood or mucus
- Severe stomach pain or tenderness

INFLAMMATION OF THE KIDNEYS (nephritis)

- Changes in the amount or colour of your urine
- Swelling in your ankles
- Loss of appetite

INFLAMMATION OF THE SKIN

- Rash
- Itching
- Skin blistering

INFLAMMATION OF THE HEART (myocarditis)

- Chest pain
- Shortness of breath
- Irregular heartbeat

INFLAMMATION OR PROBLEMS OF THE MUSCLES

- Muscle weakness
- Tiredness and/or pain
- Rapid fatigue of the muscles, in one or more areas of your body

INFLAMMATION OF THE SPINAL CORD

- Pain, numbness, tingling, or weakness in arms or legs
- Bladder/bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation

INFLAMMATION OF THE EYES (uveitis)

- Eye redness
- Eye pain
- Light sensitivity
- Changes in vision

INFLAMMATION OF THE BRAIN OR MEMBRANES AROUND THE BRAIN/SPINAL CORD (encephalitis/meningitis)

- Seizures
- Neck stiffness
- Headache
- Fever
- Chills
- Vomiting
- Eye sensitivity to light
- Confusion
- Sleepiness

IMFINZI side effects may be different from those experienced with previous treatments. These side effects can sometimes be serious or life threatening, so it is important to be aware of them.

Your details

My name: _____

Date of birth: ____/____/_____ (DD/MM/YYYY)

Next of kin/contact details: _____

I started my IMFINZI treatment on: ____/____/_____ (DD/MM/YYYY)

Blood type: _____

Cancer type: _____

Other medications: _____

Known allergies: _____

Any other notes: _____

Oncologist contact information

My Oncologist: _____

Oncologist's contact No: _____

Oncologist's out of hours clinic contact: _____

What's normal for me?

To help you notice any changes, use the space below to **write down what's normal for you before starting IMFINZI.**

Bowel movements

I usually have: _____ bowel movements per day

Shortness of breath

My breathing usually disrupts my daily activities:

A little ○○○○○ A lot

Tiredness

I usually sleep: _____ hours a day

Pain

On a scale of 1–10 my pain is usually: _____ (where 10=severe)

My pain usually lasts: _____ hours

I would normally describe my pain as: _____

Other signs of side effects related to my cancer or previous treatment

Side effects I usually experience:*

_____

_____

*Remember, you may experience some side effects prior to starting treatment with IMFINZI. These may be related to your cancer or previous treatment you received.

INFORMATION FOR HEALTHCARE PROFESSIONALS

Managing immune-mediated adverse reactions (imARs) associated with IMFINZI (durvalumab)[2]

The information on this page is for healthcare professionals only

- Treatment with IMFINZI can cause imARs.[2,3]
- Suspected imARs must be promptly investigated to confirm or exclude alternative causes.[2,3]
- Onset of imARs can occur up to several months after the last dose of IMFINZI.[2,3]
- IMFINZI treatment may be withheld or discontinued based on the severity of the imAR. This will be managed by the patient's oncologist/Cancer Care Team.[2,3]
- Contact the patient's oncologist/Cancer Care Team (details overleaf) as soon as possible after the patient presents, preferably before you initiate treatment for management of their imAR(s).
- If you are unable to contact the patient's oncologist/Cancer Care Team, **do not** delay treatment initiation – early diagnosis and management is essential to minimise serious consequences.[2,3]
- Corticosteroid treatment, endocrine therapy, or immunosuppressive agents may be prescribed by a healthcare professional to treat imARs in a patient receiving IMFINZI. Please refer to the treatment guidance adjacent and the IMFINZI Data Sheet.[2,3]
- Tell the oncologist/Cancer Care Team as soon as possible about any treatment you initiate, and discuss any further treatment/modifications the patient may require urgently to manage their imAR(s).
- Remind the patient to contact their oncologist/Cancer Care Team to seek further advice and or treatment follow up.

No dose reduction or escalation for IMFINZI is recommended. In general, withhold IMFINZI for severe (Grade 3) imARs. Permanently discontinue IMFINZI for life-threatening (Grade 4) imARs, recurrent severe (Grade 3) imARs that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids. For non-imARs, withhold IMFINZI for Grade 2 and 3 ARs until ≤Grade 1 or baseline. IMFINZI should be discontinued for Grade 4 ARs (with the exception of Grade 4 laboratory abnormalities, about which the decision to discontinue should be based on accompanying clinical signs/symptoms and clinical judgment).[2]

IMMUNE-MEDIATED ADVERSE REACTIONS	SEVERITY[a]	IMFINZI TREATMENT MODIFICATION	ADDITIONAL MANAGEMENT ADVICE
Pneumonitis/interstitial lung disease	Grade 2	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	Grade 3 or 4	Permanently discontinue	Initiate 2-4 mg/kg/day methylprednisolone or equivalent (or in accordance with local imAR management guidelines where these differ) followed by taper
Hepatitis	ALT or AST >3-≤5 x ULN or total bilirubin >1.5-≤3 x ULN	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	ALT or AST >5-≤ 10 x ULN	Withhold dose	
	ALT or AST >10 x ULN or total bilirubin x 3 ULN	Permanently discontinue	
	Concurrent ALT or AST >3 x ULN and total bilirubin >2 x ULN[b]		
Hepatitis with tumour involvement of the liver with abnormal baseline values[c]	ALT or AST >2.5-≤5 x BLV and ≤20 x ULN	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	ALT or AST >5-7 x BLV and ≤20 x ULN or concurrent ALT or AST 2.5-5 x BLV and ≤20 x ULN and total bilirubin >1.5-<2 x ULN[b]	Withhold dose	
	AST or ALT >7 x BLV or >20 x ULN whichever occurs first or bilirubin >3 x ULN	Permanently discontinue	
Colitis or diarrhoea	Grade 2 or 3	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	Grade 4	Permanently discontinue	
	Intestinal perforation of ANY grade	Permanently discontinue	Consult a surgeon immediately if intestinal perforation of ANY grade is suspected
Endocrinopathies: hyperthyroidism, thyroiditis	Grade 2-4	Withhold dose until clinically stable	Symptomatic management
Endocrinopathies: hypothyroidism	Grade 2-4	No changes	Initiate thyroid hormone replacement as clinically indicated.
Endocrinopathies: adrenal insufficiency, hypophysitis/hypopituitarism	Grade 2-4	Withhold dose until clinically stable	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper and hormone replacement as clinically indicated
Endocrinopathies: Type 1 diabetes mellitus	Grade 2-4	No changes	Insulin can be initiated as clinically indicated
Nephritis	Grade 2 with serum creatinine > 1.5-3 x (ULN or baseline)	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	Grade 3 with serum creatinine > 3 x baseline or > 3-6 x ULN; Grade 4 with serum creatinine > 6 x ULN	Permanently discontinue	
Rash or dermatitis (including pemphigoid)	Grade 2 for > 1 week or Grade 3	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	Grade 4	Permanently discontinue	
Myocarditis	Grade 2-4	Permanently discontinue	Initiate 2-4 mg/kg/day prednisone or equivalent followed by taper[d]
Myositis/polymyositis / rhabdomyolysis	Grade 2 or 3	Withhold dose[e]	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	Grade 4	Permanently discontinue	
Infusion-related reactions	Grade 1 or 2	Interrupt or slow the rate of infusion	Consider pre-medications for prophylaxis of subsequent infusion reactions
	Grade 3 or 4	Permanently discontinue	Manage severe infusion-related reactions per institutional standard, appropriate clinical practice guidelines and/or society guidelines
Infection	Grade 3 or 4	Withhold dose until clinically stable	
Myasthenia gravis	Grade 2-4	Permanently discontinue	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
Encephalitis	Grade 2-4	Permanently discontinue	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
Guillain-Barré syndrome	Grade 2-4	Permanently discontinue	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
Other immune-mediated adverse reactions[f]	Grade 2 or 3	Withhold dose	Initiate 1-2 mg/kg/day prednisone or equivalent followed by taper
	Grade 4	Permanently discontinue	

ALT: alanine aminotransferase; AR: adverse reaction; AST: aspartate aminotransferase; BLV: baseline value; imAR: immune-mediated adverse reaction; ULN: upper limit of normal. [a]Common Terminology Criteria for Adverse Events, version 4.03. [b]For patients with alternative cause follow the recommendations for AST or ALT increases without concurrent bilirubin elevations. [c]If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement. [d]If no improvement within 2-3 days despite corticosteroids, promptly start additional immunosuppressive therapy. Upon resolution (Grade 0), corticosteroid taper should be initiated and continued over at least 1 month. [e]Permanently discontinue IMFINZI if adverse event does not resolve to ≤Grade 1 within 30 days or if there are signs of respiratory insufficiency. [f]Includes immune thrombocytopenia, pancreatitis, immune-mediated arthritis, and uveitis.