This checklist is intended for use by healthcare professionals, prior to starting treatment and during follow-up visits, to identify and monitor patient signs and symptoms associated with adverse reactions related to KEYTRUDA® (pembrolizumab) treatment.

"Early identification of adverse reactions and treatment interventions are important in the general safe use of KEYTRUDA®."

KEYTRUDA® (pembrolizumab) is indicated for:

- Treatment of adult patients with unresectable or metastatic melanoma who have not received prior treatment with ipilimumab. Subjects with BRAF V600 mutant melanoma may have received prior BRAF inhibitor therapy.

- Treatment of adult patients with unresectable or metastatic melanoma and disease progression following ipilimumab therapy and, if BRAF V600 mutation positive, following a BRAF or MEK inhibitor.

- First-line treatment, as monotherapy, of adult patients with metastatic NSCLC or stage III disease where patients are not candidates for surgical resection of definitive chemoradiation, expressing PD-L1 (Tumour Proportion Score [TPS] ≥1%) as determined by a validated test, with no EGFR or ALK genomic tumour aberrations. A positive association was observed between the level of PD-L1 expression and the magnitude of the treatment benefit.

- Treatment of adult patients with metastatic NSCLC as monotherapy, in adults whose tumours express PD-L1 (TPS ≥1%) as determined by a validated test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received authorized therapy for these aberrations prior to receiving KEYTRUDA®.

**Patient name:**  
**Date:**

<table>
<thead>
<tr>
<th>First visit (prior to starting treatment)</th>
<th>Follow-up visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of current medications:†</td>
<td>Have you had a change in your medications?‡</td>
</tr>
</tbody>
</table>

† Includes prescription and nonprescription (natural or herbal) products.
‡ For example, have you stopped taking or started taking any new medications, increased dosage or frequency?

ALK=anaplastic lymphoma kinase; EGFR=epidermal growth factor receptor; NSCLC=non-small cell lung carcinoma; PD-L1=programmed cell death ligand 1
Patient name:  
Date:  

<table>
<thead>
<tr>
<th>First visit (prior to starting treatment)</th>
<th>Follow-up visit</th>
</tr>
</thead>
</table>

When a patient indicates **YES**, it may be helpful to record the **severity of the symptom**: a 1-to-10 scale describing the level of distress a specific adverse reaction is causing.

**SEVERITY OF SYMPTOMS**  
**NOTES**

### LUNG PROBLEMS (pneumonitis)

**Have you experienced:**
- Shortness of breath?  
  - Y  
  - N  
- Chest pain?  
  - Y  
  - N  
- Coughing?  
  - Y  
  - N  
- ✷ Is it new?  
  - Y  
  - N  
- ✷ Has it gotten worse?  
  - Y  
  - N

### INTESTINAL PROBLEMS (colitis)

**Do you have:**
- Diarrhea or more bowel movements than usual?  
  - Y  
  - N  
- Stools that are black, tarry or sticky?  
  - Y  
  - N  
- Stools that have blood or mucus?  
  - Y  
  - N  
- Severe stomach pain or tenderness?  
  - Y  
  - N  
- Nausea or vomiting?  
  - Y  
  - N

### HORMONE GLAND PROBLEMS (thyroid, pituitary, adrenal and pancreas)

**Have you had:**
- Weight gain?  
  - Y  
  - N  
- Weight loss?  
  - Y  
  - N  
- Increased sweating?  
  - Y  
  - N  
- Hair loss?  
  - Y  
  - N  
- Constipation?  
  - Y  
  - N  
- Dizziness?  
  - Y  
  - N  
- Fainting?  
  - Y  
  - N  
- Headaches?  
  - Y  
  - N  
- ✷ That will not go away?  
  - Y  
  - N  
- ✷ That are unusual?  
  - Y  
  - N

**Have you experienced:**
- Rapid heartbeat?  
  - Y  
  - N  
- Your voice getting deeper?  
  - Y  
  - N  
- Feeling cold?  
  - Y  
  - N

### SKIN PROBLEMS

**Have you had:**
- A rash?  
  - Y  
  - N  
- Itching?  
  - Y  
  - N  
- Blisters, peeling or skin sores?  
  - Y  
  - N  
- Sores or ulcers in your mouth, nose, throat or genital area?  
  - Y  
  - N

### LIVER PROBLEMS (hepatitis)

**Have you noticed:**
- Nausea or vomiting?  
  - Y  
  - N  
- Yellowing of your skin or the whites of your eyes?  
  - Y  
  - N  
- Pain on the right side of your stomach?  
  - Y  
  - N  
- Feeling less hungry than usual?  
  - Y  
  - N  
- Bleeding or bruising more easily than normal?  
  - Y  
  - N  
- Is your urine dark?  
  - Y  
  - N
### KIDNEY PROBLEMS (including nephritis and kidney failure)

<table>
<thead>
<tr>
<th>Have you noticed a change:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>– In the amount you urinate?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– In the colour of your urine?</td>
<td>Y □ N □</td>
</tr>
</tbody>
</table>

### PROBLEMS IN OTHER ORGANS

<table>
<thead>
<tr>
<th>Have you experienced:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>– Changes in your eyesight?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Severe or persistent muscle or joint pain?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Muscle weakness?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Irregular heartbeat?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Feeling tired?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Chest pain (myocarditis)</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Confusion?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Fever?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Memory problems?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Seizures (encephalitis)?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Swollen lymph nodes?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Tender lumps on skin?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Stomach/abdominal pain?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Nausea or vomiting?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Eye pain (sarcoidosis)?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Pain, numbness, tingling, or weakness in arms or legs (myelitis)?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Frequent urination, urinary incontinence or difficulty urinating (myelitis)?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Constipation (myelitis)?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>Have blood tests revealed low red blood cells (anemia)?</td>
<td>Y □ N □</td>
</tr>
</tbody>
</table>

### BLOOD SUGAR PROBLEMS (type 1 diabetes mellitus)

<table>
<thead>
<tr>
<th>Do you feel:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>– Hungrier than usual?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Thirstier than normal?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>Have you noticed:</td>
<td></td>
</tr>
<tr>
<td>– An increase in urination?</td>
<td>Y □ N □</td>
</tr>
<tr>
<td>– Any weight loss?</td>
<td>Y □ N □</td>
</tr>
</tbody>
</table>

### Monitoring and laboratory tests

| Liver function                                 | Y □ N □ |
| Thyroid function                               | Y □ N □ |
| Serum electrolytes                              | Y □ N □ |
| Hyperglycemia or other diabetes symptoms        | Y □ N □ |

### INFUSION REACTIONS

While receiving KEYTRUDA® treatment and/or shortly after infusions, have you experienced:

| – Chills?                                       | Y □ N □ |
| – Shortness of breath or wheezing?              | Y □ N □ |
| – Itching or rash?                              | Y □ N □ |
| – Flushing?                                     | Y □ N □ |
| – Dizziness?                                    | Y □ N □ |
| – Fever?                                        | Y □ N □ |
| – Feeling like passing out?                     | Y □ N □ |

### OTHER

| Are you experiencing any other side effects that were not discussed here? | Y □ N □ |

Please note: This is not an exhaustive list of all potential side effects.
Consult the product monograph at www.merck.ca/static/pdf/KEYTRUDA-PM_E.pdf for important information about:

- Relevant warnings and precautions regarding: immune-mediated adverse reactions, severe infusion-related reactions, embryofetal toxicity, pregnant and nursing women, pediatric patients, patients with moderate or severe hepatic impairment and patients with severe renal impairment. Monitor liver, thyroid function and electrolytes during treatment.

- Conditions of clinical use, adverse reactions, drug interactions and dosing instruction.

The product monograph is also available by calling us at 1-800-567-2594 or by email at medinfocanada@merck.com.

Should you have any questions regarding KEYTRUDA® therapy, please contact our Medical Information Centre at 1-800-567-2594.


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