### Incidence of Most Frequent Side Effects

| Side Effect | N=511 | N=471 | N=389 | Percent of Patients/Receiving/Use
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<tbody>
<tr>
<td>Abdominal Area</td>
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| Diarrhea | 29 | 26 | 24 | 26%
| Vomiting | 12 | 11 | 11 | 12%
| Abdominal Pain | 26 | 24 | 22 | 24%
| Constipation | 14 | 12 | 11 | 12%
| Nausea | 12 | 11 | 10 | 10%
| Headache | 11 | 10 | 9 | 9%
| Upper Respiratory Infection | 7 | 6 | 6 | 6%
| Urinary Incontinence | 6 | 5 | 5 | 5%
| Gastroesophageal Reflux Disease | 4 | 4 | 4 | 4%
| Acne | 3 | 3 | 3 | 3%
| Fatigue | 2 | 2 | 2 | 2%
| Skin Rash | | | | |
| Rash | 2 | 2 | 2 | 2%
| Insomnia | | | | |
| Sleep Disorder | 1 | 1 | 1 | 1%
| Anorexia | | | | |
| Anemia | | | | |
| Depression | | | | |
| Anxiety | | | | |
| Asthenia | | | | |
| Fever | | | | |
| Cardiovascular Disorders | | | | |
| Urinary Tract Infection | 2 | 2 | 2 | 2%
| UTI | | | | |
| Uterine Fibroids | | | | |
| Fallopian Tube Infection | | | | |
| Reproductive System Disorders | | | | |
| Body as a Whole | | | | |
| Headache | 22 | 21 | 18 | 21%
| Abnormal Vision | 16 | 15 | 13 | 15%
| Neck Pain | 12 | 11 | 10 | 10%
| Fatigue | 12 | 11 | 10 | 10%
| signs and symptoms of overexposure, especially during the initial screening and dose escalation phases of treatment, but also during the initial administration of bacillus calmette-guerin (bcg) directly after a period of immunotherapy.

### Side Effect Management

**Product Information:**

- **Warnings:**
  - Intraocular pressure or retinal detachment while on or recently after completion of therapy.
- **Precautions:**
  - See Instructions for use.
- **Contraindications:**
  - Myeloma, multiple myeloma, or lymphoma.
- **Cautions:**
  - Pregnancy.
- **Adverse Reactions:**
  - Blood dyscrasias, leukemia, lymphoma.
- **Overdosage:**
  - None known.
- **Dosage and Administration:**
  - 20 mg/dose, 3 times weekly for 3 months.
  - 40 mg/dose, 3 times weekly for 6 months.
- **Storage:**
  - Room temperature.
- **Disposal:**
  - None known.

### Instructions for Use

- **Product Description:**
  - Baclofen Injection (intrathecal) is indicated for the treatment of spasticity in adult patients with spinal cord injury (SCI) or multiple sclerosis (MS).
- **Contraindications:**
  - Patients with a history of allergy to baclofen or any component of the product.
- **Warnings:**
  - Headache.
- **Precautions:**
  - Heart failure.
- **Adverse Reactions:**
  - Fatigue, sleepiness, dizziness, nausea, vomiting, abdominal pain, fever.
- **Dosage and Administration:**
  - 15 mg/dose, 3 times weekly for 3 months.
- **Storage:**
  - Room temperature.
- **Disposal:**
  - None known.

### References

- Mylen Pharmaceuticals Inc.
- Mylen Pharmaceuticals, Inc.
- Data: N00000000000000000000
- OCTOBER 2021