MITOMYCIN FOR INJECTION

There is only one Canadian supplier of mitomycin for injection (see below). Although listed in the Drug Product Database, Hospira is not currently marketing its brand of mitomycin in Canada.

<table>
<thead>
<tr>
<th>DIN</th>
<th>Company</th>
<th>Product</th>
<th>Active Ingredient</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>02230450</td>
<td>TEVA CANADA LIMITED</td>
<td>MITOMYCIN FOR INJECTION</td>
<td>MITOMYCIN</td>
<td>5 MG / VIAL</td>
</tr>
<tr>
<td>02230451</td>
<td>TEVA CANADA LIMITED</td>
<td>MITOMYCIN FOR INJECTION</td>
<td>MITOMYCIN</td>
<td>20 MG / VIAL</td>
</tr>
</tbody>
</table>

**Labelled Indications**

Adjunct palliative treatment for adenocarcinoma of stomach and colon
Topical therapy for superficial carcinoma of the urinary bladder

**Off-label Indications**

Treatment of various cancers
Prevention of scarring in glaucoma surgery; prevention of corneal haze after refractive surgery
Topical treatment of tracheal stenosis

**Shortage management:**

**Extemporaneous preparation:** High risk product due to cytotoxicity.

- 0.5 mg/ml solutions prepared with Sterile Water for Injection are stable for 1 week at room temperature and 2 weeks refrigerated. Protect from light.
- When diluted to 20 to 40 mcg/ml, stable for 3 hours in D5W and 12 hours in Normal Saline at room temperature.
- As long as bulk chemical remains available, compounding pharmacies can prepare the injectable formulation.

**Therapeutic Alternatives:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Alternative</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer treatment</td>
<td>No single agent can be substituted for mitomycin</td>
<td>Choice of alternative must be patient-specific and based on renal function, liver function, and the neoplasm type and location.</td>
</tr>
<tr>
<td></td>
<td>If considering use of mitomycin in combination, ensure adequate supply of mitomycin on hand to complete treatment before starting; if not, select alternative protocol.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glaucoma surgery (trabeculectomy)</th>
<th>5-fluorouracil</th>
<th>Evaluate need for antifibrotic agent; reserve use for high risk patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bevacizumab</td>
<td></td>
</tr>
</tbody>
</table>

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Refractive surgery

Ophthalmic corticosteroids e.g. fluorometholone

Reserve mitomycin for high risk patients – severe myopia, deeper ablation

Tracheal stenosis

Benefit of mitomycin for this indication is questionable

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medSask, December, 2014

References: