Sulfasalazine Shortage

Suppliers of sulfasalazine tablets in Canada.¹

<table>
<thead>
<tr>
<th>DIN</th>
<th>Manufacturer</th>
<th>Brand name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Regular Release Tabs</td>
<td></td>
</tr>
<tr>
<td>00598461</td>
<td>Pharmascience</td>
<td>PMS-Sulfasalazine</td>
<td>500 mg</td>
</tr>
<tr>
<td>02064480</td>
<td>Pfizer</td>
<td>Salazopyrin</td>
<td>500 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delayed Release Tabs</td>
<td></td>
</tr>
<tr>
<td>00598488</td>
<td>Pharmascience</td>
<td>PMS-Sulfasalazine E.C.</td>
<td>500 mg</td>
</tr>
<tr>
<td>02064472</td>
<td>Pfizer</td>
<td>Salazopyrin EN-tabs</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

Indications for regular release tablets²:
- adjunctive therapy of severe ulcerative colitis, proctitis, distal ulcerative colitis, and Crohn’s disease

Indications for delayed release tablets²:
- active rheumatoid arthritis (RA)
- patients experiencing gastrointestinal adverse reactions from the regular tablets*

Sulfasalazine trials for RA used only delayed release tablets, thus regular release tablets are not indicated for RA.⁵ However, no data has been found to suggest sulfasalazine regular tablets would be ineffective for RA. Gastrointestinal adverse effects can be expected to increase when switching to regular release tablets.²,⁴

In the event Salazopyrin® regular tablets also become unavailable:
- Bulk sulfasalazine powder is available for compounding⁵
- Patients with acute or maintenance ulcerative colitis can be switched to⁴,⁶:
  o 5-ASA (mesalamine) – the active moiety of sulfasalazine; often better tolerated though more expensive⁶
  o Olsalazine – like sulfasalazine is converted to 5-ASA by colonic bacteria⁸
- Note: sulfasalazine is effective for acute therapy of mild Crohn’s Disease (CD);⁴,⁶ role of 5-ASA is controversial.⁶ Patients with mild acute CD may need to be switched to:
  o Oral budesonide (ileo and right colonic only) or prednisone⁴,⁶
- Appropriate treatment of patients with RA depends on previous history⁸,⁹:
  o Sometimes sulfasalazine is considered early in treatment; therefore, depending on history, DMARDS like hydroxychloroquine, leflunomide, or even methotrexate may be viable options.⁹
  o However, sulfasalazine is more typically added as a third DMARD; as such, a switch to biologics may need to be considered.⁸,⁹

*Not an official indication but information is included in the monograph.
References:

3. Phone communication with Pfizer Canada Medical Information, 1-800-463-6001. 3 Feb 2015
5. Phone communication with Medisca Customer Service, 1-800-665-6334. 18 Feb 2015
7. Product monograph for Dipentum. UCB Canada Inc. Oakville, ON L6H 5R7