Exempted Codeine Products – Information for the Consumer

A. What are Exempted Codeine Products?

Products which contain codeine and can be purchased without a prescription:

- Tablets: contain not more than 8mg of codeine phosphate per tablet
- Liquids: contain not more than 20mg of codeine phosphate per 30ml

These products must also contain two or three additional medical ingredients: many products contain acetaminophen or ASA and caffeine.

B. What are the regulations for purchasing Exempted Codeine Products?

**Size restriction**: maximum of fifty (50) dosage units in a solid dosage form (tablets, capsules) or 100ml of a liquid form can be sold to an individual at one time.

**Who can sell Exempted Codeine Products**: only a pharmacist or a pharmacist intern under the direct supervision of a pharmacist.

**What will be recorded when you purchase an Exempted Codeine Product**: on your personal Pharmaceutical Information Program (PIP) profile, the pharmacist will document:

- Date of purchase
- Product name
- Quantity sold

*Your PIP profile is accessible by your Saskatchewan Health Number or your name.*

*Your responsibilities when purchasing an Exempted Codeine Product*: tell the pharmacist or pharmacist intern what you are using it for and the date you last purchased an Exempted Codeine Product.

*Products containing codeine are not recommended for children less than 12 years of age.*

C. What will your pharmacist discuss with you when you purchase an Exempted Codeine Product?

1. Ensure that it is being used for a recognized medical or dental purpose
   - Relief of short term mild to moderate pain
   - Cough suppressant

2. The proper dosing of the product for the specific purpose
   - Pain Relief: Usually 1-2 tablets every 4-6 hours
   - Cough Suppressant: Usually 15ml every 6-8 hours or 1-2 tablets every 4-6 hours
Table 1: Maximum Daily Dose

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Daily Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>360mg</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>4000mg</td>
</tr>
<tr>
<td>ASA</td>
<td>4000mg</td>
</tr>
<tr>
<td>Caffeine</td>
<td>2500mg</td>
</tr>
</tbody>
</table>

3. Side effects

Table 2: Side Effects of Specific Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>Constipation, Decreased mental alertness, Decreased breathing rate, Decreased blood pressure</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>Allergic reaction, rash</td>
</tr>
<tr>
<td>ASA</td>
<td>Dizziness and fatigue, Heartburn, nausea, stomach pain, Bleeding</td>
</tr>
<tr>
<td>Caffeine</td>
<td>Increased heart rate, Dizziness, headache, insomnia, restlessness, Increased urinary frequency</td>
</tr>
</tbody>
</table>

4. The risks of over-use of the ingredients in the Exempted Codeine Products:
   - Medication Overuse Headache: use of combination analgesic products (including Exempted Codeine Products) on 10 days a month or more can result in worsening of a pre-existing headache disorder
   - Inappropriate Use: addiction (codeine); liver damage (acetaminophen)

Health Canada is considering dramatically reducing the daily recommended dosage of acetaminophen from the current 4 (four) grams per day to 2.6 grams per day in light of growing concerns about liver damage resulting from accidental and intentional overdoses.