CREATINE MONOHYDRATE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes:
- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
- The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: April 12, 2011

Proper name(s): N-(aminoiminomethyl)-N-methylglycine monohydrate (Merck 2011; US NLM 2011)

Common name(s): Creatine monohydrate (Merck 2011; US NLM 2011)

Source material(s): Synthetic (Merck 2011; Weiss and Krommer 1998)

Route(s) of administration: Oral

Dosage form(s):
- The acceptable pharmaceutical dosage forms include, but are not limited to chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, or powders.
  Note: Liquids and solutions are not permitted due to lack of stability of the finished product (Dash and Sawhney 2002).
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s):
- Statement(s) to the effect of:
  - Increases [body/muscle/lean] [mass/size] when used in conjunction with a resistance training regimen (Brose et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997).
Improves [strength/power/performance] in repetitive bouts of brief, highly-intense physical activity (e.g. sprints, jumping, resistance training) (by increasing [muscle/intramuscular] [creatine/phosphocreatine/energy] levels) (Okudan and Gökbel 2005; Brose et al. 2003; Preen et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997; Hultman et al. 1996).

Dose(s) and Duration of use:

Note: Product licence applicants must include both a loading and maintenance phase dose on the Product Licence Application and product label.

Table 1 Dose and duration of use for creatine monohydrate

<table>
<thead>
<tr>
<th>Phase</th>
<th>Dose (g/day)</th>
<th>Duration of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loading Phase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option 1</td>
<td>15-20; not to exceed 5 g per dose</td>
<td>5-7 days</td>
</tr>
<tr>
<td>Option 2</td>
<td>3-5</td>
<td>Use for a minimum of 4 weeks</td>
</tr>
<tr>
<td>Maintenance Phase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option 3</td>
<td>2-5</td>
<td>No statement required</td>
</tr>
</tbody>
</table>


2. Reference: Hultman et al. 1996


Directions for use: No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

- Consult a health care practitioner prior to use if you have a kidney disorder (Pline and Smith 2005; Pritchard and Kalra 1998).
- Consult a health care practitioner prior to use if you are pregnant or breastfeeding.
- May result in weight gain (Volek and Rawson 2004; Bemben et al. 2001; Mihic et al. 2001).

Contraindication(s): No statement required.

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD Natural Health Products Ingredients Database and must meet the limitations outlined in the list.
Specifications:

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- The finished product and/or raw material specifications must have limits for the following impurities: not more than 100 ppm creatinine; not more than 50 ppm dicyandiamide; non-detectable dihydrotriazine. The method used to detect dihydrotriazine must have a limit of detection of not more than 5 ppm.

**Note:** The information detailed in this section is not to be submitted with a compendial PLA, although it may be requested at Health Canada’s discretion.

References cited:


References reviewed:


