NATURAL HEALTH PRODUCT

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 and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

February 24, 2023

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source information</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-(Aminoiminomethyl)-N-methylglycine monohydrate</td>
<td>Creatine monohydrate</td>
<td>Source material(s) Preparation(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Creatine monohydrate Synthetic</td>
</tr>
</tbody>
</table>


Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.
Note
Liquids and solutions are not permitted due to lack of stability of the finished product (Dash and Sawhney 2002).

Use(s) or Purpose(s)

- Increases body/(lean)muscle 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(s) of use

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Table 2. Dose(s) and duration(s) of use for creatine monohydrate

<table>
<thead>
<tr>
<th>Phase(s)</th>
<th>Dose(s) (g/day)</th>
<th>Duration(s) of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loading Phase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option 1¹</td>
<td>15-20; not to exceed 5 g per dose</td>
<td>5-7 days</td>
</tr>
<tr>
<td>Option 2²</td>
<td>3-5</td>
<td>Use for a minimum of 4 weeks</td>
</tr>
<tr>
<td>Maintenance Phase³</td>
<td>2-5</td>
<td>No statement required</td>
</tr>
</tbody>
</table>

² Reference: Hultman et al. 1996
Direction(s) for use

Table 3. Direction(s) for use

<table>
<thead>
<tr>
<th>Phase(s)</th>
<th>Direction(s) for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loading Phase</td>
<td>Option 1 Step 1 (Loading Phase): Start with a loading phase of 5-7 days (15-20 g/d) and follow with a maintenance phase (2-5 g/d)</td>
</tr>
<tr>
<td></td>
<td>Option 2 Step 1 (Loading Phase): Start with a loading phase of 4 weeks (3-5 g/d) and follow with a maintenance phase (2-5 g/d)</td>
</tr>
<tr>
<td>Maintenance Phase</td>
<td>Step 2 (Maintenance Phase): No statement required</td>
</tr>
</tbody>
</table>

Risk information

Caution(s) and warning(s)

▸ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.
▸ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have kidney disease/disorder (Pline and Smith 2005; Pritchard and Kalra 1998).
▸ May result in weight gain (Volek and Rawson 2004; Bemben et al. 2001; Mihic et al. 2000).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).
Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.
- 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.

References cited


References reviewed


