

## INSTRUCTIONS FOR USE

SIKLOS (See – k – los)  
(hydroxyurea)  
tablets

Read this Instructions for Use before you start taking SIKLOS and each time you get a refill. There may be new information. This Instructions for Use does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about SIKLOS when you start taking it and at regular checkups.

---

### Important Information:

- Wash your hands with soap and water before and after handling SIKLOS tablets or bottles containing SIKLOS.
  - Wear disposable gloves when handling SIKLOS tablets or bottles containing SIKLOS.
  - Take SIKLOS 1 time a day at the same time each day.
  - Powder spilled from a broken tablet should be wiped up right away with a damp disposable paper towel and thrown away in a closed container, such as a plastic bag to avoid harm to other people. The spill area should then be cleaned using a detergent solution followed by clean water.
  - When the tablet is broken, avoid touching the broken surfaces.
  - If contact with crushed tablets happens on the skin, wash the skin area right away and thoroughly with soap and water.
  - If contact with crushed tablets happens in the eyes, flush the eyes thoroughly with water or isotonic eyewash used for that purpose for at least 15 minutes.
- 

### SIKLOS is supplied in 2 different strengths:

■ **Siklos® 1,000 mg** 

**SIKLOS 1,000 mg tablet** has three separation lines (score lines) and can be broken at these score lines to provide smaller doses. Each 1,000 mg tablet can be divided into 4 equal parts (each part is 250 mg).

■ **Siklos® 100 mg**: 

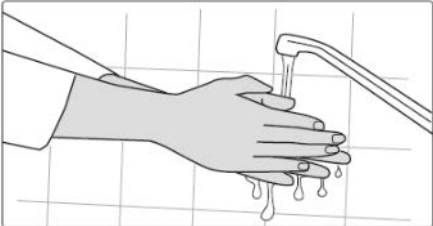
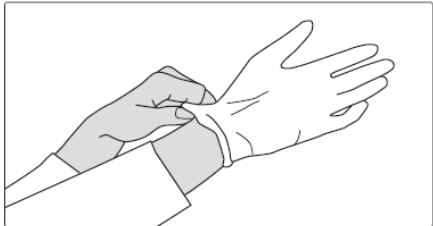
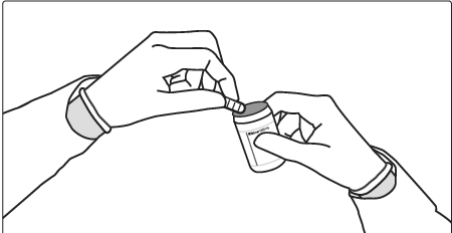
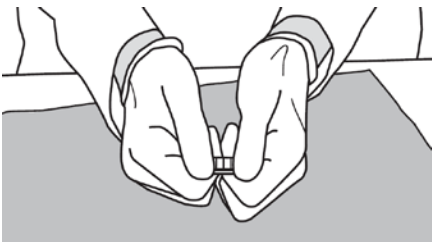


**Do not break the SIKLOS 100 mg into smaller tablets.**

---

### SIKLOS 1,000 mg Tablet Breaking Instructions:

**You will need the following supplies to break a SIKLOS 1,000 mg tablet:**

- SIKLOS 1,000 mg tablets
  - A damp disposable paper towel
  - A tablet cutter
  - Disposable gloves
-

<p><b>Step 1:</b> Place a damp disposable paper towel on a flat surface where the tablets will be broken.</p>	
<p><b>Step 2:</b> Wash and dry your hands before handling SIKLOS tablets or bottles containing the tablets.</p>	
<p><b>Step 3:</b> Check your prescribed dose. You may need more than 1 tablet to get your prescribed dose.</p>	
<p><b>Step 4:</b> Put on disposable gloves.</p>	
<p><b>Step 5:</b> Remove the SIKLOS 1,000 mg tablet out of the bottle needed to get your dose.</p>	
<p><b>Step 6:</b> Use your index fingers and thumbs to hold each end of the SIKLOS 1,000 mg tablet.</p>	
<p><b>Step 7:</b> While holding the ends of the SIKLOS 1,000 mg tablet, push down on the tablet to break the tablet on the score line to get your prescribed dose.</p> <p>SIKLOS 1,000 mg tablets can be broken as:</p> <ul style="list-style-type: none"> <li>• 1/4 of a tablet for a dose of 250 mg of SIKLOS:</li> </ul> 	

- 1/2 of a tablet for a dose of 500 mg of SIKLOS:



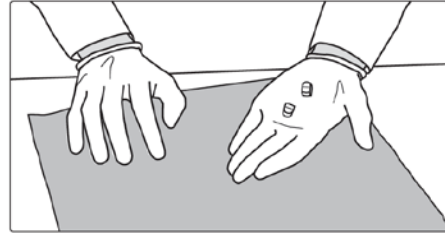
- 3/4 of a tablet for a dose of 750 mg of SIKLOS:



- a whole tablet for a dose of 1,000 mg of SIKLOS (**no breaking needed**):



**Note:** You may need to use a tablet cutter to get the smaller tablets (1/4 of a tablet).



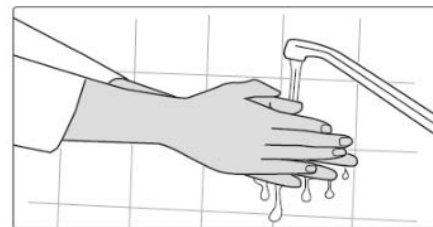
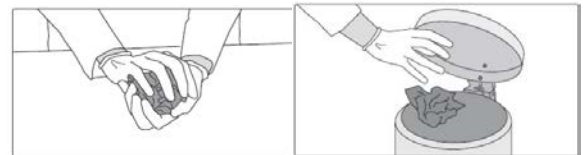
**Step 8:** Take your prescribed dose by swallowing it with a glass of water.

**Important:** If you have difficulty swallowing SIKLOS tablets, please stop here and follow the instructions below, "For people who cannot swallow SIKLOS tablets".



**Step 9:** Throw away the damp disposable paper towel in the trash. Pull off disposable gloves and throw away in the trash.

Wash and dry your hands.

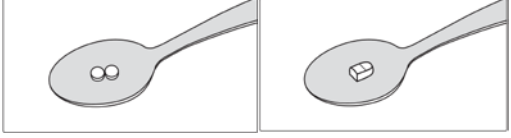
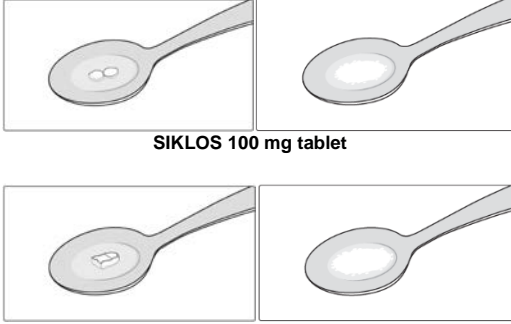




**Step 10:** Store any unused broken tablet in the bottle and put the bottle back in the box. **Broken tablets must be used within three months.**

**For people who cannot swallow SIKLOS tablets**

**You will need the following supplies to prepare and take your dose by dissolving the tablet:**

- Your bottle of SIKLOS 1,000 mg tablets or SIKLOS 100 mg tablets
  - **Note:** If you have been prescribed SIKLOS 1,000 mg and need to break your tablets, use the **SIKLOS 1,000 mg Tablet Breaking Instructions above** to get your prescribed dose **before** you begin the steps below.
- A teaspoon
- Water to dissolve tablets

<p><b>Step 1:</b> Get your prescribed dose of SIKLOS tablets. Put your prescribed dose of SIKLOS tablets onto the teaspoon.</p>	 <p>SIKLOS 100 mg tablet      SIKLOS 1,000 mg tablet (broken)</p>
<p><b>Step 2:</b> Add a small amount of water to the teaspoon. The tablet dissolves within about 1 minute.</p>	 <p>SIKLOS 100 mg tablet</p> <p>SIKLOS 1,000 mg tablet (broken)</p>
<p><b>Step 3:</b> Swallow the mixture right away.</p>	
<p><b>Step 4:</b> After you take your prescribed dose of SIKLOS tablets, drink a glass of water. When you are finished drinking a glass of water, continue to Step 9 and Step 10 above.</p>	

**Storing your SIKLOS tablets:**

- Store SIKLOS at room temperature between 68°F to 77°F (20°C to 25°C).

- Keep the SIKLOS bottle tightly closed.

**Keep SIKLOS and all medicines out of the reach of children.**

Distributed by: MEDUNIK USA.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: 05/2018

## Special form to illustrate daily dose and how to handle tablets

Date: ...../...../.....

Additional explanation of the medical prescription for:

Last Name ..... First name .....

Weight ..... kg

Your doctor has prescribed ..... mg of SIKLOS<sup>®</sup> per day.

That means, take every day:



**Siklos<sup>®</sup>** 2 strengths: **100 mg** and **1,000 mg**  
 hydroxyurea

**Siklos<sup>®</sup> 1,000 mg**

1/4 tablet: 250 mg



1/2 tablet: 500 mg



3/4 tablet: 750 mg



..... entire tablet(s): 1,000 mg



RED pack



Read the instructions carefully before you start using SIKLOS<sup>®</sup>, as it contains important information, especially on handling and disposing of broken tablets.

### How do I use broken tablets of Siklos<sup>®</sup> 1,000 mg?

Your doctor may find it necessary to adjust your dosage of Siklos<sup>®</sup> to obtain the proper treatment response. The tablet is marked with separation lines (score lines) and may be easily broken at these score lines to provide any of the following doses. Store the unused broken tablet in the bottle and put the bottle back in the box.

