

Siklos® 100 mg
hydroxyurea

Siklos® 1,000 mg
hydroxyurea

New!

SCORED TABLET

TRIPLE SCORED TABLET



Siklos® is the first and only hydroxyurea-based treatment for pediatric sickle cell anemia patients 2 years of age and older.

WARNING: LOW BLOOD CELL COUNT and CANCER
See full prescribing information for complete Boxed Warning.

- **Low blood cell counts are common with SIKLOS®, including low red blood cells, white blood cells, and platelets, and can be severe and life threatening. If your white blood cell count becomes very low, you are at increased risk for infection.** Your healthcare provider will check your blood cell counts before and every 2 weeks during treatment with SIKLOS®. Your healthcare provider may change your dose or tell you to stop taking SIKLOS® if you have low blood cell counts. Tell your healthcare provider right away if you get any of the following symptoms: fever or chills; shortness of breath; body aches; unusual headache; feeling very tired; bleeding or unexplained bruising.
- **Cancer.** Some people have developed cancer, such as leukemia and skin cancer, after taking SIKLOS® for a long time. Your healthcare provider will check you for cancer. You should protect your skin from the sun using sunblock, hats, and sun-protective clothing.

Please see Important Safety Information, including **Boxed Warning**, throughout this brochure.

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HOW SIKLOS® HELPS

Siklos® helps keep red blood cells round and flexible so they travel more easily through the blood vessels. This may help reduce painful crises and complications of the disease.



WHY SIKLOS®?

- Proven safe and effective in clinical trials
- The only hydroxyurea-based treatment specifically indicated and approved for patients 2 years of age and older
- Allows doctors to adjust your child's dose to his/her weight in increments of 50mg
- Dissolvable in water for children who have trouble swallowing tablets



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**IMPORTANT SAFETY INFORMATION
CONTINUED FROM INSIDE SPREAD**

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**WHAT IS THE MOST IMPORTANT INFORMATION
YOU SHOULD KNOW ABOUT SIKLOS?, continued...**

- **For males taking SIKLOS:** SIKLOS can affect your sperm. If you have a female sexual partner who can become pregnant, you should use effective birth control during treatment with SIKLOS and for at least 6 months after treatment.
- **SIKLOS may cause fertility problems in males.** Talk to your healthcare provider if this is a concern for you.

WHO SHOULD NOT TAKE SIKLOS

Do not take SIKLOS if you are allergic to hydroxyurea or any of the ingredients in SIKLOS. See the Medication Guide for a list of the ingredients in SIKLOS.

**WHAT SHOULD YOU TELL YOUR HEALTH CARE
PROVIDER BEFORE TAKING SIKLOS?**

Tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems or are receiving hemodialysis
- have liver problems
- have human immunodeficiency virus (HIV) or take HIV medicines. **Taking SIKLOS with certain HIV medicines can cause serious reactions and may lead to death.**

- have increased levels of uric acid in your blood (hyperuricemia)
- have a history of receiving interferon therapy or are currently receiving interferon therapy
- have leg wounds or ulcers
- plan to receive any vaccinations. You should not receive “live vaccines” during treatment with SIKLOS.
- are pregnant or plan to become pregnant. See **“What is the most important information I should know about SIKLOS?”**
- are breastfeeding or plan to breastfeed. It is not known if SIKLOS can pass into your breast milk. Do not breastfeed during treatment with SIKLOS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**WHAT ARE THE POSSIBLE SIDE EFFECTS OF SIKLOS?
SIKLOS may cause serious side effects, including:**

See **“What is the most important information I should know about SIKLOS?”**

- **Skin ulcers, including leg ulcers, and death of skin tissue (gangrene)** have happened in people who take SIKLOS. This has happened most often in people who receive interferon therapy or have a history of interferon therapy. Your healthcare provider will decrease your dose or stop treatment with SIKLOS if you develop any skin ulcers.
- **Enlarged red blood cells (macrocytosis).** Macrocytosis is common in people who take SIKLOS and can make it difficult to detect a decrease of folic acid. Your healthcare provider may prescribe a folic acid supplement for you.

The most common side effects of SIKLOS include:

infections, headache, fever, skin problems (e.g., skin reactions, dry skin, changes in skin and nail color), stomach and intestine (gastrointestinal) problems (e.g. nausea, constipation), decrease in vitamin D and weight gain.

These are not all the possible side effects of SIKLOS.

You are encouraged to report negative side effects of prescription drugs to the FDA at www.fda.gov/medwatch, or 1-800-FDA-1088.

Please read the Full Prescribing Information, including **Boxed Warning**, Medication Guide and Instructions for Use, at www.SIKLOSusa.com.

For more information, please contact Medunik USA Customer Service at: **1-844-633-8645** or info@medunik.com.