Siklos® hydroxycarbamide

in SICKLE CELL DISEASE
Patient Guide

Siklos® 100 mg

Film-coated tablet (bottle of 60 tablets)

Siklos® 1 000 mg

Film-coated tablet (bottle of 30 tablets)

Important information about your treatment or your child's treatment

Keep this booklet in a safe place as you may wish to refer to it again.

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1 Your doctor has prescribed Siklos®

Your doctor has prescribed Siklos® for you to treat the condition you have which is called sickle cell disease. This is an inherited disease which affects the red blood cells. In the course of this disease, some cells become abnormal, rigid and take a crescent or sickle shape, which leads to anaemia (loss of red blood cells). These sickle cells also get stuck in blood vessels, blocking blood flow. This can cause acute pain crises and organ damage which require hospitalizations.
Siklos® reduces the number of painful crises and the number of disease-related hospital admissions.

Siklos® can be used in adults, adolescents and children older than two years.

Siklos® has been prescribed for you. Never give it to someone else, even if he or she has the same disorder for which you are being treated.

Take this medication exactly as it has been prescribed for you by your doctor. Take your treatment regularly and do not change the dose of Siklos® by yourself.

Siklos® may interact with other medicines. Please tell your doctor if you are taking or have recently taken any other medicines, even those obtained without a prescription.

Before starting the treatment, read the package leaflet available at https://www.ema.europa.eu/en/documents/product-information/-siklos-epar-product-information_en.pdf
(The package leaflet is also present in each box of Siklos®)

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PLEASE NOTE

Siklos® (hydroxycarbamide) is available in 2 different strengths: 100 mg and 1 000 mg.
Your doctor may prescribe either or both strengths during the course of your treatment in order to achieve the best possible adjustment of the daily dose.

Siklos® 100 mg

Off-white oblong-shaped, film-coated tablets **with 1 score line on both sides.**

Each half tablet is embossed “H” for Hundred on one side.

Each tablet contains **100 mg hydroxycarbamide and can be divided into two equal 50 mg parts.**

Siklos® 100 mg is presented in a plastic bottle containing **60 tablets.**

Golden outer packaging

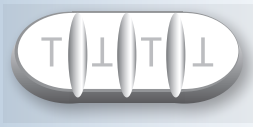
Siklos® 1 000 mg

Off-white, capsule shaped film-coated tablets **with 3 score lines on both sides.**

Each quarter of tablet is embossed “T” for Thousand on one side.

Each tablet contains **1 000 mg hydroxycarbamide and can be divided into four equal 250 mg parts.**

Siklos® 1 000 mg is presented in a plastic bottle containing **30 tablets**.



Red outer packaging

As part of your treatment, your doctor may prescribe both Siklos® 100 mg tablets and Siklos® 1 000 mg tablets to be taken each day.
Ensure that you understand the prescribed dose and know the difference between the two tablet strengths Siklos® 100 mg and Siklos® 1 000 mg. Your doctor will tell you how much of Siklos® to take each day and will describe the dose in whole, half or quarter tablets.
Ask your doctor or pharmacist if you have any questions.

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DOSING SHEET

Your doctor will give you a "Dosing Sheet" if you are prescribed both strengths of Siklos® simultaneously. The "Dosing Sheet" will better explain the types of tablets you must take every day. You should show this sheet to your pharmacist to ensure that you take the correct daily dose prescribed by your doctor. An extract from the dosing sheet is provided below for your information.

Date: ...../...../.....
Name: ..... Weight: ..... kg
Prescriber name: .....
Your doctor has prescribed ..... mg of Siklos® per day.
This means that each day you should take:

Siklos® 100 mg

Each half-tablet is embossed "H" for Hundred on one side

- ☐ ½ tablet: **50 mg** 
- ☐ .... entire tablet(s) of **100 mg** = ... mg 

GOLD box

Siklos® 1 000 mg

Each quarter-tablet is embossed "T" for Thousand on one side

- ☐ ¼ tablet: **250 mg** 
- ☐ ½ tablet: **500 mg** 
- ☐ ¾ tablet: **750 mg** 
- ☐ .... entire tablet(s) of **1 000 mg** = ... mg 

RED box

Please show this sheet to your pharmacist with the medical prescription.

Before starting your treatment, please read the patient information guide; it contains important information on Siklos®, especially on precautions for handling the tablets.

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2 Siklos® tablets must be handled with care

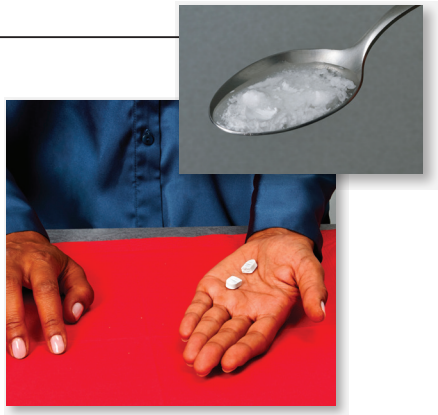
IMPORTANT

Siklos® is a cytotoxic medicine (it has specific toxic effects on certain cells) and must be handled with care.
Siklos® boxes must be kept out of the reach and sight of children.
Pregnant women should avoid handling Siklos® tablets.
Siklos® must be taken every day at the same time, preferably in the morning before breakfast. Swallow the tablet, with a glass of water, without sucking or chewing.

Wash your hands before and after handling the tablets.

How to divide Siklos® 1 000 mg or Siklos® 100 mg tablets?

The Siklos® 1 000 mg and Siklos® 100 mg tablet break easily along the score lines, with each end being held between the fingers.
In case the prescribed dose requires breaking the tablet, this should be done away from food.



Powder spilled from the broken tablet should be wiped up with a damp disposable tissue which must be thrown out to avoid ingestion of powder by other people.

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When the tablet is broken, you must avoid touching the broken surface.

Put back unused tablet parts in the bottle corresponding to the right strength form (i.e., 100 mg embossed H (Hundred) or 1 000 mg embossed T (Thousand) and put the bottle back in the box.

Discard the disposable tissue with the tablet crumbs (if any) to the bin and wash your hands after handling tablets.

In case you cannot swallow the Siklos® 1 000 mg or Siklos® 100 mg tablets

You can disintegrate them in water immediately before taking them as follows:

Put the prescribed amount of tablets or tablet parts in a teaspoon with some water (Siklos® 1 000 mg tablets should be broken, preferably).

You may add a drop of syrup or mix the contents with food to mask any bitter taste.

Swallow the content of the spoon as soon as the tablet is disintegrated.

Then drink a large glass of water or any other drink.

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3 Fertility - pregnancy & breastfeeding

If you are a woman of childbearing potential

The risk of fœtal abnormalities cannot be ruled out if you are pregnant while under treatment with Siklos®, so an **appropriate contraception** is strongly recommended during treatment.

If you wish to have children, please discuss this with your doctor to decide whether or not you should continue treatment with Siklos®. If you become pregnant or think you may be pregnant while you are still taking Siklos®, please tell your doctor.

The active substance of Siklos® passes into human breastmilk. You must not breastfeed while taking Siklos®.

If you are a man

It is important for you to know that Siklos® can have an effect on sperm production while you are being treated and therefore on your ability to have children. This point should be discussed with your doctor before you start treatment with Siklos®.
Finally, if your partner becomes pregnant or plans to become pregnant, please discuss this with your doctor.

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4 Reporting Side effects with Siklos®

Like any medicine, Siklos® can cause side effects in some people.
Please read carefully the leaflet before you start taking the medicine.

This leaflet is available at the following address: https://siklos.eu/ir/
and on the EMA website:
https://www.ema.europa.eu/documents/product-information/siklos-epar-product-information_en.pdf.

If you get any side effects, talk to your doctor or, pharmacist or nurse.
This includes any possible side effects not listed in the leaflet.

You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects, you can help provide more information
on the safety of this medicine.

For further information, please contact: Theravia
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