

Siklos®

hydroxycarbamide

in **SICKLE CELL
DISEASE**

Patient Guide



*Film-coated tablets
hydroxycarbamide*



*Film-coated tablets
hydroxycarbamide*

**Important information
about your treatment or
your child's treatment**

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 at the end of this document carefully.

(The package leaflet is also present in each box of Siklos®)

PLEASE NOTE

Siklos® (hydroxycarbamide) is available in 2 different strengths: 100 mg and 1000 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” on one side.

Each tablet contains 100 mg hydroxycarbamide and can be divided into 2 equal 50 mg parts.

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

Golden outer packaging



Siklos® 1000 mg

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

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

Each tablet contains 1000 mg hydroxycarbamide and can be divided into four equal 250 mg parts.

Siklos® 1000 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® 1000 mg tablets to be taken each day.

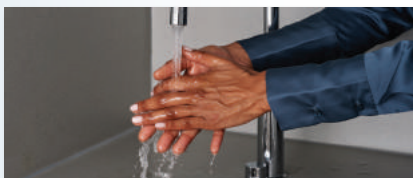
Ensure that you understand the prescribed dose and know the difference between the two tablet strengths Siklos® 100 mg and Siklos® 1000 mg. Your doctor will tell you how much of Siklos® to take each day and will describe the dose in whole, half or quarter tablets.

Ask your doctor or pharmacist if you have any questions.

2 Siklos® tablets must be handled with care

IMPORTANT

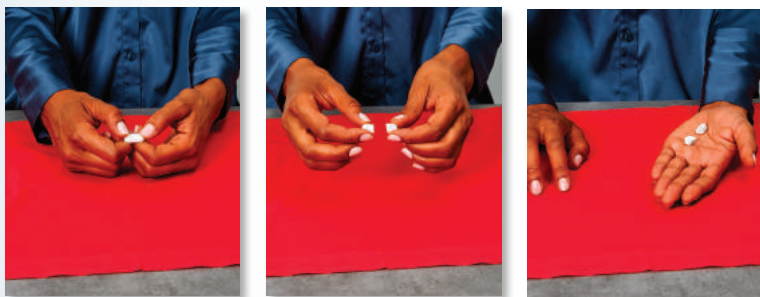
Siklos® is a cytotoxic medicine (it has specific toxic effects on certain cells) and must be handled with care. Siklos® boxes must be kept out of the reach and sight of children. Pregnant women should avoid handling Siklos® tablets. **Siklos® must be taken every day at the same time, preferably in the 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® 1000 mg or Siklos® 100 mg tablets?

The Siklos® 1000 mg and Siklos® 100 mg tablets 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.

In case the prescribed dose requires breaking the tablet in halves or quarters, the tablet can be broken easily.

Siklos® 100 mg

50 mg

100 mg

Siklos® 1000 mg

250 mg

500 mg

750 mg

1000 mg

1000 mg



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 or 1000 mg) 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 Siklos® 1000 mg or Siklos® 100 mg tablets

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



Place the prescribed dose in a teaspoon with some water (Siklos® 1000 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.

3 When you are treated with Siklos®, it is very important to be regularly monitored by your doctor

Siklos® contains hydroxycarbamide, a substance which inhibits the growth and proliferation of some cells, such as blood cells. These effects lead to a reduction of circulating of red blood cells, white and coagulation cells.

Your doctor will prescribe blood tests for you in order to regularly check your blood cell counts:

- before treatment,
- **every two weeks during the first 2 months of treatment, then, at 2 month intervals in most cases.**

For children

The doctor will also monitor children's growth, which may be affected by sickle cell disease if it is not treated correctly. The impact of treatment with Siklos® on children's growth is not known either.

If you are a woman of childbearing potential

The risk of foetal 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 breast-milk. 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.

4 Important signs or symptoms about the disease

Some signs and symptoms may require you to call a doctor or to visit an Emergency department. These may be caused by disease progression or show that your treatment is not working or be a side effect linked to the medicinal product.

You should never hesitate to discuss your condition, or your Siklos® treatment with any doctor, especially if it is not your usual doctor. This will help the doctor to choose the right treatment and to administer it more rapidly.

Painful crises

Extremely painful episodes are the major symptom of the sickle cell disease which can start in childhood but also in adulthood.

The pain (vaso-occlusive crisis or VOC), which affects mainly the bones and joints, is often difficult to alleviate. Other organs may be affected (lungs, kidneys, brain, inner ear, etc.), which explains why the symptoms vary greatly between patients.

The crises may occur suddenly and resolve rapidly or last several days. The episodes of acute pain may occur several times a year.

You should consult a doctor urgently or go to hospital in the following cases:

- pain which is not relieved by usual painkillers (analgesics)
- your temperature above 38.5°C, even if there is no pain
- vomiting
- a sudden pallor, fatigue or impairment of your health status or a sudden increase of the volume of your spleen (your doctor will tell you how to palpate your spleen)
- if you are a man and you have an unwanted, painful erection which lasts for more than three hours (priapism).

4 Important signs or symptoms about the disease

When the vaso-occlusive crises affect the lungs, it is called “acute chest syndrome” (ACS): The patient has chest pains, fever and difficult breathing. He/she is out of breath.

This can occur in both adults and children. If it does, a doctor must be seen **urgently**.

Infections

When you have sickle cell disease, you are more susceptible to infections (illness with fever). This is mainly because your spleen is less effective at filtering out certain types of bacteria. Any infection can trigger a vaso-occlusive crisis or an acute chest syndrome.

It is therefore important for you to consult your doctor if you have a fever or any other sign or symptom of infection.

5 Side effects which have been observed with Siklos®

Like any medicine, Siklos® can cause side effects in some people.

Tell your doctor immediately if you experience any of the following, all these are serious side effects of Siklos®. You may need medical attention in case of:

- Severe infection
- Tiredness and/or looking pale
- Unexplained bruising (accumulation of blood under the skin) or bleeding
- Headache
- Difficulties in breathing
- Or any other sign or symptom with suspicion of painful crises linked with the disease.

Tell your doctor as soon as possible if you notice any of the following side effects of Siklos®:

- Fever or chills
- Feeling sick, weak, lacking energy or a general feeling of being unwell
- Rash (itching red eruption of the skin)
- Ulcers or wounds on your legs
- Sore (open skin infection) on your skin
- Disorientation (confusion) and dizziness.

Reporting of side effects:

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

You can also report side effects directly *via HPRA Pharmacovigilance Earlsfort Terrace - IRL - Dublin 2 - Tel: +353 1 6764971 - Fax: +353 1 6762517 - Website: www.hpra.ie - e-mail: medsafety@hpra.ie.*

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

For further information, please contact:
Addmedica - email: pv@addmedica.com

