

Hydroxycarbamide 500 mg Hard Capsules

hydroxycarbamide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hydroxycarbamide is and what it is used for
2. What you need to know before you use Hydroxycarbamide
3. How to use Hydroxycarbamide
4. Possible side effects
5. How to store Hydroxycarbamide
6. Contents of the pack and other information

1. WHAT HYDROXYCARBAMIDE IS AND WHAT IT IS USED FOR

Hydroxycarbamide is an anti-cancer medicine. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy. Each capsule contains 500mg hydroxycarbamide as the active ingredient.

Hydroxycarbamide is used in the treatment of:

- Essential thrombocythemia or polycythemia vera.
- Chronic myeloid leukaemia (CML) in the chronic or accelerated phase of the disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HYDROXYCARBAMIDE

Do not use Hydroxycarbamide:

- if you are allergic to hydroxycarbamide or any of the other ingredients of this medicine (listed in section 6)
- if you have insufficient blood cells
- if you have severe anaemia

Warnings and precautions

Talk to your doctor or pharmacist before using Hydroxycarbamide

- if you have any kidney or liver problems
- if you are pregnant, planning to become pregnant or are breast feeding
- if you have ever suffered from gout
- if you take any anti-HIV medicines
- if you have leg ulcers
- if you have a known lack of vitamin B12 or folate
- if you are currently taking any other medicines for cancer treatment, especially interferon therapy
- if hemolytic anemia (disorder in which red blood cells are destroyed faster than they can be made) is detected when the blood tests are checked, your doctor will stop treatment with Hydroxycarbamide.

The complete status of the blood, including bone marrow examination, as well as kidney function and liver function should be determined prior to, and repeatedly during the treatment.

In long term use of Hydroxycarbamide, secondary leukaemia has been reported.

Skin cancer has been reported in patients receiving long term hydroxycarbamide. You should protect your skin from the sun and regularly inspect your skin yourself during the treatment and after discontinuation of the therapy with hydroxycarbamide. Your doctor will also inspect your skin during routine follow-up visits.

Other medicines and Hydroxycarbamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Special care will also be taken if you are taking any of the following medicines:

- Antiretroviral medicines (those that inhibit or destroy a retrovirus such as HIV), e.g. didanosine, stavudine and indinavir.
- Myelosuppressive medicines (decrease production of red, white, or coagulating blood cells) and radiation therapy.
- Some vaccines (if you have doubts, please ask your pharmacist or your doctor).

It may be necessary to adjust the dose of some medicines if they are taken at the same time as Hydroxycarbamide.

Hydroxycarbamide with food or drink

You can take this medicine with food or drink, before or after meals.

Pregnancy, breast-feeding and fertility

Hydroxycarbamide is not recommended during pregnancy. Please contact your doctor if you think you may be pregnant. The use of effective contraception is strongly recommended.

If you become pregnant or plan to become pregnant while taking Hydroxycarbamide, your doctor will discuss with you the potential benefits and risks of continuing using Hydroxycarbamide.

For the male patients taking Hydroxycarbamide, if your partner becomes pregnant or plans to become pregnant, your doctor will discuss with you the potential benefits and risks of continuing using Hydroxycarbamide.

The active substance of Hydroxycarbamide passes into human breast-milk. Hydroxycarbamide is not recommended during breast-feeding, your doctor will discuss with you the potential benefits and risks of continuing using Hydroxycarbamide.

Driving and using machines

The ability to drive or use machines can be diminished during the treatment with Hydroxycarbamide. You should discuss with your doctor.

Hydroxycarbamide contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Hydroxycarbamide contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. HOW TO USE HYDROXYCARBAMIDE

People who are not taking Hydroxycarbamide should not be exposed to it. To decrease the risk of exposure, wear disposable gloves when handling Hydroxycarbamide. Anyone handling Hydroxycarbamide should wash their hands before and after contact with the capsules. Pregnant women should not handle Hydroxycarbamide.

You should take your medicine as your doctor has instructed. Your pharmacist may also help if you are not sure.

You may be instructed to take your medicine on either a daily basis or an irregular basis.

In chronic myeloid leukaemia, the usual dose is 40 mg/kg of your bodyweight, once a day. The dose is individually adjusted according to the white cell count.

In polycythemia vera, the usual dose is 15 - 20 mg/kg of your bodyweight, once a day. This dose is then individually adjusted to 1-2 capsules (500 - 1000 mg) depending on white cell count.

In essential thrombocythemia, the usual dose is 15 mg/kg of your body weight, once a day. The dose is individually adjusted according to the white cell count.

Elderly patients may be more sensitive to the effects of hydroxycarbamide and may be given a lower dose.

You can take this medicine at any time of the day, before or after meals. The capsules should be swallowed whole with a glass of



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The following information is intended for healthcare professionals only:

Special precautions for disposal and other handling

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water. However, if you find it difficult to swallow them, the contents of the capsule can be emptied into a glass of water and taken immediately. If some of the powder floats on the surface of the water, DON'T WORRY this is just filler from the capsule. DO NOT inhale the contents of the capsules and if you spill any on the skin wipe it immediately.

While you are being treated with hydroxycarbamide it is important that you drink plenty of fluids. This will help your kidneys work well.

You should keep taking your capsules until your doctor tells you to stop.

Your doctor will do regular blood tests whilst you are taking Hydroxycarbamide.

If you use more Hydroxycarbamide than you should

If you take too many capsules you should go to your nearest hospital Casualty Department immediately and take the medicine carton with you.

If you forget to use Hydroxycarbamide

If you forget to take a dose of this medicine DO NOT take the missed dose at all. Take your next dose when it is due, DO NOT take a double dose to make-up for the one you have missed.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience symptoms such as:

- fever, cough or breathing problems, this could be a sign of serious lung disease (frequency not known)

Gastrointestinal side effects are common but require rarely dose reduction or cessation of treatment.

Very Common (affects more than 1 in 10 people)

- Blood disorders (reduction in white blood cells, red blood cells and platelets).
- Loss of appetite (anorexia).
- Sickness, nausea, vomiting, diarrhoea, constipation, abdominal pain, stomach discomfort, indigestion, inflammation of the pancreas.
- Black tarry stools or blood in the stools.
- Skin changes and muscle weakness (dermatomyositis) - you may experience symptoms such as muscle tenderness, muscle weakness or tiredness (especially when climbing stairs, walking or rising from a chair etc).
- Skin problems may occur including rashes, darkening of the skin, peeling of the skin, purple raised patches of skin and redness. There may be a worsening of existing redness or discomfort in the skin or mucous membranes if you have had radiation treatment in the past.
- Difficulty or pain passing urine and kidney problems.
- Absence or low amount of sperm in the semen (azoospermia or oligospermia).
- Fever, weakness, loss of energy, chills, feeling sick.

Common (affects less than 1 in 10 people)

- Large and immature blood cells (megaloblastosis).
- Skin cancer.
- Hallucination, disorientation, convulsion, dizziness, somnolence, headache.
- Pulmonary fibrosis, pulmonary oedema, lung infiltration and dyspnoea (laboured breathing).
- Hepatic enzyme increased, inflammation of the liver (hepatitis), problems with the flow of the bile (cholestasis).

Uncommon (affects less than 1 in 100 people)

- Yellow coloration (jaundice).

Rare (affects less than 1 in 1,000 people)

- Gangrene.
- Inflammation of the lung (allergic alveolitis).
- Hypersensitivity reaction.

Very rare (affects less than 1 in 10,000 people)

- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints.

Not known (cannot be estimated from the available data)

- Weight gain.
- Muscle pain.
- Porphyria cutanea tarda.
- Kidney failure.
- Urination problems.
- Enlargement of the breast in males (Gynecomastia).
- Hemolytic anemia.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE HYDROXYCARBAMIDE

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP: MM/YYYY. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Hydroxycarbamide contains

- The active substance is hydroxycarbamide
- The other ingredients are lactose monohydrate, citric acid monohydrate, magnesium stearate, disodium phosphate anhydrous, and for the hard capsules gelatin E441, erythrosine E127, titanium dioxide E171, black iron oxide E172 (i), patent blue V E 131 and yellow iron oxide E172 (iii).

Hydroxycarbamide is presented as hard gelatin capsules.

What Hydroxycarbamide looks like and contents of the pack

Hydroxycarbamide capsules are pink, opaque capsules with light green, opaque caps, and 'HH3' printed on them in black.

Hydroxycarbamide 500 mg capsules are packed in blisters, corresponding to 30, 50 or 100 capsules per pack.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder:

Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó, nº8, 8A/8B, Fervença
2705-906 Terrugem SNT
Portugal

Manufacturer:

Tecnimede, S.A.
Quinta da Cerca,
Caixaria 2565-187
Dois Portos
Portugal

Distributed by:

Consilient Health (UK) Ltd.
No.1 Church Road,
Richmond upon Thames,
Surrey, TW9 2QE

This leaflet was last revised in 07/2022.



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To minimise the risk of dermal exposure, always wear impervious gloves when handling capsules containing hydroxycarbamide. This includes all handling activities in clinical settings, pharmacies, storerooms and home healthcare settings, including during unpacking and inspection, transport within a facility, and dose preparation and administration. Local guidelines on handling cytotoxics should always be followed.

Any unused product or waste should be disposed of in accordance with local requirements.