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## HYDROXYCARBAMIDE 500 mg Capsules

*Each capsule contains 500 mg hydroxycarbamide*

**Cytotoxic**

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## CONSUMER MEDICINE INFORMATION

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### WHAT IS IN THIS LEAFLET

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**Please read this leaflet carefully before you start taking Hydroxycarbamide Capsules.**

This leaflet answers some common questions about Hydroxycarbamide Capsules.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Hydroxycarbamide Capsules against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### WHAT HYDROXYCARBAMIDE IS USED FOR

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Hydroxycarbamide is used to treat melanoma, resistant chronic myelocytic leukemia (CML), and recurrent metastatic or inoperable carcinoma of the ovary. Hydroxycarbamide used concomitantly with irradiation therapy is intended for use in the local control of primary squamous cell (epidermoid) carcinomas of the head and neck, excluding the lip, and carcinoma of the cervix.

Hydroxycarbamide Capsules contain the active ingredient hydroxycarbamide. Hydroxycarbamide belongs to a group of medicines called anti-neoplastic medicines. These medicines interfere with the growth of cancer cells.

Hydroxycarbamide Capsules are available by prescription only.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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### BEFORE YOU TAKE HYDROXYCARBAMIDE

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*When you must not take it*

**Do not take Hydroxycarbamide Capsules:**

- if you are allergic to hydroxycarbamide or any of the other ingredients of this medicine (listed in this leaflet).
- if you have history of any **blood problems**
- if you have severe anemia

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking hydroxycarbamide.

Your doctor will do regular blood tests before and whilst you are taking hydroxycarbamide. You may need to control or treat the source conditions before starting treatment with hydroxycarbamide.

**Pregnancy, breast-feeding and fertility**

You should not take this medicine if you are pregnant, planning to become pregnant or are breastfeeding, unless your doctor recommends it.

When appropriate both male and female patients should discuss contraceptive measure before and during treatment with hydroxycarbamide.

In addition, if you are pregnant, planning to be or breastfeeding you should not handle the capsules.

Your doctor will do regular blood tests before and whilst you are taking hydroxycarbamide. You may need to control or treat the source conditions before starting treatment with hydroxycarbamide.

**Take special care with Hydroxycarbamide Capsules if:**

- you have any **kidney or liver** problems
- you are **pregnant**, planning to become pregnant or are breast feeding
- you have ever suffered from **gout**
- you have leg ulcers
- you have previously received radiotherapy or chemotherapy, or are currently taking any other **medicines for cancer treatment**, especially interferon therapy
- you have folic acid deficiency

In long term use of hydroxycarbamide, secondary leukemia has been reported. Skin cancer has also been reported in patient receiving long term hydroxycarbamide. You should protect your skin from the sun, regularly inspect your skin yourself and be screened by your doctor for secondary malignancies during routine follow-up visits.

**Do not take this medicine after the expiry date printed on the pack and blister.**

The expiry date is printed on the carton and on each blister after “EXP” (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

**Do not take this medicine if the packaging is torn or shows signs of tampering.**

If the packaging is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**If you have not told your doctor about any of the above, tell him/her before you are given hydroxycarbamide.**

***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including those that you buy without a prescription from your pharmacy, supermarket or health food shop.**

In particular, tell your doctor if you are taking:

- Antiretroviral medicines (those that inhibit or destroy a retrovirus such as HIV), e.g., didanosine, stavudine and indinavir
- Myelosuppressive medicines (including chemotherapies) and radiation therapy
- Some vaccines, if you recently had a vaccination or are planning to have one, tell your doctor.

Always tell your doctor about other medicines you may be taking or have recently taken including those obtained without a prescription as some medicines can affect each others actions.

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

hydroxycarbamide.

Your doctor or pharmacist will be able to tell you what to do when taking hydroxycarbamide with other medicines.

**Taking with food, drink or alcohol**

You should check with your doctor before drinking alcohol to find out if it is advisable for you.

**Hydroxycarbamide Capsules contain 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.

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## **HOW TO TAKE HYDROXYCARBAMIDE CAPSULES**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.**

***How much to take***

Your doctor or pharmacist will tell you how much and how often you should take Hydroxycarbamide Capsules.

It is important that you take the full course of treatment that your doctor has prescribed for you.

The recommended dose is 20-30 mg of hydroxycarbamide per kg of your bodyweight **once a day** or 80 mg per kg of your body weight **once every third day**.

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

***How to take it***

The capsules should be swallowed whole with a glass of 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, **DO NOT 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.

***When to take it***

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

Take your tablet at the same time each day. You can take this medicine at any time of the day, before or after meals.

If you are going to have radiation therapy, this medicine will usually be started 7 days before starting radiation treatment.

***How long to take it***

Your doctor will determine the duration of time that you need to take the capsules. You should keep taking your capsules until your doctor tells you to stop.

***If you forget to take it***

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 a forgotten dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

***If you take too much (overdose)***

**Immediately telephone your doctor, or the Poisons Information Centre (New Zealand: 0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, and take the medicine carton with you if you think you or anyone else may have taken too much Hydroxycarbamide Capsules. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

The symptoms of overdose include; soreness, swelling of hands and feet and redness of skin.

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## **WHILE YOU ARE TAKING HYDROXYCARBAMIDE**

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***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are taking hydroxycarbamide.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Hydroxycarbamide Capsules.**

**If you become pregnant while you are taking Hydroxycarbamide Capsules, tell your doctor immediately.**

**If you develop an allergic reaction (e.g. a skin rash) while taking hydroxycarbamide, even following a single dose, stop taking it and tell your doctor.**

***Things you must not do***

Do not give your Hydroxycarbamide Capsules to anyone else, even if they have the same condition as you.

Do not change the dose.

Do not use hydroxycarbamide to treat other conditions unless your doctor tells you to.

Do not stop taking your capsules because you are feeling better, unless your doctor told you to do so. If you do not complete the full course prescribed by your doctor.

***What to be careful of***

**Be careful driving or operating machinery until you know how hydroxycarbamide affects you.**

Hydroxycarbamide Capsules may cause dizziness in some patients. You should not drive or operate any machinery unless it has been shown not to affect you and have discussed it with your doctor.

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## **SIDE EFFECTS**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking hydroxycarbamide.**

All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need to stop taking the capsules or have medical treatment if you get some of the serious side effects.

**Do not be alarmed by the following lists of side effects.**  
**You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**If you notice any of the following symptoms:**

**Swelling of the face, lips, tongue or throat; itching or skin rashes; difficulty breathing, unexplained fever, chills or sore throat, breathing difficulties, wasting of muscles and peeling of the skin and nails**  
**You should stop taking the capsules and tell your doctor immediately as these may be signs of an allergic reaction.**

If you notice any of these symptoms you should see your doctor immediately.

- unexplained shortness of breath or cough with fever, skin ulceration, especially with severe infection
- blood disorders (reduction in white blood cells, red blood cells and platelets)
- lower back pain or pain in your side
- black tarry stools or blood in the stools
- unusual bleeding or bruising
- numbness or tingling of hands or feet
- fever, cough or breathing problems, this could be a sign of serious lung disease (frequency not known)

The following side effects have been seen in some people:

- 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), a rash on the face, hands or other parts of the body (which in some cases maybe scaly, purple and raised)
- absence or low amount of sperm in the semen (azoospermia or oligospermia)
- loss of appetite
- weakness, loss of energy
- sickness, diarrhea, constipation, abdominal pain
- sores on the lips or mouth
- difficulty or pain passing urine
- 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
- temporary hair loss
- kidney problems
- skin cancer
- problems with the flow of the bile (cholestasis), the bile which is made by the liver to aid in digestion of food may not flow properly. A build up of bile can cause itchiness, yellow skin, very dark urine and very pale stools.
- inflammation of the liver (hepatitis) which cause flu-like symptoms, including tiredness, loss of appetite, fever, aching, and feeling sick/being sick, pressure or pain below the right ribs and might also include yellowing of the skin or eyes
- drowsiness, dizziness, fits, confusion or hallucinations (seeing hearing or feeling things that are not there)
- headache
- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## AFTER TAKING HYDROXYCARBAMIDE

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### *Storage*

**Keep your capsules in the blister pack until it is time to take them.**

If you take the capsules out of the box or the blister pack they may not keep well.

Store below 30°C. **Keep your capsules in a cool dry place.**

**Do not store Hydroxycarbamide Capsules or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep your capsules where children cannot reach them.** A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking Hydroxycarbamide Capsules or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

**Return any unused medicine to your pharmacist.**

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## PRODUCT DESCRIPTION

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### *What it looks like*

Hydroxycarbamide Capsules are gelatin capsules with an opaque pink body and an opaque light green cap, containing a white to off-white homogeneous powder.

They are available in blister packages of 100 capsules supplied with its package leaflet in a carton box.

### *Ingredients*

**Active ingredient per tablet:** Hydroxycarbamide 500 mg

#### **Inactive ingredients:**

##### Excipients

Lactose Monohydrate

Citric Acid

Disodium Phosphate

Magnesium Stearate

Size 0 Pink Op/Light Green Op248 Capsule

##### Capsule Composition

Gelatin

Titanium dioxide

Erythrosin - FD&C Red 3

Indigotine - FD&C Blue 2

Quinoline yellow

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## Sponsor

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