

HYDROXYCARBAMIDE

(SYNONYM: HYDROXYUREA)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hydroxycarbamide Medsurge. It does not contain all 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 (hydroxyurea) 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.

What Hydroxycarbamide (hydroxyurea) is used for

Hydroxycarbamide (hydroxyurea) is used to treat various types of cancers such as melanoma, leukemia and cancer of the ovary.

Hydroxycarbamide Medsurge contains hydroxycarbamide (hydroxyurea), an anti-cancer medicine. It interferes with the replication of cells and causes cell death, particularly in cancer cells.

Hydroxycarbamide (hydroxyurea) may be used alone or in combination with other treatments for cancer. Your doctor will inform you if this is necessary.

Your doctor may have prescribed hydroxycarbamide (hydroxyurea) for another reason.

Ask your doctor if you have any questions about why hydroxycarbamide (hydroxyurea) was prescribed for you.

This medicine is available only with a doctor's prescription.

Hydroxycarbamide (hydroxyurea) is not recommended for use in children as its safety and effectiveness in patients under 18 years of age has not been established.

Before you take hydroxycarbamide (hydroxyurea)

When you must not take it

Do not take hydroxycarbamide (hydroxyurea) if you have an allergy to:

- hydroxycarbamide (hydroxyurea)
- any of the ingredients listed at the end of this leaflet.

Do not take hydroxycarbamide (hydroxyurea) if you have marked depression of white blood cells (bone marrow depression) or red blood cells (severe anaemia).

Your doctor will be able to advise whether hydroxycarbamide (hydroxyurea) is appropriate in this situation.

Do not take hydroxycarbamide (hydroxyurea) if you are pregnant or intend to become pregnant.

Hydroxycarbamide (hydroxyurea) may cause harm to the unborn baby

if it is given to a man or woman before conception, or to a pregnant woman. You should use some kind of birth control while you are having hydroxycarbamide (hydroxyurea) and for at least 12 months after you stop using it. Hydroxycarbamide (hydroxyurea) may cause birth defects if either the male or female is using it at the time of conception.

Do not take Hydroxycarbamide Medsurge after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Hydroxycarbamide Medsurge if the packaging shows signs of tampering.

Before you start to take it

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

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver problems
- kidney problems
- blood problems or anaemia
- lowered immunity due to treatment with other medicines used to treat cancer (including radiation therapy)
- your immune system is not working properly (you get a lot of infections requiring treatment with antibiotics)

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone.

Do not have hydroxycarbamide (hydroxyurea) with any medicine that lowers your immune system, unless you have discussed this with your doctor.

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Hydroxycarbamide (hydroxyurea) passes into breast milk. Therefore there is a possibility that the breast-fed baby may be affected.

Tell your doctor if you are a sexually active man.

Hydroxycarbamide (hydroxyurea) may cause birth defects if either the male or female is using it at the time of conception. Men who take hydroxycarbamide (hydroxyurea) are advised to use a condom to avoid pregnancy in their partner.

If you have not told your doctor about any of the above, tell them before you start hydroxycarbamide (hydroxyurea).

If you are not sure whether you should have hydroxycarbamide (hydroxyurea), talk to your doctor.

If you have not told your doctor about any of the above, tell them before you start having hydroxycarbamide (hydroxyurea).

Taking other medicines

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

Some medicines and hydroxycarbamide (hydroxyurea) may interfere with each other.

These include:

- Vaccinations. Hydroxycarbamide (hydroxyurea) may suppress the body's normal defense mechanisms and result in a more

severe than normal reaction with the virus

- Some other medicines that are used to treat other forms of cancer
- Medicines used to treat gout
- Medicines used to treat HIV infection including Videx® (didanosine) and Zerit® (stavudine)

These medicines may be affected by hydroxycarbamide (hydroxyurea), or affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking hydroxycarbamide (hydroxyurea).

How to take hydroxycarbamide (hydroxyurea)

How much to take

Your doctor will decide what dose you will receive. Your dose of hydroxycarbamide (hydroxyurea) capsules is worked out based on your body weight and height and on the type of cancer you have. The dose worked out for you may be different to the dose for another patient.

Hydroxycarbamide (hydroxyurea) may be given alone or together with other anti-cancer treatments or drugs.

Ask your doctor if you want to know more about the dose of hydroxycarbamide (hydroxyurea) you receive.

How to take it

Hydroxycarbamide (hydroxyurea) capsules may be given to you at the hospital or surgery, or you may take them yourself at home.

Swallow the capsules whole with a glass of water.

Or if you have problems with swallowing the capsules, you can empty the capsule contents into a glass of water, stir and drink it straight away. Some of the materials present in the capsule may float to the surface of the water.

When to take it

Hydroxycarbamide Medsurge is taken as a single dose and can be taken each day, or once every three days. Your doctor will decide how you should take the capsules and will explain this to you.

Take hydroxycarbamide (hydroxyurea) at about the same time each day that you are to take it.

Hydroxycarbamide (hydroxyurea) may or may not be given at the same time as other anti-cancer treatments or agents.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Several courses of hydroxycarbamide (hydroxyurea) therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any side effects have been controlled.

Do not stop taking hydroxycarbamide (hydroxyurea) unless your doctor tells you to - even if you feel better.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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

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

If you have too much (overdose)

If you are in hospital hydroxycarbamide (hydroxyurea) will be given to you by the hospital staff, so it is most unlikely that too many capsules would be given. However, if an overdose should be given, your doctor will give you the appropriate treatment.

If you are taking hydroxycarbamide (hydroxyurea) at home - Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident or Emergency at your nearest hospital, if you think that you or someone else may have taken too many hydroxycarbamide (hydroxyurea) capsules. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include acute skin inflammation, soreness, discolouration of the skin, fluid retention associated with the hands & feet followed by scaling of the skin in these areas, soreness & inflammation of the mouth.

While you are taking hydroxycarbamide (hydroxyurea)

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor in order to get the best effect from your treatments.

If you forget an appointment, contact your doctor immediately.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking hydroxycarbamide (hydroxyurea).

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking hydroxycarbamide (hydroxyurea).

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking hydroxycarbamide (hydroxyurea).

If you become pregnant while having hydroxycarbamide (hydroxyurea), tell your doctor.

Avoid exposing your skin to sunlight. Use appropriate clothing, a hat, and sunscreen if you must go in the sun. Check your skin regularly for any changes. If you notice any changes, tell your doctor.

You must maintain an adequate fluid intake.

Hydroxycarbamide (hydroxyurea) can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk if infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Things you must not do

Do not give hydroxycarbamide (hydroxyurea) to anyone else, even if they have the same condition as you.

Do not take hydroxycarbamide (hydroxyurea) to treat any other complaints unless your doctor tells you to.

Do not stop taking hydroxycarbamide (hydroxyurea), or lower the dose, without checking with your doctor.

If you empty the contents of the capsules into water for swallowing, do not allow the powder to come into contact with your skin. Also avoid inhaling the contents when opening the capsules. If the powder is accidentally spilled, you should wipe up the powder using a damp paper towel and the paper towel should be disposed of immediately. You should also dispose of the empty capsules immediately after taking your required dosage.

Things to be careful of

Be careful driving or operating machinery until you know how

hydroxycarbamide (hydroxyurea) affects you.

As with other medicines used to treat cancer, hydroxycarbamide (hydroxyurea) may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to hydroxycarbamide (hydroxyurea) before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are taking hydroxycarbamide (hydroxyurea).

Like other medicines that treat cancer, hydroxycarbamide (hydroxyurea) may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

These are the more common side effects of hydroxycarbamide (hydroxyurea).

- High fever (greater than 39°C) that requires hospitalisation
- nausea, vomiting
- diarrhoea or constipation
- loss of appetite
- dizziness
- feeling tired or sleepy
- fever; high temperature, chills
- stomach pain or discomfort
- discolouration or ulcers on the skin
- decay of the skin or nails
- nail discolouration

Tell your doctor or nurse as soon as possible if you notice any of the following:

These are very rare side effects, which might possible occur. You may need medical attention.

- sore mouth
- frequent infections such as fever, severe chills
- tiredness, headaches, being short of breath, dizziness
- convulsions
- pain in lungs or difficulty breathing coughing, this could be a sign of serious lung disease
- Systemic lupus erythematosus, which may joint pain and/or swelling, especially in the hands or feet, skin rashes, made worse by being in the sun, sores in the mouth or nose, anaemia (low number of red blood cells).

If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- sudden life-threatening allergic reactions; sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

If you are receiving radiation treatment with hydroxycarbamide (hydroxyurea), or are taking other medications as well as hydroxycarbamide (hydroxyurea), the side effects listed above may occur more frequently or be more severe.

Other side effects not listed above may occur in some patients. Tell your doctor or nurse if you notice anything that is making you feel unwell.

The benefits and side effects of hydroxycarbamide (hydroxyurea) may take some time to occur. Therefore even after you have finished your hydroxycarbamide (hydroxyurea) treatment you should tell your doctor immediately if you

notice any of the side effects listed above.

After taking hydroxycarbamide (hydroxyurea)

Storage

Hydroxycarbamide (hydroxyurea) capsules should be stored below 25°C in a cool dry place. The container must be tightly closed.

Do not store Hydroxycarbamide Medsurge or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Pay particular attention to this when you are opening the capsules to dissolve the contents in water.

Disposal

If your doctor tells you to stop taking Hydroxycarbamide Medsurge, or you find that the expiry date has passed, return any that you have not taken to your treating clinic/ hospital, doctor or pharmacist, so they can be disposed of safely.

Product description

What it looks like

Hydroxycarbamide Medsurge capsules have an opaque pink body and an opaque light green cap containing a white to off-white powder. They are supplied in blister (PVC/Aclar film, sealed with aluminium foil) in pack of 30, 100.

Not all presentations may be marketed.

Ingredients

Active ingredients:

Each capsule contains 500mg of hydroxycarbamide (hydroxyurea).

Inactive ingredients:

Each capsule also contains citric acid, lactose monohydrate, magnesium stearate, disodium phosphate, gelatin, titanium dioxide, sodium lauryl sulfate & capsule colourants (erythrosine, indigo carmine and quinoline yellow).

Sponsor

Australian Sponsor

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