

HYDROXYCARBAMIDE MEDSURGE CAPSULES

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Hydroxycarbamide Medsurge?

Hydroxycarbamide Medsurge capsules contain the active ingredient hydroxycarbamide (hydroxyurea). Hydroxycarbamide Medsurge is used to treat various types of cancers such as leukemia and cancer of the ovary.

For more information, see Section [1. Why am I using Hydroxycarbamide Medsurge?](#) in the full CMI.

2. What should I know before I use Hydroxycarbamide Medsurge?

Do not use if you have ever had an allergic reaction to Hydroxycarbamide Medsurge or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Hydroxycarbamide Medsurge?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Hydroxycarbamide Medsurge and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Hydroxycarbamide Medsurge?

- Hydroxycarbamide Medsurge capsules may be given to you at the hospital or surgery, or you may take them yourself at home
- Swallow Hydroxycarbamide Medsurge capsules with a glass of water
- Hydroxycarbamide Medsurge is taken as a single dose and can be taken each day, or once every three days, at about the same time each day.

More instructions can be found in Section [4. How do I use Hydroxycarbamide Medsurge?](#) in the full CMI.

5. What should I know while using Hydroxycarbamide Medsurge?

Things you should do	<ul style="list-style-type: none">Be sure to keep all your doctor's appointments so your progress can be checkedRemind any doctor, dentist, nurse or pharmacist you visit that you are using Hydroxycarbamide Medsurge
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine or change the dosage without checking with your doctor
Driving or using machines	<ul style="list-style-type: none">Hydroxycarbamide Medsurge may cause dizziness, light-headedness, or tiredness in some people. If this occurs do not drive.Be careful driving or operating machinery until you know how Hydroxycarbamide Medsurge affects you
Looking after your medicine	<ul style="list-style-type: none">Hydroxycarbamide Medsurge capsules should be stored below 25°C in a cool dry place. The container must be tightly closed.

For more information, see Section [5. What should I know while using Hydroxycarbamide Medsurge?](#) in the full CMI.

6. Are there any side effects?

If you get any of the following side effects, tell your doctor immediately or go to Accident and Emergency at your nearest hospital: chills, fever, fast heartbeat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body. Tell your doctor or nurse as soon as possible if you notice any of the following: nausea, vomiting, diarrhoea, stomach pain or discomfort, constipation. High fever (greater than 39°C) that requires hospitalization, feeling tired or sleepy, fever, high temperature, chills. Discolouration or ulcers on the skin, decay of the skin or nails, nail discolouration. Fever, severe chills. Pain in lungs or difficulty breathing, coughing. Sore mouth, tiredness, headaches, being short of breath, dizziness, convulsions. 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. Itching of the skin, joint aches, blisters that look like hives on the upper body, legs, arms, palms, hands, or feet and may involve the face or lips. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HYDROXYCARBAMIDE MEDSURGE

Active ingredient(s): *Hydroxycarbamide (hydroxyurea)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hydroxycarbamide Medsurge. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hydroxycarbamide Medsurge.**

Where to find information in this leaflet:

1. [Why am I using Hydroxycarbamide Medsurge?](#)
2. [What should I know before I use Hydroxycarbamide Medsurge?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Hydroxycarbamide Medsurge?](#)
5. [What should I know while using Hydroxycarbamide Medsurge?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Hydroxycarbamide Medsurge?

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

Hydroxycarbamide Medsurge is used to treat various types of cancers such as, leukemia and cancer of the ovary.

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

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

2. What should I know before I use Hydroxycarbamide Medsurge?

Warnings

Do not use Hydroxycarbamide Medsurge if:

- you are allergic to hydroxyurea, or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you can use this medicine.
- 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 Medsurge is appropriate in this situation.
- you are pregnant or intend to become pregnant

- the packaging shows signs of tampering

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

- liver or kidney problems
- any condition which reduces your blood cell “counts” such as white cells (leukopenia), neutrophils (neutropenia) or platelets (thrombocytopenia).
- infection or high temperature. Your doctor may decide to delay your treatment until the infection has gone.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breast feeding

Tell your doctor and do not take Hydroxycarbamide Medsurge if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Women who take Hydroxycarbamide Medsurge are advised to use birth control during therapy and for at least 6 months after therapy.

If you have not told your doctor about any of the above, or not sure whether you should have Hydroxycarbamide Medsurge, talk to your doctor.

3. What if I am taking other medicines?

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

Some medicines and Hydroxycarbamide Medsurge may interfere with each other. These include:

- Vaccinations. Hydroxycarbamide Medsurge may suppress the body's normal defence 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 Medsurge 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hydroxycarbamide Medsurge.

4. How do I take Hydroxycarbamide Medsurge?

How much to take

Your doctor will decide what dose you will receive. Your dose of Hydroxycarbamide Medsurge capsules is worked out based on your body weight and height, the type of cancer you have, and other medicines you are taking. The dose that worked out for you may be different to the dose for another patient.

Hydroxycarbamide Medsurge 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 Medsurge you receive.

How to take Hydroxycarbamide Medsurge

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

Swallow Hydroxycarbamide Medsurge capsules 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 Hydroxycarbamide Medsurge

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 Medsurge at about the same time each day that you are to take it.

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

How long it is given

- Several courses of Hydroxycarbamide Medsurge 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 Medsurge unless your doctor tells you to- even if you feel better.

If you forget to take Hydroxycarbamide Medsurge

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 you missed.

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

If you take too much Hydroxycarbamide Medsurge

If you are in hospital Hydroxycarbamide Medsurge 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 Medsurge at home and think that you or someone else may have taken too many Hydroxycarbamide Medsurge capsules, you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**),
- or contact your doctor,
- or go to the Emergency Department at your nearest hospital.

You should 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, discoloration of the skin, fluid retention associated with the hands & feet followed by scaling of the skin in these areas, soreness & inflammation of the mouth.

5. What should I know while using Hydroxycarbamide Medsurge?

Things you should do

Be sure to keep all your doctor's appointments and follow-up appointments in order to get the best effect from your treatments, and so your progress can be checked.

Remind any doctor, dentist, nurse or pharmacist you visit that you are having Hydroxycarbamide Medsurge.

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.

Tell your doctor, dentist or pharmacist straight away that you are taking Hydroxycarbamide Medsurge if you:

- are about to be started on any new medicine.
- plan to have surgery that needs a general anaesthetic.

Hydroxycarbamide Medsurge 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 of 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 should not do

- give Hydroxycarbamide Medsurge to anyone else, even if they have the same condition as you.
- Take Hydroxycarbamide Medsurge to treat any other complaints unless your doctor tells you to.
- stop taking Hydroxycarbamide Medsurge, 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Hydroxycarbamide Medsurge affects you.

As with other medicines used to treat cancer, Hydroxycarbamide Medsurge may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Hydroxycarbamide Medsurge 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.

Looking after your medicine

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

Follow the instructions on the label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Pay particular attention to this when you are opening the capsules to dissolve the contents in water.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are having Hydroxycarbamide Medsurge.

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut and digestion-related: <ul style="list-style-type: none">• nausea• vomiting• diarrhoea• stomach pain or discomfort• constipation Signs of infections such as: <ul style="list-style-type: none">• high fever (greater than 39°C) that requires hospitalisation• feeling tired or sleepy• fever• high temperature• chills Skin and hair: <ul style="list-style-type: none">• discoloration or ulcers on the skin• decay of the skin or nails• nail discoloration	Tell your doctor if you have any of these side effects and they worry you.
Signs of frequent infections such as: <ul style="list-style-type: none">• fever• severe chills Respiratory: <ul style="list-style-type: none">• pain in lungs or difficulty breathing	Tell your doctor or nurse as soon as possible if you notice any of

<ul style="list-style-type: none"> coughing <p>These could be a sign of serious lung disease.</p> <p>Other:</p> <ul style="list-style-type: none"> sore mouth tiredness headaches being short of breath dizziness convulsions <p>Signs of systemic lupus erythematosus:</p> <ul style="list-style-type: none"> 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). 	these side effects
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Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction such as:</p> <ul style="list-style-type: none"> itching of the skin joint aches blisters that look like hives on the upper body, legs, arms, palms, hands, or feet and may involve the face or lips 	<p>Tell your doctor or nurse straight away if you notice any of these serious side effects.</p>
<p>Signs of a sudden life-threatening allergic reaction:</p> <ul style="list-style-type: none"> chills fever fast heartbeat shortness of breath wheezing or coughing difficulty breathing dizziness flushing sweating swelling of the face, tongue or other parts of the body 	<p>Tell your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these life-threatening side effects.</p>

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

The benefits and side effects of Hydroxycarbamide Medsurge may take some time to occur. Therefore, even after you have finished your Hydroxycarbamide Medsurge treatment you should tell your doctor immediately if you notice any of the side effects listed above.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Hydroxycarbamide Medsurge contains

Active ingredient (main ingredient)	hydroxycarbamide (hydroxyurea)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> citric acid dibasic sodium phosphate erythrosine gelatin indigo carmine lactose monohydrate magnesium stearate quinoline yellow sodium lauryl sulfate titanium dioxide
Potential allergens	NA

Do not take this medicine if you are allergic to any of these ingredients.

What Hydroxycarbamide Medsurge looks like

Hydroxycarbamide Medsurge 500 mg capsules are Size 0 hard gelatin capsules with an opaque pink body and an opaque light green cap containing a white to off-white powder.

They are supplied in PVC/PCTFE(Aclar)/Al blister packs of 100 (AUST R 313761).

Who distributes Hydroxycarbamide Medsurge

Medsurge Healthcare Pty Ltd

Unit 1&2, 6-7 Gilda Court

Mulgrave, Victoria 3170

Telephone: 1300 788 261

Website: www.medsurgehc.com

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