

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 HYDREA?

HYDREA contains the active ingredient hydroxycarbamide. HYDREA 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 HYDREA?](#) in the full CMI.

2. What should I know before I use HYDREA?

Do not use if you have ever had an allergic reaction to HYDREA 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 HYDREA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYDREA 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 HYDREA?

- HYDREA capsules may be given to you at the hospital or surgery, or you may take them yourself at home
- Swallow HYDREA capsules with a glass of water
- HYDREA 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 HYDREA?](#) in the full CMI.

5. What should I know while using HYDREA?

Things you should do	<ul style="list-style-type: none">• Be sure to keep all your doctor's appointments so your progress can be checked• Remind any doctor, dentist, nurse or pharmacist you visit that you are using HYDREA
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">• HYDREA 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 HYDREA affects you
Looking after your medicine	<ul style="list-style-type: none">• Store HYDREA below 25°C, in a tightly closed container, in a dark place, protected from light, where children cannot reach it

For more information, see Section [5. What should I know while using HYDREA?](#) 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 heart beat, 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.

HYDREA®

Active ingredient: *hydroxycarbamide (hi-DROX-eee-Car-bah-myd)*

Consumer Medicine Information (CMI)

This leaflet answers some common questions about HYDREA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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 HYDREA.

Where to find information in this leaflet:

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

1. Why am I using HYDREA?

HYDREA contains the active ingredient **hydroxycarbamide**, an anti-cancer medicine. It interferes with the replication of cells and causes cell death, particularly in cancer cells.

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

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

HYDREA 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 HYDREA?

Warnings

Do not use HYDREA if:

- you are allergic to hydroxycarbamide, 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 HYDREA 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.

Talk to your doctor if you are using a continuous glucose monitor (CGM) to test your blood glucose. Hydroxycarbamide may affect your sensor glucose results and may lead to low blood sugar (hypoglycaemia). Talk to the healthcare provider that prescribed your CGM about whether it is safe to use while you are taking HYDREA.

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

Pregnancy and breastfeeding

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

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

HYDREA 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.

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

Women who take Hydrea 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 HYDREA, 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 vaccinations, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

- Vaccinations. HYDREA 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 HYDREA, 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 HYDREA.

4. How do I use HYDREA?

How much to take

Your doctor will decide what dose you will receive. Your dose of HYDREA 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 worked out for you may be different to the dose for another patient.

HYDREA 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 HYDREA you receive.

How to take HYDREA

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

Swallow HYDREA capsules with a glass of water.

When to take HYDREA

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

HYDREA 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 HYDREA 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 HYDREA unless your doctor tells you to - even if you feel better.

If you forget to take HYDREA

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 use too much HYDREA

If you are in hospital HYDREA 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 HYDREA at home and think that you or someone else may have taken too many HYDREA 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, 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.

5. What should I know while using HYDREA?

Things you must 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 HYDREA.

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 HYDREA if you:

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

HYDREA 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

<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). 	
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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>Signs of a sudden life-threatening allergic reaction:</p> <ul style="list-style-type: none"> chills fever fast heart beat 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 or nurse straight away if you notice any of these serious side effects.</p> <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 HYDREA, or are taking other medications as well as HYDREA, 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 HYDREA may take some time to occur. Therefore even after you have finished your HYDREA 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 HYDREA contains

Active ingredient (main ingredient)	hydroxycarbamide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> citric acid lactose monohydrate magnesium stearate dibasic sodium phosphate gelatin titanium dioxide capsule colourants (erythrosine, indigo carmine and iron oxide yellow) OPACODE monogramming ink S-1-277002 BLACK

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

What HYDREA looks like

HYDREA 500 mg capsules have an opaque green and opaque pink capsule shell, with "CHP 500" marked on each capsule. They are supplied in bottles of 100 capsules. (Aust R 47486).

Who distributes HYDREA

Link Medical Products Pty Ltd

5 Apollo Street

Warriewood, NSW, 2102

Ph: 1800 181 060

linkhealthcare.com.au

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