

HYDREA®

hydroxycarbamide (hi-DROX-eee-Car-bah-myd)
(hydroxyurea) (hi-DROX-eee-U-re-aah)

Consumer Medicine Information

What is in this leaflet

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking HYDREA against the benefits they expect it will have for you. This leaflet does not contain everything about HYDREA. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What HYDREA is used for

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

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

HYDREA 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 HYDREA for another reason. Ask your doctor if you have any questions about why HYDREA was prescribed for you.

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

HYDREA 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 are given HYDREA

When you must not take HYDREA

- **You must not take HYDREA if you have an allergy to HYDREA, or any of the ingredients listed at the end of this leaflet.**
- **Do not take HYDREA 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 HYDREA is appropriate in this situation.

- **Do not take HYDREA if you are pregnant or intend to become pregnant.**

HYDREA 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 HYDREA and for at least 12 months after you stop using it. HYDREA may cause birth defects if either the male or female is using it at the time of conception.

- **Do not take HYDREA 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 HYDREA if the packaging shows signs of tampering**

Before you start to take HYDREA

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as 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 HYDREA 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 breast-feeding 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.

If you have not told your doctor about any of the above, tell them before you start HYDREA.

If you are not sure whether you should have HYDREA, talk to your doctor.

If you have not told your doctor about any of the above, tell them before you start having HYDREA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including vaccinations, or any 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 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 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.

Your doctor may have more information on medicines to be careful with or avoid while having HYDREA.

How to take 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 and on the type of cancer you have. 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 it

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.

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

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.

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.

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 take too much (Overdose)

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 - Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) or go to Accident or Emergency at your nearest hospital, if you think that you or someone else may have taken too many HYDREA 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 HYDREA

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 having HYDREA.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having HYDREA.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are having HYDREA.

If you become pregnant while having HYDREA, 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.

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 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 HYDREA to anyone else, even if they have the same condition as you.

Do not take HYDREA to treat any other complaints unless your doctor tells you to.

Do not stop taking HYDREA, 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 HYDREA affects you.

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

Like other medicines that treat cancer, HYDREA 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 HYDREA.

- 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 HYDREA, or are taking other medications as well as HYDREA, 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 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.

Product Description

What it looks like

HYDREA capsules have an opaque green and opaque pink capsule shell, with "BMS 303" marked on each capsule. They are supplied in bottles of 100 capsules.

Ingredients

Active:

The active ingredient in HYDREA capsules is hydroxycarbamide (hydroxyurea).

Each capsule contains 500mg of hydroxycarbamide (hydroxyurea).

Inactive:

Each capsule also contains citric acid, lactose monohydrate, magnesium stearate, dibasic sodium phosphate heptahydrate, gelatin, titanium dioxide & capsule colourants (erythrosine,

indigo carmine and iron oxide yellow) and OPACODE monogramming ink
S-1-277002 BLACK (ARTG PI No: 107581).

Storage

HYDREA capsules should be stored below 30°C in a cool dry place. The container must be tightly closed.

Do not store HYDREA 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 HYDREA, return any that you have not taken to your treating clinic/hospital, doctor or pharmacist, so they can be disposed of safely.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,

4 Nexus Court, Mulgrave,

Victoria 3170, Australia

Registration Numbers:

AUST R 47486 - HYDREA Capsules 500mg - 100 per bottle

Where to get further information

Your doctor is the best person to answer any further questions you may have about HYDREA.

Anything your doctor tells you about HYDREA should be followed even if it is different from what is in this leaflet.

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