

Package leaflet: Information for the patient

Hydrea 500 mg Hard Capsules

Hydroxycarbamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Hydrea (Capsules) is and what it is used for
2. What you need to know before you take Hydrea
3. How to take Hydrea
4. Possible side effects
5. How to store Hydrea
6. Contents of the pack and other information

1. What Hydrea is and what it is used for

The name of your medicine is Hydrea. Each capsule contains hydroxycarbamide as the active ingredient. Hydroxycarbamide belongs to a group of medicines called anti-neoplastic medicines. These medicines interfere with the growth of cancer cells.

Hydrea is used to treat some types of cancer such as cervical cancer; and a type of leukaemia called chronic myeloid leukaemia (CML). The precise reason why you are being given Hydrea is best discussed with your doctor.

2. What you need to know before you take Hydrea

Do not take Hydrea Capsules:

- if you are allergic to hydroxycarbamide or any of the other ingredients of this medicine (listed in section 6).
- if you have history of any **blood problems**
- if you have severe anaemia

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydrea.

If hemolytic anemia (disorder in which red blood cells are destroyed faster than they can be made) is detected when the blood tests are checked, your doctor will stop treatment with Hydrea.

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

In long term use of Hydrea, secondary leukaemia has been reported. Skin cancer has been reported in patients receiving long term hydroxycarbamide. You should protect your skin from the sun and regularly inspect your skin yourself during the treatment and after discontinuation of the

therapy with hydroxycarbamide. Your doctor will also inspect your skin during routine follow-up visits.

Take special care with Hydrea 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

Children

There is limited experience with the use of Hydrea in this age group.

Other medicines and Hydrea

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- 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 Hydrea.

Hydrea with food, drink and alcohol

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

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 effective contraceptive measures before and during treatment with Hydrea. For male patients only, this medicine can affect the production of sperm so you might want to discuss the possibility of conservation (by storage of sperm) with your doctor.

When appropriate both male and female patients should discuss effective safe contraceptive measures before, during therapy, and for at least 3 months and 6 months respectively after treatment with Hydrea.

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

Driving and using machines

You may feel drowsy. You should not drive or operate any machinery unless it has been shown not to affect you and have discussed it with your doctor.

Hydrea contains 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.

3. How to take Hydrea

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose is 20-30mg of Hydrea 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 Hydrea and may be given a lower dose.

You can take this medicine at any time of the day, before or after meals. 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 Hydrea it is important that you drink plenty of fluids. This will help your kidneys work well.

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

You should keep taking your capsules until your doctor tells you to stop.

If you take more Hydrea than you should

If you take too many capsules you should go to your nearest hospital Casualty Department immediately and take the medicine carton with you. The symptoms of overdose include; soreness, swelling of hands and feet and redness of skin.

If you forget to take Hydrea

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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following symptoms, you should stop taking the capsules and tell your doctor immediately as these may be signs of an allergic reaction:

- **swelling of the face, lips, tongue or throat**
- **itching or skin rashes**
- **difficulty breathing**
- **unexplained fever, chills or sore throat**
- **wasting of muscles**
- **peeling of the skin and nails**

Tell your doctor immediately if you have a high fever (>39°C) with stomach, lung, muscle, liver, skin and heart problems within 6 weeks of taking Hydrea.
The following side effects have been seen in some people:

Very common: may affect more than 1 in 10 people

- 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
- 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).
- sores on the lips or mouth
- difficulty or pain passing urine
- absence or low amount of sperm in the semen (azoospermia or oligospermia).
- loss of appetite
- sickness, diarrhoea, constipation, abdominal pain
- weakness, loss of energy
- skin problems may occur including 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

Common: may affect up to 1 in 10 people

- unexplained shortness of breath or cough with fever
- numbness or tingling of hands or feet
- skin cancer
- headache
- 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)

Rare: may affect up to 1 in 1000 people

- skin ulceration with severe infection
- tumour lysis syndrome (complications of substances released from treated cancer cells entering the blood)

Very rare: may affect up to 1 in 10000 people

- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints

Not known: frequency cannot be estimated from available data

- Change in the color of the nails
- **fever, cough or breathing problems, this could be a sign of serious lung disease (frequency not known)**
- Hemolytic anemia

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance,
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrea

Do not store your tablets above 25°C.
Store in the original package in order to protect from moisture.
Do not use this medicine after the expiry date which is stated on the blister or carton after EXP.
The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children or pets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hydrea contains

- Each Hydrea capsule contains 500 mg of the active ingredient hydroxycarbamide.
- The other ingredients are citric acid anhydrous, erythrosine (E127), gelatin, indigotine (E132), lactose monohydrate, magnesium stearate, sodium laurilsulfate (as processing aid), sodium phosphate, titanium dioxide (E171), yellow iron oxide (E172) and Opacode S-1-277002.

What Hydrea looks like and contents of the pack

Hydrea capsules are pink, opaque capsules with green, opaque caps, and 'CHP 500' printed on them in black.

Hydrea capsules are packed in blister packs of 100 capsules.

People who are not taking Hydrea should not be exposed to it. To decrease the risk of exposure, wear disposable gloves when handling Hydrea. Anyone handling Hydrea should wash their hands before and after contact with the capsules. Pregnant women should not handle Hydrea.

For any information about this medicine, please contact the Marketing Authorisation Holder.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489 Greifswald
Germany

Manufacturer

Latina Pharma S.p.A.,
Via Murillo, 7,
04013 Sermoneta (LT),
Italy.

or

Haupt Pharma Amareg GmbH
Donaustauer Straße 378,
93055 Regensburg
Germany

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