Package leaflet: Information for the user

Hydroxyurea medac 500 mg capsule, hard

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. See section 4.

What is in this leaflet

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

1. What Hydroxyurea medac is and what it is used for

Hydroxyurea medac contains the active substance hydroxycarbamide, which belongs to a group of medicines used in certain blood diseases, and which interferes with the growth of cancer cells**.**

This medicine has been prescribed by your doctor for the treatment of blood diseases (tumours of the bone marrow: chronic myeloid leukaemia, essential thrombocythaemia and polycythaemia vera).

2. What you need to know before you take Hydroxyurea medac

Do not take Hydroxyurea medac
- if you are allergic to hydroxycarbamide or any of the other ingredients of this medicine (listed in section 6).
- if your blood cell count is too low.

Warnings and precautions
Talk to your doctor or pharmacist before taking Hydroxyurea medac.

Treatment with hydroxycarbamide requires extensive supervision. You will have blood tests before and during treatment to check that you have enough blood cells as well as sufficient kidney and liver function to receive this medicine. The blood tests will normally be carried out once a week.
You should inform your doctor if you have ever suffered from gout. You should inform your doctor if you have folic acid deficiency.

In case you have decreased red blood cell counts (anaemia) before or develop it during treatment red blood cells may be replaced when needed. If haemolytic anaemia (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 Hydroxyurea medac.

You should drink plenty of fluids during treatment.

If you suffer from kidney and/or liver problems you should inform your doctor before treatment with this medicine is started.

If you receive long-term treatment with hydroxycarbamide secondary leukaemia may develop. To what extent this is due to your underlying disease or to the treatment with hydroxycarbamide is presently unknown.

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.

You may get leg ulcers. In this case your doctor will decide if you should continue to take this medicine. The ulcers usually heal slowly over some weeks if you stop taking this medicine.

Other medicines and Hydroxyurea medac
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you have previously received or are still receiving any similar medicines or irradiation therapy side effects can occur more frequently and more severely. These effects primarily include decrease in the number of blood cells (suppressed bone marrow function), inflammation of the mucous membrane of the stomach and inflammation of the skin.

Previous or simultaneous irradiation can result in reddening and irritation of the skin.

Hydroxycarbamide may increase the activity of NRTI (nucleoside reverse transcriptase inhibitors) which are medicines used for the treatment of HIV (e.g. didanosine, stavudine). Hydroxycarbamide in combination with didanosine, stavudine, and indinavir has been shown to cause a drop in white cell count (CD4 lymphocytes decreased). The combination of hydroxycarbamide and NRTI may increase the risk of side effects of NRTI.

If you recently had a vaccination or are planning to have one, tell your doctor.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
There is a risk of harmful effects on the developing baby. You should therefore not take this medicine during pregnancy unless it is specifically prescribed by your doctor.

You must use effective contraception before the start of, during and for six months after treatment with this medicine. If you become pregnant while taking or after having taken this medicine, you should contact your doctor.

Breast-feeding
Hydroxyurea medac must not be taken during breast-feeding. The active substance of Hydroxyurea medac passes into breastmilk. Consult the doctor for advice.

Fertility
During treatment and for three months after treatment has stopped men are advised to use effective contraception. Please ask your doctor about the possibility of sperm conservation before first starting treatment.
Genetic counselling is recommended for patients intending to have children after therapy.

Driving and using machines
Your ability to react may be impaired during treatment with Hydroxyurea medac. You should bear this in mind when heightened attention is required, e.g. when driving and using machines.

Hydroxyurea medac contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Hydroxyurea medac contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Hydroxyurea medac

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

Adults
In chronic myeloid leukaemia the common initial dose is 40 mg/kg bodyweight daily. The dose is then adjusted individually depending on the white blood cell count.

In polycythaemia vera the common initial dose is 15 – 20 mg/kg bodyweight daily. The dose is then adjusted individually to 1 – 2 capsules (500 – 1,000 mg) depending on the blood cell count.

In essential thrombocythaemia the common initial dose is 15 mg/kg bodyweight daily with individual dose adjustment depending on the blood cell count.

Elderly patients
Elderly patients may be more sensitive to hydroxycarbamide, and may require a lower dose.

The capsules should be swallowed whole and must not disintegrate in the mouth. The capsules should be handled with care. You should use gloves or wash your hands thoroughly after handling them. Even if the risks for the foetus are minimal, pregnant women should avoid handling the capsules.

If you take more Hydroxyurea medac than you should
If you have taken a larger dose of this medicine than you have been prescribed always contact a doctor or a hospital. You may experience symptoms affecting the mucous membranes and skin.

If you forget to take Hydroxyurea medac
It is important to follow the course of medication exactly as prescribed by your doctor.
Do not take a double dose to make up for a forgotten dose. If you have missed one single dose, continue treatment as prescribed. If you have missed several doses, continue treatment as prescribed, but contact your doctor for further advice.

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.

Contact your doctor immediately if you experience symptoms such as:
- Fever, cough or breathing problems, this could be a sign of serious lung disease (frequency not known)

- High fever (>39°C) with stomach, lung, muscle, liver, skin and heart problems within 6 weeks of taking Hydroxyurea medac (frequency rare)

Very common (may affect more than 1 in 10 people)
- Absence or low amount of sperm in semen (azoospermia or oligospermia)
- Decrease in the number of blood cells (suppressed bone marrow function), especially white blood cells (leukocytopenia), including type of white blood cell which help the body to fight disease (CD4 lymphocytes decreased), red blood cells (anaemia) and platelets (thrombocytopenia)
- Feeling sick (nausea), vomiting, loss of appetite, mouth sores (stomatitis), diarrhoea, constipation, abdominal pain, inflammation of the lining (mucositis), digestion troubles (dyspepsia)
- Black tarry stools or blood in the stools
- In combination with certain HIV treatments: inflammation of the pancreas (pancreatitis) with stomach or abdominal pain.
- Fever caused by the medicine, chills, feeling of discomfort (malaise), weakness, loss of energy
- Skin ulcers, especially leg ulcers
- Skin eruptions in form of spots and blisters (maculopapular rash), redness of the face, redness of hands and feet (hand-foot syndrome)
- Skin changes such as purple-coloured rash and thinning of the skin; darkening and wasting of nails and skin, itching, small, violet skin bumps; scaling of the skin, blackening and death of skin
- Loss of hair (alopecia)
- Temporary kidney problems with elevation of certain blood parameters like uric acid, urea and creatinine
- Difficulties in passing urine

Common (may affect up to 1 in 10 people)
- Enlarged immature red blood cells (megaloblastosis)
- Skin cancer
- Increase in liver enzymes
- 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
- 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
- Neurological disturbances including headache, dizziness, drowsiness, disorientation, hallucinations and fits
- Acute and chronic lung reactions with changes in lung tissue seen in x-ray and shortness of breath, as well as fever in acute reactions and dry cough in chronic reactions
- In combination with certain HIV treatments: numbness and tingling or pain in arms and legs (peripheral neuropathy) and abdominal pain, nausea or vomiting or yellow skin (hepatotoxicity)

Uncommon (may affect up to 1 in 100 people)
- Thick and scaly patches of skin (actinic keratosis)
- High levels of break down product of red blood cells (bilirubin) in blood

Rare (may affect up to 1 in 1,000 people)
- Allergic reactions
- Metabolic complications due to break-down products of cancer cells (tumour lysis syndrome)
- Skin ulceration with severe infection

Very rare (may affect up to 1 in 10,000 people)
- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints
- Reduced kidney function

Not known (frequency cannot be estimated from the available data)
- High blood levels of potassium which can cause abnormal heart rhythm
- Fever, cough or breathing problems, this could be a sign of serious lung disease; allergic inflammation of air sacs
- Haemolytic anaemia
- Dry skin

Cases of low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma have been observed in post-marketing surveillance.

If you receive long-term treatment with hydroxycarbamide secondary leukaemia (blood cancer) may develop. To what extent this is due to your underlying disease or to the treatment with hydroxycarbamide is presently unknown.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Hydroxyurea medac

Do not store above 25 °C.

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 Hydroxyurea medac contains
- The active substance is hydroxycarbamide. Each capsule contains 500 mg hydroxycarbamide.
- The other ingredients are lactose monohydrate**,** calcium citrate, disodium citrate, magnesium stearate, gelatin and titanium dioxide (colorant E171).

What Hydroxyurea medac looks like and contents of the pack
White hard capsules (capsules).
Available pack sizes: 50 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

medac
Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6
22880 Wedel
Germany
Phone: +49 4103 8006 0
Fax: +49 4103 8006 100

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Austria, Denmark, Finland, Greece, Iceland, Netherlands, Norway, Portugal, Sweden: Hydroxyurea medac

Germany: Syrea

United Kingdom (Northern Ireland): Hydroxycarbamide

This leaflet was last revised in 2023-04-05