Package leaflet: Information for the user

Lomustine medac 40 mg hard capsules
lomustine

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 Lomustine medac is and what it is used for

Lomustine medac belongs to a group of medicines against cancer known as nitrosourea alkylating agents. These medicines inhibit the growth of cancer cells.
Lomustine medac is used for the treatment of various types of cancer, and especially for treating brain tumours, malignant melanoma (a type of skin cancer) and lymphoma (tumour in the lymph nodes).

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

Do not take Lomustine medac
- if you are allergic to lomustine, to other nitrosourea alkylating agents or any of the other ingredients of this medicine (listed in section 6),
- if the tumour previously failed to respond to other nitrosourea alkylating agents,
- if your blood-cell count is too low (certain blood samples are always taken before the treatment in order to check your blood-cell count),
- if you have impaired kidney function,
- if you are pregnant,
- if you are breast-feeding,
- if you are allergic to wheat,
- if you receive vaccinations against yellow fever or other live vaccines at the same time.

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

Please note that lomustine may have an effect on your bone marrow function and that this effect may occur after a certain amount of time. This may increase the risk of bleeding or getting an infection. The toxic effects of lomustine on your blood formation system will increase over the time you are taking this medicine. Therefore, your doctor will monitor your blood counts, probably once a week during treatment, and up to 6 weeks after the treatment has been stopped.

You should take lomustine exactly as prescribed by your physician and not repeat the prescribed dose at least for 6 weeks.

Due to the cumulative effect on bone marrow, your doctor may decide to reduce the dose of lomustine based on your blood values.

Before you start taking lomustine, your doctor will check that your lungs, liver and kidney are working properly. These tests will be performed throughout the whole treatment.

Long-term use of lomustine may possibly increase the risk of developing another cancer in the future.

Please note that you are handling a cancer medicine. Take care not to come into contact with the contents of the capsule and wash your hands with soap and water after handling lomustine.

You must not receive live vaccines during treatment with lomustine and until at least 3 months after the end of treatment.

Other medicines and Lomustine medac
No special studies regarding interactions between lomustine and other medicines have been performed. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Treatment may be affected if you use certain other medicines such as medicines that contain:
- Theophylline (medicine against bronchial asthma, lung disease),
- Cimetidine (used in the treatment of e.g. stomach ulcers),
- Medicines that are used to treat epilepsy (convulsions) e.g. phenobarbital,
- Other cytostatic medicines (medicines that inhibit cell growth) and radiation therapy due to an increased risk of adverse effects on the bone marrow. You may be more prone to infections.

You should also inform your doctor if you have been vaccinated recently. Parallel vaccination with yellow fever vaccines may increase the risk of fatal complications. You should therefore not receive vaccination with live vaccines (e.g. yellow fever vaccine) until at least 3 months after the end of treatment with lomustine.

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.

Contraception
Women must use effective contraceptives before the start of, during treatment and for 7 months after treatment is concluded.
Men must use effective contraception before the start of, during and for 4 months after treatment is concluded.

Pregnancy
You must not take lomustine during pregnancy or if you are trying to become pregnant. . If you do become pregnant during treatment or suspect you might be pregnant, speak to your doctor as soon as possible. You should be offered advice regarding the risk of harmful effects on the child through treatment. You should consult your doctor first if you are planning to become pregnant.

Breast-feeding
Do not take lomustine when you are breast-feeding, because lomustine might be excreted in your breast milk. If treatment with lomustine is necessary, you must stop breast-feeding.

Fertility
Lomustine can have a genetically harmful effect. Men who are treated with lomustine should not father a child during their therapy and for 4 months afterwards. As lomustine may affect your fertility, ask your doctor to inform you about possible precautions like sperm conservation before the start of treatment.

Genetic counselling is recommended for patients intending to have children after therapy.

Driving and using machines
This medicine can cause e.g. nausea and vomiting which may reduce your ability to drive or use machines.

Lomustine medac contains lactose and wheat starch
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains only very low levels of gluten (from wheat starch). It is regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One capsule contains no more than 4 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

3. How to take Lomustine medac

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

The dose is determined by your doctor, who will tailor it to your individual needs.

The dose depends on your blood counts and other cytostatic therapy. Your doctor will calculate the dose according to your weight and the blood counts. Your doctor will reduce the dose if you are also receiving other cytostatics or radiotherapy.

The dose for a person of normal build can be expected to be approximately 200 mg lomustine. Lomustine medac capsules are usually taken at one time or spread over 3 days every six to eight weeks. You should take lomustine exactly as prescribed by your doctor and in an interval not less than 6 weeks.

Swallow the capsules unopened and whole together with at least half a glass of water. Do not break the Lomustine medac capsules. If you get the contents of the capsules on your skin or in your mouth by mistake, rinse with plenty of water.

It is important to carry out the treatment precisely as directed by your doctor. Do not discontinue the treatment prematurely without having first contacted your doctor.

Your doctor can change the dose and dosing frequency depending on your blood tests, your general condition, other treatment and the effect Lomustine medac has on you. Ask your doctor, nurse or your pharmacist if you have any questions about your treatment.

If you think that the effect of Lomustine medac is too strong or too weak, contact your doctor or pharmacist.

If you take more Lomustine medac than you should
If you have taken more lomustine than you should, contact your doctor as soon as possible before taking the next dose. Overdose with lomustine has been reported, including fatal cases.

An overdose might express in bone marrow depression (unexplained bruising or bleeding or susceptibility to infections), abdominal pain, diarrhoea, nausea, vomiting, lack of appetite, lethargy, a feeling of dizziness, symptoms of liver damage such as yellowing of the skin and whites of the eyes, cough, shortness of breath, and signs of a nervous-system disease. Multiple organ failure is a possibility in very severe cases.

Tell your doctor immediately if you experience any of these symptoms. In case of an overdose your doctor will decide on any measures that may be necessary, depending on the severity of the intoxication. No specific remedy (antidote) is available. The usual general measures (gastric lavage, appropriate supportive measures) should therefore be started.

If you forget to take Lomustine medac
If you have missed one or more doses, contact your doctor or your pharmacy immediately for advice. Do not take a double dose to make up for a forgotten capsule.

4. Possible side effects

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

Contact your doctor immediately if any of the following side effects occur:

Very common (may affect more than 1 in 10 people)
- Suppression of your bone marrow activity that causes a decrease in the production of blood cells
- Decreased number of platelets (blood cells that help to clot blood). You may suffer from unusual bleedings and bruises.
- Decreased number of certain white blood cells. Your vulnerability for infections may increase.
- Decreased number of red blood cells. You may observe signs of anaemia like weakness, tiredness, laboured breathing with a feeling of apprehension.
- Nausea and/or vomiting and loss of appetite. Nausea and vomiting may occur approximately 3–6 hours after you have taken your dose and usually last for less than 24 hours, possibly followed by reduced appetite for 2–3 days. Your doctor may prescribe other medicines (antiemetics) which you can take concurrently to relieve this. It might also help to take lomustine on an empty stomach.

Common (may affect up to 1 in 10 people)
- Infection, including infection seen in patients with a weakened immune system (e.g. shingles)
- Abnormal coordination
- Difficulties in orientation
- Inflammation of the mucous membranes in the mouth
- Diarrhoea
- Effect on the liver function (usually transient) and increased liver enzyme values. Your doctor will check for this. You should contact your doctor immediately if symptoms of liver damage such as yellowing of the skin and whites of the eyes occur.

Uncommon (may affect up to 1 in 100 people)
- Apathy
- State of being confused
- Stuttering
- Severe reduction of kidney function, injury of the kidneys (inability of the kidney to perform its normal functions). You should contact your doctor immediately if symptoms of kidney damage such as swelling of the hands, ankles or feet or changes in frequency of urination or decrease or absence of urine occur.

Rare (may affect up to 1 in 1,000 people)
- Lung disease affecting the connective tissue causing scarring in the lungs, shortness of breath and dry cough. You should contact your doctor immediately if symptoms like dry-non-productive cough or shortness of breath occur.
- Hair loss

Other possible side effects:

Common (may affect up to 1 in 10 people)•
- Abnormal lack of energy; abnormal drowsiness or sluggishness
- Difficulty in speaking
- Inability to coordinate muscle movements

Rare (may affect up to 1 in 1,000 people)
- Lung damage with tissue scarring and thickening
- Cholestatic jaundice, a condition in which the skin, whites of the eyes and mucous membranes turn yellow due to high levels of bilirubin, a yellow-orange bile pigment, caused by blocked bile flow from the liver
- Abnormal spermatogenesis
- Disturbances in the production of an egg during menstrual cycle

Very rare (may affect up to 1 in 10,000 people)
- Second, unrelated cancer including cancer of the white blood cells (acute leukaemia) and a disease in which the bone marrow does not make enough healthy blood cells or platelets (myelodysplastic syndrome)
- Lasting visual impairment (in combination with radiation treatment)

Not known (frequency cannot be estimated from the available data)
- Lung infiltration (increase in the density of the lung tissue as a result of inflammation)
- Higher nitrogen and waste product levels in your blood (azotaemia)
- Shrinkage of kidney (renal atrophy)
- High levels of bilirubin seen in blood tests (break-down product of the red blood pigment). Your doctor will check for this.

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 the national reporting system listed in Appendix V.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lomustine medac

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

Do not store above 25 °C.
Store the capsules in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton.

Do not throw away any medicines via 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 Lomustine medac contains

- The active substance is lomustine. Each capsule contains 40 mg lomustine.
- The other ingredients are anhydrous lactose, wheat starch, talc and magnesium stearate. The capsule shell consists of gelatin and the colourants titanium dioxide (E 171) and indigotine (E 132).

What Lomustine medac looks like and contents of the pack
Hard capsule, blue
Pack size: 5 capsules, 20 capsules.
Not all pack sizes may be marketed.

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medac
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