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

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.

Please note that lomustine may have an effect on your blood formation system 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 (poisonous) 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.

Do not take Lomustine medac
- if you are allergic to lomustine or any of the other ingredients of this medicine (listed in section 6)
- if you have previously shown hypersensitivity to similar medicines (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 have coeliac disease (a serious digestive disorder of the small intestine) or are allergic to wheat• if you have had a vaccination against yellow fever or another live vaccine vaccination and suffer from immunosuppression
- if you are pregnant
- if you are breast-feeding

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

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.

Both female and male patients of reproductive age should use contraceptives during treatment and for at least 6 months after treatment ends. See also the section "Pregnancy and breast-feeding".

Long-term use of nitrosoureas has been reported to be possibly associated with the development of new cancerous tumours (secondary cancers).

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

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 (used against e.g. asthma)
- cimetidine (used in the treatment of e.g. stomach ulcers)
- phenobarbital (used in the treatment of epilepsy)
- other cytostatic medicines (medicines that inhibit cell growth), because co-administration can lead to complications as a result of interactions between the medicines.

You should also inform your doctor if you have been vaccinated recently.

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
Lomustine medac should not be taken during pregnancy or if you are planning to become pregnant. Both men and women should use contraceptives during treatment with lomustine and also for at least 6 months after treatment is concluded.
You should consult your doctor first if you are planning to become pregnant. Also contact your doctor immediately if you become pregnant while treatment is in progress, as taking lomustine might affect your unborn baby detrimentally.

Breast-feeding
You should not breast-feed while you are being treated with Lomustine medac, because lomustine might be excreted in your breast milk. If treatment with lomustine is necessary, you must stop breast-feeding.

Fertility
Men who are treated with lomustine should not father a child during their therapy and up to 6 months afterwards. As lomustine may affect your fertility, ask your doctor to inform you about possible precautions like sperm conservation before you start with the treatment.

Driving and using machines
Lomustine medac can have adverse effects on the ability to drive vehicles and use machines, e.g. because of nausea and vomiting.

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 also contains wheat starch. Patients with wheat allergy or coeliac disease should not take this medicine (see above “Do not take Lomustine medac”).

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 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
Seek medical advice immediately. Accidental overdose with lomustine has been reported, including fatal cases.
An overdose might express in abdominal pain, diarrhoea, regurgitation, lack of appetite, lethargy, a feeling of dizziness, cough or shortness of breath, unexplained bruising or bleeding or susceptibility to infections.

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)

- Various types of effects on the blood, such as too little red and white blood cells. This can manifest itself in the fact that yousuffer repeated infections, e.g. sore throat or cough. You should contact your doctor immediately if this occurs.
- Low levels of blood platelets which can lead to bleeding and bruising.

- Nausea, vomiting and loss of appetite. Nausea and vomiting usually occur approximately 3-6 hours after you have taken your dose and can last for 24–48 hours, possibly followed by reduced appetite for 2–3 days. Your doctor may prescribe other medicines (anti-emetics) 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)
- Effect on the liver (usually transient) and increased liver-enzyme values. **Rarely** jaundice due to impaired bile flow occur. 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, difficulties in orientation, confusion and stuttering

Rare (may affect up to 1 in 1,000 people)
- Pneumonia. You should contact your doctor immediately if symptoms like dry-non-productive cough or shortness of breath occur.

Very rare (may affect up to 1 in 10,000 people)
- Kidney failure, decrease in kidney size and kidney damage. 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.

Other possible side effects:

Common (may affect up to 1 in 10 people)
- Inflammation in the mouth (stomatitis)
- Diarrhoea

Rare (may affect up to 1 in 1,000 people)
- Lung reactions with changes in lung tissue seen in x-ray, shortness of breath and dry cough

Very rare (may affect up to 1 in 10,000 people)
- Appearance of cancer of another type (secondary malignancy)
- Lasting visual impairment (in combination with radiation treatment)
- Hair loss

Not known (frequency cannot be estimated from the available data)
- Acute leukaemia (blood cancer) and myelodysplastic syndrome (blood disorder associated with insufficient production of blood cells in the bone marrow)
- Abnormal coordination
- Sleepiness, sluggishness
- Difficulty speaking, unclear speech
- Increase in bilirubin (break-down product of the red blood pigment)

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.

Marketing Authorisation Holder and Manufacturer
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This leaflet was last revised in 2024-01-15