**Package leaflet: Information for the user**

**Lomustine "medac" 40 mg 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

This medicine contains an active ingredient called lomustine.

Lomustine belongs to a group of medicines called antineoplastic or cytotoxic agents. These medicines affect growth and proliferation of cancer cells.

Lomustine "medac" capsules are used to treat tumours and other malignant growths or diseases, for example, cancer of the lung or skin.

## 2. What you need to know before you takeLomustine "medac"

**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 had a similar medicine before which you had to stop taking because of side effects or because it was ineffective.
- if you have any blood disorder.
- if you have severe kidney problems.
- if you have coeliac disease (your body cannot digest gluten) or wheat allergy.
- if you have had a vaccination against yellow fever or another live vaccine vaccination and suffer from immunosuppression.
- if you are pregnant or breastfeeding.

You and your partner should avoid becoming pregnant or fathering a child during treatment and for at least 6 months after your treatment with lomustine has stopped.

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

- You should take lomustine exactly as prescribed by your physician and not repeat the prescribed dose at least for 6 weeks.
- Your doctor will check your blood weekly during your therapy and up to 6 weeks afterwards.
- Lomustine might impair the function of your blood-building system, and increase the risk of bleeding and infections. This effect might occur after a certain time of therapy.
- As the toxic effects of lomustine to your blood-building system are cumulative your doctor might decide to adjust the dosage of your therapy.
- Tell your doctor if you have any liver problems. Before you start with lomustine, your doctor will check the function of your liver and additionally of your lung and kidneys. These tests will be repeated during the time of your therapy.
- Long term use of nitrosoureas has been reported to be possibly associated with the development of secondary cancers.

**Other medicines and Lomustine "medac"**
No special studies regarding interactions between lomustine and other medicines have been performed, but tell your doctor if you are taking any of the following medicines:
- theophylline – medicine used in the treatment of respiratory tract diseases, e.g. asthma
- cimetidine – medicine largely used in the treatment of heartburn and peptic ulcers
- other chemotherapeutic medicines, because co-administration can lead to complications due to interactions between the medicines.

Tell your doctor if you have ever taken phenobarbital – an anticonvulsant, or any other antiepileptic medicine.

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

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

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

Pregnancy
Pregnant women should not take this medicine. It is important to tell your doctor if you are pregnant or think you might be pregnant, because safe use in pregnancy has not been established. If you become pregnant while you are treated with lomustine tell your doctor immediately, as taking lomustine might affect your unborn baby detrimentally. If you are of childbearing age you should avoid becoming pregnant.

Breastfeeding
You should not breast-feed your baby while being treated with this medicine, because lomustine might pass into your breast milk. As a risk to the nursing child potentially exists, a decision should be made whether to discontinue breast-feeding or to discontinue lomustine therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the mother.

Fertility
Men who are treated with lomustine should not father a child during their therapy and up to 6 month 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**
No special studies have been performed, but Lomustine "medac" capsules can impair your ability to drive and use machines, e.g. because of nausea and vomiting.

**Lomustine "medac" contains lactose and wheat starch**
This medicine 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.

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"").

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

## 3. How to take Lomustine "medac"

**Care must be taken whenever handling anticancer products. Caution! Do not break open the Lomustine "medac" capsules. If you accidentally get the powder on your skin or in your mouth, wash it off with plenty of water. Wash your hands with soap and water after handling this product.**

Always take this medicine exactly as your doctor has told you, and in an interval of no less than 6 weeks. Check with your doctor or pharmacist if you are not sure.

Lomustine "medac" capsules are taken by mouth. Swallow the capsules whole, do not chew or break them.

**Use in adults**
Your doctor will decide the exact dose to give you and how often to give it. Usually the dose depends on your height and weight. You may expect to receive 200 – 240 mg lomustine. Lomustine "medac" capsules are usually taken **once** every 6 to 8 weeks either as a single dose or as a divided dose over 3 days, e.g. 80 mg/day.

The dose you take may be reduced if you are taking other medicines to treat your condition or if you have a blood disorder.

**Use in children**
Lomustine "medac" capsules may be used in children with certain types of tumours. You must only use Lomustine "medac" for children as prescribed by the doctor.
Lomustine "medac" capsules are usually taken **once** every 6 to 8 weeks either as a single dose or as a divided dose over 3 days, e.g. 40 mg/day.

**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"**
It is important to complete the course of medication exactly as prescribed by your doctor. If you think you have missed a dose for any reason please tell your doctor or nurse immediately. Your doctor will decide how to proceed with the intake of Lomustine "medac".
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.

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

**Not known (frequency cannot be estimated from the available data)**
- Various types of effects on the blood, such as too little red and white blood cells. This can manifest itself in the fact that you suffer repeated infections, e.g. sore throat or cough. You should contact your doctor immediately if this occurs. • 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.
- Stomatitis (inflammation inside the mouth) and diarrhoea
- Apathy, difficulties in orientation, confusion and stuttering
- Hair loss

Other possible side effects:

**Very common (may affect more than 1 in 10 people)**
- Decrease in white blood cells
- Low levels of blood platelets which can lead to bleeding and bruising.

**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)
- Pneumonia
- Acute and chronic lung reactions with changes in lung tissue seen in x-ray, shortness of breath and dry cough
- Lasting visual impairment (in combination with radiation treatment)
- Kidney failure, decrease in kidney size and kidney damage
- Abnormal coordination
- Sleepiness, sluggishness
- Difficulty speaking, unclear speech
- Increase in liver enzymes and bilirubin (break-down product of the red blood pigment)
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**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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
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.
Keep the box in the outer carton in order to protect from light and moisture.

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

Do not throw away any medicines via wastewater or household waste. At the end of treatment return any leftover medicine to your hospital or pharmacist.

## 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 lactose, wheat starch, talc and magnesium stearate.

The capsule is made of gelatine and the colouring agents titanium dioxide (E171) and indigotine (E132).

**What Lomustine "medac" looks like and contents of the pack**

Lomustine "medac" are blue hard capsules.
Lomustine "medac" capsules are packed in a plastic box. There are 20 capsules in each pack.

**Marketing Authorisation Holder and Manufacturer**

medac
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