Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CeeNU. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking CeeNU against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CeeNU is used for

CeeNU is used to treat brain cancer. It may also be used to treat another type of cancer called Hodgkin's Disease.

CeeNU belongs to a group of medicines called cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

CeeNU works by killing cancer cells.

CeeNU is often used in combination with other medicines to treat your cancer.

Your doctor may have prescribed CeeNU for another reason. Ask your doctor if you have any questions about why CeeNU has been prescribed for you.

This medicine is available only with a doctor's prescription.

Safety and effectiveness in children have not been established.

Before you take CeeNU

Do not take CeeNU if you have a severe allergy to CeeNU or any of the ingredients listed at the end of this leaflet,

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- · rash, itching, hives or flushed, red skin
- dizziness or light headedness

Do not take CeeNU if you have, or have had, any of the following medical conditions, unless you have discussed it with your doctor:

- blood disorder with a reduced number of red or white blood cells
- · liver problems
- · kidney problems
- lung disease (including asthma)
- heart problems (including a heart attack)
- anv other cancer
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer

Tell your doctor if you have allergies to:

- · any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

You should advise your doctor if you have had surgery recently.

Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines, CeeNU is not recommended for use during pregnancy. If there is any need to consider CeeNU during your pregnancy, your doctor will discuss with you the benefits and risks of using it. CeeNU may affect your developing baby if you take it during pregnancy.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are taking CeeNU or shortly after you have stopped taking CeeNU.

You should use some kind of birth control while you are taking CeeNU and for at least 12 weeks after you stop using it.

CeeNU may cause birth defects if either the male or female is using it at the time of conception.

Do not breastfeed while taking CeeNU.

CeeNU passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and CeeNU may interfere with each other.

These medicines may be affected by CeeNU, or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

CeeNU when used in combination with other drugs or radiation therapy may further depress your immune system. Your doctor or pharmacist may have more information on medicines to be careful with or avoid while having CeeNU.

If you are not sure whether you should start taking CeeNU or if you have not told your doctor about any of the above, you MUST tell them before you start taking CeeNU.

How to take CeeNU

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. Your doctor or pharmacist will tell you how many capsules you will need to take, the time between doses and the length of time to take CeeNU. This depends on your condition and your weight and whether or not you are taking any other medicines.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many capsules you will need to take, the time between doses and the length of time to take CeeNU. This depends on your condition and your weight and whether or not you are taking any other medicines.

How to take it

Swallow CeeNU whole with a full glass of water. Do not chew the capsules.

The capsules have a special coating to stop them dissolving until they have passed through the stomach into the intestines where they work. Chewing them destroys the coating.

When to take it

Take CeeNU on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of CeeNU.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Your doctor will tell you when your treatment should be stopped.

CeeNU is given as a single oral dose. Another dose of CeeNU will not be repeated for at least six weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

If you forget to take it

If you have forgotten to take a dose of CeeNU, contact your doctor.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much CeeNU. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using CeeNU

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of CeeNU at the appropriate times to get the best effects from your treatments.

If you forget a hospital appointment, immediately contact your doctor.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking CeeNU.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking CeeNU. If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking CeeNU.

If you become pregnant while taking CeeNU, tell your doctor.

CeeNU can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections.
 Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Things you must not do

Do not give CeeNU to anyone else, even if they have the same condition as you.

Do not take CeeNU to treat any other complaints unless your doctor or pharmacist tells you to.

Do not open the capsules. If a capsule is damaged, avoid contact with your skin and eyes. If you accidentally touch or inhale the powder, carefully wash the affected area with water. Avoid inhaling the powder.

Do not drink alcohol while taking CeeNU. You may feel flushed or get headaches.

Do not take more than your doctor has prescribed. High doses of CeeNU may be associated with a serious blood disorder.

Do not take CeeNU after the expiry date printed on the pack. If you take this medicine after the expiry date has passed, it may not work as well.

Do not take CeeNU if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Things to be careful of

Be careful driving or operating machinery until you know how CeeNU affects you.

As with other anticancer medicines, CeeNU may cause nausea, disorientation or tiredness in some people. Make sure you know how you react to CeeNU before you drive a car, operate machinery, or do anything else that could be dangerous if you are disorientated or tired. If this occurs do not drive. If you drink alcohol, disorientation or tiredness may be worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking CeeNU. Like other medicines that treat cancer, CeeNU may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you.

These are the more common side effects of CeeNU.

- nausea, vomiting, loss of appetite, sore mouth
- · dry cough
- · swelling of feet or lower legs
- confusion
- · unusual hair loss or hair thinning
- · dizziness; light-headedness
- · feeling tired or drowsy

Tell your doctor or nurse as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention.

- infections, fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, bleeding gums or nose bleeds, rash of small reddish-purple spots on your skin), blood in your stool or urine
- tiredness, headaches, short of breath when exercising, dizziness, looking pale, fast heart rate
- shortness of breath or change in breathing, cough, unusual tiredness
- passing little or no urine, drowsiness, nausea, vomiting, headache and breathlessness
- liver disease with symptoms such as weakness, tiredness, confusion, yellowing of the eyes and skin, loss of appetite, weight loss and stomach pain
- lack of coordination or unsteady when walking, difficulty speaking

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you fell unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using CeeNU

The benefits and side effects of CeeNU may take some time to occur. Therefore even after you have finished your CeeNU treatment you should tell your doctor immediately if you notice any of the side effects listed.

Storage

Keep your capsules in the bottle until it is time to take them. If you take the tablets out of the pack they will not keep as well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store CeeNU or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicine.

Product description

What it looks like

Capsule 10 mg: - white, marked CPL3030/10mg

Capsule 40 mg: - white/dark green, marked CPL3031/40mg

Ingredients

Active ingredient:

lomustine

Other ingredients:

- mannitol
- · magnesium stearate

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd, 4 Nexus Court, Mulgrave, Victoria 3170, Australia

Registration Numbers

10 mg capsules AUST R 19252 40 mg capsules AUST R 19249 Date of Preparation: November 2020 AU_CMI_CeeNU_V5.0_Nov20.docx