

GLIADEL® Implants

Carmustine implant with Polifeprosan 20

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about GLIADEL. It does not contain all the available information that is known about GLIADEL. 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 treatment with GLIADEL against the benefits they expect it will have for you.

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

Keep this leaflet as you may want to read it again after your GLIADEL treatment.

WHAT GLIADEL IS USED FOR

GLIADEL is used to treat some types of brain cancers after removal by surgery.

GLIADEL works by killing cancer cells and/or stopping cancer cells from growing and multiplying.

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

Ask your doctor if you have any questions about why GLIADEL treatment has been prescribed for you.

GLIADEL is not addictive.

BEFORE YOU ARE GIVEN GLIADEL

When you must not be given it

You must not be given GLIADEL if you are breastfeeding or plan to breastfeed.

It is recommended that you do not breast-feed while undergoing GLIADEL treatment, as it may pass into the breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not use GLIADEL to treat children.

There is no experience with the use of GLIADEL in children.

If you are not sure whether you should have GLIADEL, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have any allergies to:

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

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, GLIADEL is not recommended for use during pregnancy. If there is need to consider GLIADEL during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

If you have not told your doctor about any of the above, tell them before you have GLIADEL.

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.

HOW GLIADEL IS GIVEN

How much is given

Your doctor will decide what dose you will receive. This will depend on your condition and other factors.

Ask your doctor if you want to know more about the dose of GLIADEL you receive.

How it is given

The GLIADEL Implants are placed inside your head during the surgery to remove your tumor. The usual number of implants is up to eight (61.6 mg of carmustine), however this number may be reduced by your doctor depending on your tumor size.

How long is it given

You are only given GLIADEL Implants once when your tumor is removed during surgery. The implants will then slowly dissolve away.

If you are given too much (overdose)

Your doctor will know the correct dose for you, so the chances of overdose are highly unlikely.

AFTER YOU HAVE BEEN GIVEN GLIADEL

Things you must do

If you become pregnant after being given GLIADEL tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor that you have had GLIADEL implanted.

Tell any other doctors, dentists and pharmacists who are treating you that you have had GLIADEL Implants.

In particular, GLIADEL Implants will be seen on brain scans so warn any doctors before you have any brain scans after the GLIADEL has been implanted.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you have had GLIADEL implanted.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after being given GLIADEL Implants.

GLIADEL helps most people with brain tumors, but like other chemotherapeutic medicines, it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. 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

If any of the following happen, tell your doctor or pharmacist immediately:

- high temperature
- pain – head, neck, chest or back
- headache
- confusion or stupor
- fits or seizures

- weakness or paralysis of one side of the body
- unusual tiredness, sleepiness or weakness
- nausea or vomiting
- pain or burning feeling when urinating
- shortness of breath or difficulty in breathing
- oral thrush – sore creamy yellow raised patches in the mouth
- rash
- difficulty in talking
- diarrhoea or constipation
- difficulty swallowing
- problems seeing
- dizziness
- depression, problems sleeping, abnormal thinking
- clumsiness and lack of coordination

Most of these side effects are usually mild to moderate. However, they may also be signs of a more serious side effect. You may need medical attention

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- pneumonia – chest infection with cough and yellow/green sputum
- a blood clot in your leg or severe chest pain with a shortness of breath
- decreased level of consciousness
- coma

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

STORAGE

GLIADEL implants are stored in the freezer at or below -20°C in the pharmacy department of your hospital.

GLIADEL DESCRIPTION

What it looks like

GLIADEL Implants are an off-white to pale yellow flat disc approximately 1.45 cm in diameter and 1 mm thick.

Active Ingredients

GLIADEL Implants contain 7.7 mg of carmustine as the active ingredient.

Other Ingredients

The other ingredient in GLIADEL Implants is an inactive copolymer called Polifeprosan 20. This copolymer consists of two polymers - carboxypropane and sebacic acid.

Sponsor

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