

**PACKAGE LEAFLET**

**GLIADEL 7.7 mg Implant**  
Carmustine

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Read all of this leaflet carefully before you receive GLIADEL Implants.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

**In this leaflet:**

1. What GLIADEL Implants are and what they are used for
2. Before you receive GLIADEL Implants
3. How GLIADEL Implants are used
4. Possible side effects
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**1. WHAT GLIADEL IMPLANTS ARE AND WHAT THEY ARE USED FOR**

GLIADEL Implants are a way to deliver the anticancer substance carmustine directly to the site of the brain tumour after the tumour has been removed by surgery. Carmustine belongs to a group of anticancer substances that act by slowing the growth of cancer cells in brain.

GLIADEL Implants can be used in combination with radiation for the treatment of brain tumours.

GLIADEL Implants have been shown to prolong survival in patients with brain tumours.

**2. BEFORE YOU RECEIVE GLIADEL IMPLANTS**

**Do not use** GLIADEL Implants if you are allergic to carmustine or Polifeprosan 20.

**Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Pregnancy and breast-feeding**

Ask your doctor for advice before taking any medicine. GLIADEL Implants have not been studied in pregnant women. The active ingredient, carmustine, has been shown to adversely affect the development of unborn babies. GLIADEL Implants should not be used if you are pregnant or breast-feeding.

**Driving and using machines**

Driving is not advisable after treatment. You must check with your doctor before driving or operating any tools or machines.

### 3. HOW GLIADEL IMPLANTS ARE USED

#### GLIADEL Implants are for use in adults only

Your surgeon or pharmacist will ensure that the product is available for your surgery. After the surgeon removes your brain tumour, he or she inserts up to eight implants into the space the tumour once occupied. Your surgeon will decide how many implants to place into the cavity created by the removal of your brain tumour. The implants are placed in such a manner that they cover as much of the cavity as possible. After your surgery, the implants slowly dissolve over a 2 to 3 week period releasing carmustine directly to the surrounding cells.

If you have any further questions on the use of this product, ask your surgeon.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Gliadel Implants can cause side effects, although not everybody gets them.

If you experience any of the following side effects as a **new event**, or if a side effect that you have **worsens**, tell your doctor immediately or go to the casualty department at your nearest hospital.

The most common adverse events observed during trials in either newly-diagnosed malignant glioma (brain tumour) (120 patients) or recurrent diagnosed malignant glioma (110 patients) are presented below.

The following four categories of side effects are possibly related to treatment with GLIADEL Implants.

1. **Seizures** were very common. Most of them had a mild to moderate intensity and occurred within 5 days of the surgical treatment.
2. **Brain swelling** was very common. The development of brain swelling could necessitate a new surgical intervention either to remove the implants or the remnants of the implants.
3. Mild to severe **wound healing problems** were very common.
4. **Infections in the brain** (infections within the skull) such as meningitis and abscess(es) (localised collections of pus) were common.

The following side effects were seen in the patients during the trials. They were similar to those encountered by patients who have surgery for their brain cancer without the insertion of GLIADEL Implants.

*Side effects continued over the page*

### **Very common side effects ( > 10 patients in every 100)**

#### **- Metabolism & nutrition disorders**

Abnormal (slow) healing of the surgical wound

#### **- Nervous system disorders**

Weakness, especially on one side of the body; convulsion (fits); confusion; swelling of the brain; depression; somnolence (drowsiness); problems with speech

#### **- Vascular disorders**

Vein inflammation

#### **- Gastrointestinal disorders (stomach and intestinal related disorders)**

Nausea (feeling sick); vomiting; constipation

#### **- Skin and subcutaneous (tissue under the skin) disorders**

Rash; hair loss

#### **- Renal (kidney) and urinary disorders**

Infection of the urinary tract

#### **- General disorders and administration site conditions**

A worsening of your condition; infection; headache; feeling of weakness; fever or pain

### **Common side effects (between 1 and 10 patients in every 100)**

#### **- Blood and lymphatic (immune) system disorders**

Reduction in red blood cells which can make the skin pale and cause weakness and breathlessness; reduction in blood platelets which increases the risk of bleeding; increase in white blood cells

#### **- Endocrine disorders (hormonal disorders)**

Diabetes mellitus (abnormally high sugar level in blood)

#### **- Metabolism & nutrition disorders**

Peripheral oedema (excess fluid in the arms and legs); low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma; low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm;

#### **- Nervous system disorders**

Amnesia (loss of memory); an increase in the blood pressure in the skull due to abnormal build up of fluid; changes in your personality; excessive anxiety; paralysis of the face; lack of coordination; diminished sensitivity to stimulation; abnormal burning or prickling sensation; abnormal thinking; problems with walking; dizziness; epileptic seizures (fits); hallucinations; insomnia (little or poor sleep); tremor (small shaking movements); meningitis (inflammation of the brain); abscess (localised collection of pus); loss of consciousness

**- Eye disorders**

Blurred or abnormal vision; swelling of the eye lining; eye pain

**- Respiratory disorders (Lung related disorders)**

Lung infection or pneumonia which causes breathlessness, cough and raised temperature

**- Gastrointestinal disorders (Stomach and intestinal related disorders)**

Yeast infection of the mouth; diarrhoea; constipation; faecal incontinence (uncontrolled bowel movements); difficulty in swallowing; bleeding in the stomach or in bowels.

**- Muscle, skeletal and soft tissue related disorders**

General infection

**- Renal (kidney) and urinary disorders**

Urinary incontinence

**- General disorders and administration site conditions**

Abdominal, back and chest pain; swelling of the face; abscess (localised collection of pus); accidental injury; allergic reaction; neck pain and infection in the blood stream.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see below).

Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE GLIADEL IMPLANT**

Keep out of the reach and sight of children.

Store in a freezer at or below -20°C.

Unopened outer sachets may be kept at a temperature of not more than 22°C for a maximum of six hours.

The product may be refrozen only once if the sachets have been unopened and kept for a maximum of 6 hours at a temperature of not more than 22°C. After the refreezing, the product should be used within 30 days.

Do not use GLIADEL Implants after the expiry date which is stated on the outer carton and/or the sachet. The expiry date refers to the last day of that month.. Your surgeon or hospital pharmacist will check the expiry date before implants are used.

**6. FURTHER INFORMATION**

### **What Gliadel Implants contain**

Each implant contains 7.7mg of the active ingredient carmustine.

The implants also contain the inactive ingredient polifeprosan 20.

### **What GLIADEL Implants look like and contents of the pack**

GLIADEL Implants are available in boxes containing eight implantable wafers. These wafers are off-white to pale yellow flat discoid implants. Each wafer is individually packaged in an aluminium foil laminate sachet.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorization Holder**

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**This leaflet was last revised in February 2015.**