

## APPROVED PATIENT INFORMATION LEAFLET

### Read all of this leaflet carefully before you start taking TEMODAL Capsules

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TEMODAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## SCHEDULING STATUS

S4

## PROPRIETARY NAME AND DOSAGE FORM

TEMODAL<sup>®</sup> 5 mg Capsules

TEMODAL<sup>®</sup> 20 mg Capsules

TEMODAL<sup>®</sup> 100 mg Capsules

TEMODAL<sup>®</sup> 140 mg Capsules

TEMODAL<sup>®</sup> 180 mg Capsules

TEMODAL<sup>®</sup> 250 mg Capsules

### 1. WHAT TEMODAL CONTAINS

Each TEMODAL capsule contains temozolomide 5 mg, 20 mg, 100 mg 140 mg, 180 mg or 250 mg.

**The active substance is** Temozolomide

**The other ingredients are:** Colloidal silicon dioxide, glycolate, lactose, sodium starch, stearic acid and tartaric acid.

### 2. WHAT TEMODAL IS USED FOR

TEMODAL is used for the treatment of certain brain cancers in adults

- newly diagnosed and TEMODAL is first used together with radiotherapy and after that alone.
- malignant diagnosed and TEMODAL is used if they return or get worse after standard treatment.

### **3. BEFORE YOU TAKE TEMODAL**

#### **Do not take TEMODAL**

- If you are allergic (hypersensitive) to temozolomide or any of the other ingredients of TEMODAL.
- If you have had an allergic reaction to dacarbazine (an anti-cancer medicine, sometimes called DTIC).
- If certain kinds of blood cells are severely reduced, such as your white blood cell count and platelet count. These blood cells are important for fighting infection and for proper blood clotting. Your doctor will check your blood to make sure you have enough of these cells before you begin treatment.

#### **Take special care with TEMODAL**

- You should be observed closely for the development of a serious form of chest infection called *Pneumocystis carinii* pneumonia (PCP). If you are a newly-diagnosed patient (glioblastoma multiforme) you may be receiving TEMODAL for 42 days in combination with radiotherapy. In this case, your doctor will also prescribe medicine to help you prevent this type of pneumonia (PCP).
- If you have low blood counts of red blood cells (anaemia), white blood cells and platelets, or blood clotting problems before starting the treatment, or if you develop them during treatment, your doctor may decide to reduce the dose, interrupt, stop, or change your treatment. You may also need other treatments. In such cases, it may be necessary

to stop treatment with TEMODAL. Your blood will be tested frequently during treatment to monitor the side effects of TEMODAL on your blood cells.

- You may have a small risk of other changes in blood cells, including leukaemia.
- If you vomit frequently before or during treatment, ask your doctor about controlling the vomiting, and the best time to take TEMODAL until the vomiting is under control. If you vomit after taking your dose, do not take a second dose on the same day.
- If you develop fever or symptoms of an infection contact your doctor immediately.
- Do not open, crush or chew the capsules. If a capsule is damaged, avoid contact of the powder with your skin, eyes or nose. Avoid inhaling the powder. If you accidentally get some in your eyes or nose, flush the area with water.
- If you are older than 70 years of age you might be more prone to infection, bruising or bleeding.
- If you have liver or kidney problems your dose of TEMODAL may need to be adjusted.
- There is no experience in children younger than 3 years old.
- TEMODAL may cause permanent infertility. Male patients should use effective contraceptions and not father a child for up to 6 months after stopping treatment. It is recommended to seek advice on conservation of sperm prior to treatment.

### **Taking TEMODAL with food or drink**

Swallow the capsule whole with a glass of water on an empty stomach at least 1 hour before a meal.

### **Pregnancy and Breastfeeding**

If you are pregnant or breast feeding your baby while taking TEMODAL, please consult your doctor, pharmacist or healthcare professional for advice.

Effective contraceptive precautions must be taken by **both and female patients** who are taking TEMODAL (see also “**Take special care with TEMODAL**” above).

You should stop breastfeeding while taking TEMODAL.

### **Driving and using machinery**

TEMODAL may make you feel tired or sleepy. In this case, do not drive or operate any tools or machines.

### **Important information about some of the ingredients of TEMODAL**

Each capsule contains a small amount of lactose. Thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medication.

### **Taking other medicines with TEMODAL**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of TEMODAL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

## **4. HOW TO TAKE TEMODAL**

Always take TEMODAL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of TEMODAL is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will work out your dose of TEMODAL, based on your size (height and weight) and if you have a recurrent tumour and have had chemotherapy treatment in the past. You

may be given other medicines to take before and/or after TEMODAL to prevent or control nausea and vomiting.

Take your prescribed dose of TEMODAL once a day for 5 days. It is recommended that you take TEMODAL on an empty stomach at least 1 hour before you plan to eat breakfast. Do not open or chew the capsules. Swallow the capsule(s) whole with a glass of water.

### **Patients with recurrence or progression**

A treatment cycle with TEMODAL lasts 28 days. You will take the capsules once daily for the first 5 days (“dosing days”) followed by 23 days without TEMODAL. This adds up to the 28 day treatment cycle. After day 28, the next cycle will begin. You will again take TEMODAL once daily for 5 days followed by 23 days without TEMODAL. The TEMODAL dose may be adjusted, delayed or stopped depending on your blood counts and how you tolerate your medicine during each treatment cycle.

### **All patients**

TEMODAL comes in different strengths of capsules (content of active substance in mg). The colour of the capsule cap is different for each strength capsule.

You should make sure you fully understand and remember

- How many capsules you need to take every dosing day. Ask your doctor or pharmacist to write it down (including the colour).
- Which days are your dosing days.

Review the dose with your doctor each time you start a new cycle, since it may be different from the last cycle.

### **If you take more TEMODAL than you should**

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

### **If you forget to take TEMODAL**

Take the missed dose as soon as possible during the same day. If a full day has gone by, check with your doctor. Do not take a double dose to make up for a forgotten dose, unless your doctor tells you to do so.

### **5. POSSIBLE SIDE EFFECTS**

TEMODAL can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Contact your doctor **immediately** if you have a severe allergic reaction (hives, wheezing or other breathing difficulty), uncontrolled bleeding, seizures (convulsions), fever or a severe headache that does not go away.

TEMODAL treatment can cause a reduction in certain kinds of blood cells. This may cause you to have increased bruising or bleeding, anaemia (a shortage of red blood cells), fever, and reduced resistance to infections. Your doctor will monitor your blood regularly for any changes, and will decide if any specific treatment is need. In some cases your TEMODAL dose will be reduced or discontinued.

### **TEMODAL in combination treatment with radiotherapy**

The following side effects can occur and medical attention may be required.

**Frequent:** Oral infections, wound infection, reduced number of blood cells, loss of appetite, increased sugar in the blood, loss of weight, change in mental status or alertness, anxiety/depression, headache, sleepiness, difficulty speaking, impaired balance, dizziness, confusion, forgetfulness, difficulty concentrating, inability to fall asleep or stay asleep, tingling sensation, bruising, shaking, abnormal or blurry vision, double vision, hearing impairment,

blood clot in the legs, fluid retention, swollen legs, shortness of breath, cough, constipation (difficulty passing stools), nausea (feeling sick in your stomach), vomiting, diarrhoea, stomach or abdominal pain, heartburn, upset stomach, difficulty swallowing, dry mouth, hair loss, rash, skin irritation or redness, dry skin, itching, muscle weakness, painful joints, muscle aches and pains, frequent urination, difficulty with holding your urine, tiredness, allergic reaction, fever, radiation injury, facial swelling, pain, abnormal taste, abnormal liver function tests.

**Less frequent:** Flu-like symptoms, red spots under the skin, appearance of a swollen face or muscle weakness, low potassium level in the blood, weight gain, mood swings, hallucination and memory impairment, partial paralysis, impaired coordination, difficulty swallowing, impaired sensations, partial loss of vision, dry or painful eyes, deafness, infection of the middle ear, ringing in the ears, earache, palpitations (when you can feel your heart beat), blood clot in the lung, high blood pressure pneumonia, inflammation of your sinuses, bronchitis, a cold or the flu, swollen stomach, difficulty controlling your bowel movements, haemorrhoids, peeling skin, increased skin sensitivity to sunlight, change in skin colour, increased sweating, muscle damage, back pain, difficulty in urinating, vaginal bleeding, sexual impotence, absent or heavy menstrual periods, vaginal irritation, breast pain, hot flushes, shivering, discolouration of your tongue, change in your sense of smell, thirst, tooth disorder.

### **TEMODAL monotherapy recurrent or progressive**

The following side effects can occur and medical attention may be required.

**Frequent:** Reduced number of blood cells, loss of appetite, loss of weight, headache, dizziness, tingling sensation, shortness of breath, constipation (difficulty passing stools), nausea (feeling sick in your stomach), vomiting, diarrhoea, abdominal pain, upset stomach, hair loss, rash, itching, fever, tiredness, weakness, shivering, feeling unwell, pain, change in taste.

**Less Frequent:** Cough, infections including pneumonia, skin redness, urticaria (hives), skin eruption, allergic reactions.

Very rare cases of rash with skin swelling, including on the palms of the hands and soles of the feet, have been observed. Tell your doctor if this occurs.

Very rarely, patients taking TEMODAL and medicines like it may have a small risk of other changes in blood cells, including leukaemia.

**Other side effects that can occur:**

Cases of severe rash with skin swelling, including on the palms of the hands and soles of the feet, or painful reddening of the skin and/or blisters on the body or in the mouth have been observed. Tell your doctor **immediately** if this occurs.

Cases of lung side effects have been observed with TEMODAL. Patients usually present with shortness of breath and cough. Tell your doctor if you notice any of these symptoms.

Patients taking TEMODAL and medicines like it may have a small risk of developing secondary cancers, including leukaemia.

There have been cases of hepatic side effects including elevations of liver enzymes, increased bilirubin, problems with bile flow and hepatitis.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**6. STORING AND DISPOSAL OF TEMODAL**

Keep at or below 30 °C. Do not refrigerate. Protect from moisture.

Keep all medicines out of reach and sight of children.

Store in the original bottle and keep the bottle tightly closed.

## **7. PRESENTATION OF TEMODAL**

TEMODAL Capsules are packaged in amber glass bottles and closed with white, polypropylene, child resistant closures or in sachets with a child-resistant tear notch, in packs of 5 and 20 capsules.

## **8. IDENTIFICATION OF TEMODAL**

TEMODAL 5 mg Capsules: No. 3 capsule with opaque green cap and opaque white body containing a white to light pink, light tan powder. The cap is imprinted in black ink with “TEMODAL”, the body is imprinted in black ink with 2 stripes, “5 mg” and the SP logo.

TEMODAL 20 mg Capsules: No. 2 capsule with yellow cap and opaque white body containing a white to light pink, light tan powder. The cap is imprinted in black ink with “TEMODAL”, the body is imprinted in black ink with 2 stripes, “20 mg” and the SP logo.

TEMODAL 100 mg Capsules: No. 1 capsule with opaque pink cap and opaque white body containing a white to light pink, light tan powder. The cap is imprinted in black ink with “TEMODAL”, the body is imprinted in black ink with 2 stripes, “100 mg” and the SP logo.

TEMODAL 140 mg Capsules: No. 0 capsule with blue cap and opaque white body containing a white to light pink, light tan powder. The cap is imprinted in black ink with “TEMODAL”, the body is imprinted in black ink with 2 stripes, “140 mg” and the SP logo

TEMODAL 180 mg Capsules: No. 0 capsule with opaque orange cap and opaque white body containing a white to light pink, light tan powder. The cap is imprinted in black ink with “TEMODAL”, the body is imprinted in black ink with 2 stripes, “180 mg” and the SP logo

TEMODAL 250 mg Capsules: No. 0 capsule with opaque white cap and opaque white body containing a white to light pink, light tan powder. The cap is imprinted in black ink with “TEMODAL”, the body is imprinted in black ink with 2 stripes, “250 mg” and the SP logo.

#### **9. REGISTRATION NUMBERS**

TEMODAL 5 mg Capsules: 32/26/0721

TEMODAL 20 mg Capsules: 32/26/0722

TEMODAL 100 mg Capsules: 32/26/0723

TEMODAL 140 mg Capsules: 42/26/0961

TEMODAL 180 mg Capsules: 42/26/0962

TEMODAL 250 mg Capsules: 32/26/0724

#### **10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

MSD (Pty) Ltd

117 16<sup>th</sup> Road

Halfway House 1685

South Africa

Tel: 011 655 3000

#### **11. DATE OF PUBLICATION OF THIS PACKAGE INSERT**

26 October 2012