

Patient Information Leaflet

Temozolomide – TEMODAL®

What is TEMODAL®

Medicine Name	Description
Temozolomide	5 mg gelatin capsule: green with white 20 mg gelatin capsule: yellow with white 100 mg gelatin capsule: pink with white 140 mg gelatin capsule: blue with white 180 mg gelatin capsule: orange with white 250 mg gelatin capsule: white There are generic drugs of different forms PLOCA 100 mg 100 mg 140 mg 180 mg 250 mg 1

How should you take your medicine?

Your doctor has determined your medicine dosage.

In your case, the dosage is as follows: mg/day, i.e. mg gelatin capsules, gelatin capsules, to be taken once a day. (indicate whether to take continuously or not). Swallow whole with a glass of water, without opening or diluting the capsules.

With a time interval between taking the medicine and eating. If combined with radiation therapy, take on an empty stomach one hour before radiation therapy.

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

Dosage – therapy regimen

Once a day, at a set time, on an empty stomach		\$\) < 1h \(\begin{array}{c} \) 1h > \\ \end{array}\$		<		1>			1h>
With no gaps for 42 to 49 days, combined with radiation therapy OR from D1 to D5, resume	D1	D2	D3	D4	D5	D6	D 7	•••	D42/49
on D29			D1	D5	D6	•••	D28 D29		

How to get the medicine supply?

This medicine is available in a hospital pharmacy.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

What else do you need to know?

Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts and liver function), as well as clinical condition monitoring.

Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).



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Interactions with other medications and/or food

The occurrence of interactions between TEMODAL® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking. Example: There are no known interactions with plants.

What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.

SIDE EFFECTS							
Most common ones	Abnormal lab results: low multinuclear neutrophil count (neutropenia), low thrombocyte count (thrombocytopenia), low white blood cell count (leucopenia), low hemoglobin level (anemia), abnormal liver function tests Digestive problems: nausea, vomiting, constipation, weight loss Skin problems: skin rash, hair loss Infection Others: sleep disorder, anxiety, fatigue, headaches						
Some patients require special attention	Patients – carriers of hepatitis B virus or cytomegalovirus						
WHEN TO ALERT THE MEDICAL TEAM?							
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	Digestive problems > Significant and/or rapid weight loss > Severe abdominal pain > Inability to drink for 24 hours and/or eat for about 48 hours > Bowel movements fewer than 3 times a week Symptoms suggestive of infection > Temperature > 38.5 °C > Cough, throat pain, pain on urination, diarrhea with fever Pain that prevents you from doing your normal activities > Headaches Respiratory problems Increasing constant cough or problems breathing						
HOW TO PREVENT SIDE EFF	ECTS?						
Weight	Regularly check your weight in case of digestive problems.						
Infection	Avoid visiting high risk areas (crowds, contact with sick people,). A flu and pneumococcal infection vaccine might be recommended for you: it will protect you.						
Skin care	Opt for mild soap and moisturizer, pat skin dry. Avoid using any skin irritating products. For sun protection use broad spectrum sunscreen and avoid sun exposure.						
Hair care	Use a small amount of mild shampoo (for babies). Opt for a soft brush. Avoid washing your hair too often. Avoid heat sources (hairdryer, heated curlers, hot smoothing iron), dyes, highlights, or perm.						
Bleedings	Avoid taking anti-inflammatory drugs (ibuprofen, aspirin) Notify your doctor: > if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed > about surgical or dental intervention.						
Fatigue / constipation	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walki work in the garden, swimming, biking, sports Alternate periods of activity and rest.						
HOW TO ADAPT YOUR DIET?							
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes. Limit consumption of fatty, fried, and spicy foods.						
Weight loss	Opt for a higher calorie diet and "pleasure diet".						
Constipation	Opt for a high fiber diet. Drink more water.						