Temozolomide TEMODAL[®] and generics

WHAT IS TEMODAL® TÉMOZOLOMIDE ?

- Cancer drug used in the treatment of some types of brain tumors.
- Prescribed and renewed by your hospital doctor specialized in medical oncology, cancerology or hematology.
- Available in hospital pharmacy on presentation of your prescription.
 - White capsule bearing the SP logo and two stripes.
 - Dosed at **5 mg** (green cap) or **20 mg** (tellow cap) or **100 mg** (pink cap) or **140 mg** (blue cap) or **180 mg** (orange cap) or **250 mg** (white cap)
 - There exist generics in different colour.
 - Store at a temperature not over 30°C, out of reach and sight of children.
 - Do not get the capsules out of their packages to put them in a pill-box.
 - Wash your hands carefully before and after each handling of the capsules.
 - Do not throw away the opened packagings, please bring them back to your pharmacist.

How to take this medicine?

When ?	h	 = 1 take a day, at a fixed hour, <u>on an empty stomach</u>, at least 1 hour away from a meal <u>Follow your prescription</u>: Treatment to be taken every day for 42 days (or 49 days) ; on the days of a therapy session, please take the capsules 1 hour before the session. <u>OR ELSE :</u> Treatment to be taken by periods of 5 consecutive days (from day 1 to day 5) followed by 23 days without a take (from day 6 to day 28 included), then resume this cycle.
How ?	C T	Swallow the capsules whole, with water, every day at the same moment of the day. Do not chew, nor cut, crush or dissolve the capsules.

You can help yourself with **your tracking book* and a calendar** to spot the takes. Never stop or change the rhythm of administration of your treatment without your doctor's advice.

** This file is not a prescription ; refer to your latest prescription..

WHAT TO DO IN CASE OF MISSING OR VOMITING ?



In case of missing, do not take the missed dose. The next dose will be taken at the usual hour, without doubling it. Please note it in your tracking book*.

In case of vomiting, do not take a new dose. The next dose will be taken at the usual hour, without doubling it. Please note it in your tracking book*.

INTERACTIONS WITH OTHER MEDICINES AND/OR FOOD



Check with **your doctor or pharmacist** that the medicines (with or without prescription) and/or other substances (food, spices and plants, probiotics, essential oils, food supplements...) and other by-products that you are taking **are compatible with your treatment.** The molecules they contain, their measuring and consuming frequency may interact with your treatment and affect its efficiency and the outcome of side effects.



- You and your partner must use efficient contraceptive methods (condoms and one other means) during the whole treatment and **up to 6 months after the last take for women and up to 3 months after the last take for men.**
- Stop breast feeding during ther treatment

Male fertility may be irreversibly affected by the treatment with témozolomide. You can be informed by your doctor on the possibility of preserving sperm before starting the treatment.

*Tracking book available on the sites <u>www.omeditbretagne.fr</u> or <u>www.omedit-paysdelaloire.fr</u>

What side effects may occur with TEMODAL® Témozolomide ?

Like all medicines, temozolomide may bring about side effects, although you may not experience any.

Side effects		Prevention
	Hair loss	Use a large comb or a soft natural bristles hairbrush . Choose a mild shampoo, rinse your hair in tepid water and let it dry in the open air or at a low temperature. Avoid blow drying, hair setting, perms and dyeing which weaken your hair
	Head aches, fatigue	Drink in enough quantity (1,5/2 l of water/day) and favor healthy food, at regular hours. Limit psychostimulants (coffee, alcohol, tobacco). Respect moments of rest during the day while remaining active, even moderately. Go to bed at a regular hour ; avoid late bedding and staying in. Be prudent if you have to drive.
	Pains in the hands and feet, tingling, loss of sensitiveness	Care for any cut or injury (blister). Do not use hot water (check the temperature with your elbow) ; protect yourself from the cold. You may reduce the pain by taking regular exercise (walking 3 times/week) and relaxation exercise (sophrology, tai-chi, yoga). Anticipate any risk of falling (bad light, object on the ground) ; use rails, banisters or even a stick if necessary. Have a healthy and well-balanced feeding.
Fits	Digestive effects : constipation or diarrhea, ebdominal pains, nauseas, vomiting, loss of appetite	Watch over your weight and remember to hydrate well (1,5/2 litres of water / day) In case of constipation, favor food that is high in fibers (bran, cereals, wholemeal bread, gren vegetables, fruit and dried fruit) and take regular physical exercise. In case of diarrhea, favor food that is low in fibers (starchy food, carrots, bananas). Avoid food that may speed up your intestinal transit (dairy, raw fruit and vegetables, cereals, fat food, spices). In case of nauseas/vomiting, , make several small light meals during the day and eat slowly. Avoid greasy, fried and spicy food, as well as food whose smell may trigger nauseas. Avoid staying on an empty stomach as this may accentuate nauseas. Rather drink between meals. Take the antiemettic medicines you have been prescribed, if necessary.
•	Unusual bleedings, bruises	Use a soft toothbrush ; avoid using a rectal thermometer. Do not take aspirin nor anti- inflammatory (eg : ibuprofen) nor phytotherapy products (which may favor bleedings) without asking for medical advice from a health care professionnal In case of bruises, apply a cold object (ice- bag) or an appropriate cream (especially arnica-based) provided your skin has not been injured.
Ť	Swelling of the face and limbs	Keep eating low-salted food. Avoid wearing tight clothes. In case of swelling of the legs, raise your feet when sitting. Wear support stockings and put them on rested legs when rising from bed. Watch over your weight regularly. In case of such swelling, contact your doctor.



Only some of the most frequent side effects mentionned above. For further information, please refer to your medicine leaflet or ask your doctor or pharmacist for advice.

You can also ask your question ask your question to <u>center for side effects monitoring</u> or notify any side effect on the following site : <u>signalement-sante-gouv-fr</u>

In all cases, remember to make the biological tests prescribed by your doctor.

WHAT TO DO IN CASE OF SIDE EFFECT(S) ?

- Take the medication prescribed for side effects in accordance with the doses
- Respect measures of prevention.

Promptly contact your doctor in case of :

- Signs of infection (fever, cough, shivers, urinary burns)
- Paleness, short breath during effort or even at rest, heart throbs
- Bruises, nose bleedings, haemorrhages
- Fast and unexpected increase of weight
- Cough, shortness of breath or difficulty to breathe.
- Hot, painful and red arm or calf, in association with shortness of breath.
- Any persisting or worsening side effect.

Useful contacts :

Remarks :