

Temozolomide Cas No. : 85622-93-1

This medication is used to treat certain types of brain cancer. It is a chemotherapy drug that works by slowing cancer cell growth. In some patients, temozolomide decreases the size of brain tumors.

Active Pharmaceuticals Ingredients Manufacturers



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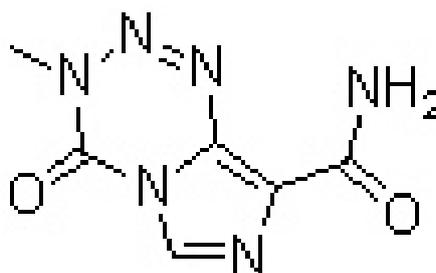
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Temozolomide

CAS No. : 85622-93-1

**Identifiers**

Molecular Weight 194.15
CAS number 85622-93-1
Formula C₆H₆N₆O₂
ATC code L01AX03
PubChem 5394
DrugBank APRD00557

**Chemical data**

Mol. mass 194.151 g/mol

Pharmacokinetic data

Bioavailability ?
Protein binding 15%
Metabolism spontaneously hydrolyzed at physiologic pH to the active species, 3-methyl-(triazene-1-yl)imidazole-4-carboxamide (MTIC) and to temozolomide acid metabolite.
Half life 1.8 hours

DOSAGE

The capsules should be swallowed whole with plenty of water and be taken at the same time every day on an empty stomach. It is important to make sure that you take the capsules exactly as you have been directed by your doctor. Chemotherapy is usually given as a course of several sessions (or cycles) of treatment over a few months. The length of your treatment and the number of cycles you have will depend on the type of cancer you are being treated for. Your nurse or doctor will discuss your treatment plan with you.

Take this medication by mouth, generally once daily for five consecutive days per 28-day treatment cycle; or take as directed by your doctor. Dosage is based on your size and response to therapy. Consult your doctor or pharmacist if you are not certain which days of the cycle to take your medication. Take this medication on an empty stomach (one hour before or three hours after a meal) or at bedtime, unless otherwise directed by your doctor. Swallow the capsules (medication) whole with a full glass of water (8oz. or 240mL). Do not crush or chew the capsules. If you vomit within 30 minutes of taking this medication, notify your doctor immediately. If you vomit before taking this medication, your doctor may be able to prescribe anti-nausea medication for you to take before therapy begins. Consult your doctor. Do not open the capsules (medication). If capsules are accidentally opened or damaged, avoid inhalation or contact of the medication with skin or mucous membranes (e.g., inside the nose).

SIDE EFFECTS

Each person's reaction to chemotherapy is different. Some people have very few side effects, while others may experience more. The side effects described in this information will not affect everyone who is given temozolomide, and may be different if you are having more than one chemotherapy drug. Lowered resistance to infection
Temozolomide can reduce the production of white blood cells by the bone marrow, making you more prone to infection. This effect can begin seven days after treatment has been given, and your resistance to infection usually reaches its lowest point 10–14 days after chemotherapy. Your blood cells will then increase steadily and will usually have returned to normal levels within 21–28 days



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Bruising or bleeding Temozolomide can reduce the production of platelets (which help the blood to clot). Let your doctor know if you have any unexplained bruising or bleeding, such as nosebleeds, blood spots or rashes on the skin, or bleeding gums.

Anaemia (low number of red blood cells) While having treatment with temozolomide you may become anaemic. This may make you feel tired and breathless. Let your doctor or nurse know if these symptoms are a problem.

Feeling sick (nausea) and being sick (vomiting) If you do feel sick this may begin soon after the treatment is given and last for a day. Your doctor can prescribe very effective anti-sickness (anti-emetic) drugs to prevent, or greatly reduce, nausea and vomiting. If the sickness is not controlled, or continues, tell your doctor; they can prescribe other anti-sickness drugs which may be more effective. Some anti-sickness drugs can cause constipation. Let your doctor or nurse know if this is a problem.

Diarrhoea This can usually be easily controlled with medicine, but it is important to let your doctor know if it is severe or continues. It is important to drink plenty of fluids if you have diarrhoea.

Constipation Constipation can usually be relieved by drinking plenty of fluids, eating a high fibre diet and taking gentle exercise. Sometimes you may need to take medicines to stimulate your bowel. These can be prescribed by your doctor.

Loss of appetite and temporary taste alterations Both of these may occur. A dietitian or specialist nurse at your hospital can give advice on boosting appetite, coping with eating difficulties and maintaining weight.

Rashes Temozolomide can cause a rash which may be itchy. Your doctor can prescribe treatment to help reduce this.

Headache Let your doctor know if you have headaches while having treatment with temozolomide.

Tiredness and feeling weak You may feel very tired. It is important to allow yourself plenty of time to rest.

PRECAUTIONS

Tell your doctor your medical history, especially of: kidney disease, liver disease, blood disorders (e.g., neutropenia, thrombocytopenia), allergies (especially to dacarbazine). This medication can lower the body's ability to fight an infection. Notify your doctor promptly if you develop any signs of an infection such as fever, chills or persistent sore throat. Use this medication with caution in the elderly because they may be more sensitive to the effects of the drug. Use this medication with caution in women because they may be more sensitive to the effects of the drug. This medication is not recommended for use during pregnancy. Consult your doctor for more details. Men and women should use effective birth control while using this medication. Consult your doctor or pharmacist for more information. It is not known if this drug passes into breast milk. Due to the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

- * It is important to take your capsules at the right times. You must take them as directed by your doctor.
- * Keep the tablets in the original packaging and store them at room temperature, away from heat and direct sunlight.
- * Keep the capsules in a safe place where children cannot reach them, as temozolomide could harm them.
- * If your doctor decides to stop treatment, return any remaining capsules to the pharmacist. Do not flush them down the toilet or throw them away.
- * If you are sick just after taking the capsules let your doctor know as you may need to take another one. Do not take another capsule without first telling your doctor.
- * If you do forget to take a capsule do not take a double dose. Tell your doctor and keep to a regular dose schedule.



DRUG DESCRIPTION

Temozolomide is a chemotherapy drug that is given as a treatment for some types of cancer. It is most commonly used to treat a type of brain tumour known as a glioma. This information describes temozolomide, how it is given and some of its possible side effects. It should ideally be read with our general information about chemotherapy and about your type of cancer.

Temozolomide is available as 5mg, 20mg, 100mg, 140mg, 180mg and 250mg capsules.

The material is a white to light tan/light pink powder Each capsule contains either 5 mg, 20 mg, 100 mg, or 250 mg of temozolomide. The inactive ingredients for Temozolomide Capsules are lactose anhydrous, colloidal silicon dioxide, sodium starch glycolate, tartaric acid, and stearic acid. Gelatin capsule shells contain titanium dioxide. The capsules are white and imprinted with pharmaceutical ink.

Temozolomide 5 mg: green imprint contains pharmaceutical grade shellac, anhydrous ethyl alcohol, isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide, titanium dioxide, yellow iron oxide, and FD&C Blue #2 aluminum lake.



This medication is used to treat certain types of brain cancers (e.g., refractory anaplastic astrocytoma).

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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