

TemoRel HARD CAPSULES

Temozolomide (20mg, 100mg, and 250mg)

What is in this leaflet

1. What TemoRel is used for
2. How TemoRel works
3. Before you use TemoRel
4. How to use TemoRel
5. While you are using it
6. Side effects
7. Storage and Disposal of TemoRel
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What TemoRel is used for

TemoRel is used for the treatment of specific forms of brain tumours:

- Newly-diagnosed glioblastoma multiforme initially along with radiotherapy and then alone
- Malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, if these tumours return or get worse after standard treatment.

How TemoRel works

TemoRel contains a medicine called temozolomide. This medicine is an anti-tumour agent. It exhibits schedule-dependent antineoplastic activity by interfering with DNA replication.

Before you use TemoRel

- When you must not use it

- Have had an allergic reaction to dacarbazine (DTIC), or any other ingredient in this medicine (listed under "Product Description"). Signs of allergic reactions include hives, itchy or skin rash, swelling of the face, lips, tongue or throat, breathlessness, wheezing, or a tight feeling in your chest.
- If you or your partner are pregnant or planning to be pregnant
- If you are breast-feeding
- If you are having very low levels of white blood cells, red blood cells or platelets.

- Before you start to use it

Tell your doctor, pharmacist or nurse before taking TemoRel

- If you vomit frequently. Your doctor may give you a medicine to control your vomiting.
- If you are anaemic or have blood clotting problems
- If you are planning to have children. TemoRel may cause infertility in men.
- If you have liver or kidney problems, TemoRel may re-activate hepatitis B and may lead to death in some cases.
- If you are allergic to any other medicines, other substances like food, preservatives or dyes.

Children and adolescents

Do not give this medicine to children below the age of 3 years because the effects have not been studied. Information of children above the age of 3 years who have taken TemoRel is limited.

Pregnancy, breast-feeding and fertility.

If you are pregnant, or planning to have children seek advice from your doctor or pharmacist before using this medicine. This is because you should not be treated with TemoRel when you are pregnant unless instructed by your doctor. TemoRel may endanger your fetus if either the male or female is using TemoRel during conception or pregnancy. Therefore a female must show a negative pregnancy test before starting to use TemoRel. Effective contraceptive measures must be undertaken by **both male and female patients who are using TemoRel**. Males who have partners that are already pregnant should use a condom to minimise exposure of the unborn baby to TemoRel that is present in the sperms (See also "Male fertility" below).

You should also stop breast-feeding whilst using TemoRel.

Male fertility

TemoRel may cause permanent infertility. You are recommended to

seek advice on conservation of sperms prior to treatment.

TemoRel contains lactose (a type of sugar). If you have been informed by your doctor that you are intolerant to some sugars, contact your doctor before using this medicine.

- If you are taking other medicines

Inform your doctor or pharmacist if you are taking, have just started taking, or will be taking other medicines, especially valproic acid (to treat or prevent seizure).

How to use TemoRel

- How much to use

Your doctor will decide your dose of TemoRel. This is 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 (antiemetic) to take before/after using TemoRel to prevent or control nausea and vomiting.

People with newly diagnosed brain tumour:

If you are a newly diagnosed patient, treatment will occur in 2 phases:

- treatment together with radiotherapy (concomitant phase)
- followed by treatment with TemoRel only (monotherapy phase).

During the concomitant phase, your doctor will start the treatment using TemoRel at a dose of 75 mg/m² (usual dose). You will be taking this dose daily for 42 days (up to 49 days) together with radiotherapy. The TemoRel dose may be delayed or stopped depending on your blood count and your tolerance to TemoRel during the concomitant phase. Once the radiotherapy is completed, you will not receive any treatment for the next 4 weeks to allow your body to recover.

Then you will start the adjuvant phase.

TemoRel HARD CAPSULES

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During the adjuvant phase, the dose and the way you take TemoRel may vary. Your dose will be decided by your doctor which may be 6 treatment cycles, each cycle lasting for 28 days. You will be taking this new dose of TemoRel alone once a day for the next 5 days (dosing days) for each cycle. The first dose is 150 mg/m². This will be followed by 23 days without TemoRel. This will complete the 28day cycle.

After Day 28, the next cycle will begin. You will receive once again TemoRel once a day for 5 days followed by 23 days without TemoRel. The TemoRel dose may be adjusted, delayed or stopped depending on your blood count and your tolerance to TemoRel during each cycle.

People with tumours that have returned or worsened after taking TemoRel only:

A treatment cycle with TemoRel lasts 28 days. You will take TemoRel only once a day for the first 5 days. The daily dose depends on whether or not you have received chemotherapy before.

If you have not received chemotherapy previously, your first dose of TemoRel will be 200mg/m² once daily for the first 5 days. If you were previously treated with chemotherapy, your first dose of TemoRel will be 150mg/m² once a day for the first 5 days. Then you will have 23 days without TemoRel. This adds up to a 28-days cycle.

After 28 days, the next cycle will begin. You will take TemoRel once a day again for 5 days followed by 23 days without TemoRel. Before each new cycle, your blood will be tested to see if the TemoRel dose needs to be adjusted. Depending on your blood test results, your doctor may change your dose for the next cycle.

- When to use it

Take TemoRel according to the dose that has been decided for you once daily, best at the same time each day.

Take the capsule on an empty stomach at least 1 hour before you plan to take your meal. Swallow 1 whole capsule with a glass of water. Do not open, crush or chew the capsule. If vomiting occurs after taking your capsule, do not take another dose that day,

If a capsule is damaged, avoid contact of the powder with your skin, eyes or nose. Flush the area with water if you accidentally get some in your eyes or nose.

Depending on the dose that has been decided, you may be required to take more than 1 capsule together, and later with capsules of different strengths

(content of active ingredient in mg)

You have to ensure that you fully understand and remember the following :-

- how many capsules you need to take daily that has been decided for you. Please ask your doctor or pharmacist to write it down for you.
- which days you need to take. Check the dose with your doctor each time you start a new cycle because the dose may be different from the previous dose.

Always take TemoRel right on time as directed by your doctor. It is very important to check with your doctor or pharmacist if you are not sure. Errors in how you take the medicine may cause serious health problems.

- How long to use it

Continue taking TemoRel for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as possible on the same day. If a day has passed, seek advice from your doctor. Do not take double dose to replace the dose that was missed., unless instructed by your doctor.

- If you use too much (overdose)

If you have accidentally taken TemoRel capsules more than instructed, you may experience low blood cell count, fever, organ failure, and possibly death. Therefore contact your doctor, pharmacist or nurse immediately.

If you have further questions regarding how to take this medicine, ask your doctor, pharmacist or nurse.

While you are using it

- Things you must do

● Tell all the doctors, dentists and pharmacists treating you that you are taking TemoRel.

● Tell your doctor immediately if you become pregnant while taking this medicine.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give TemoRel to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

TemoRel may make you feel tired or sleepy. Therefore do not drive or use any tools or machines, or cycle until you know the effects of this medicine on you. (see Side effects).

Side effects

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

Inform your doctor or pharmacist if you experience any of the following symptoms :

Infections:

- Fever, shivering, feeling unwell, sore throats including oral and wound infections.

Blood:

TemoRel HARD CAPSULES

Temozolomide (20mg, 100mg, and 250mg)

● Bruising, bleeding, pale, or unusually tired due to low blood cell count.

Metabolism:

● Loss of appetite, body weight decreasing, symptoms of increased sugar level in the blood, including feeling thirsty or passing a large amount of urine.

Psychiatric:

● Changes in emotions feeling anxious or depressed, inability to fall or stay asleep.

Nerve:

● Seizure, headache, dizziness, sleepiness, shaking, forgetfulness, confusion, difficulty in concentrating, difficulty in speaking, impaired or tingling sensation, impaired imbalance.

Eye:

● Double vision, abnormal or blurry vision.

Ear:

● Hearing impairment, ringing in the ears.

Vascular:

● Blood clot in the legs, fluid retention, swollen legs.

Respiratory:

● Cough, shortness of breath

Gastrointestinal:

● Indigestion, difficulty in swallowing, inflamed or sore mouth, abdominal pain, nausea, vomiting, constipation, diarrhea.

Liver:

● Increase in liver enzymes

Skin:

● Rash, hair loss, itching, dry skin, redness, inflammation.

Musculoskeletal:

● Weak, muscle aches and pains, painful joints

Kidney:

● Difficult to hold urine, frequent urination.

General:

Allergic reactions, face swelling, general body pain, radiation injury, different taste sensation.

If you experience any side effects, inform your doctor, pharmacist or nurse. This includes any side effects that are not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TemoRel

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Keep the bottle tightly closed in order to protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose off medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

TemoRel 20 mg hard capsule is a size “2” hard gelatin capsule with yellow colored opaque cap and white colored opaque body, black colored printing text “TEMOZOLOMIDE” on cap and “20 mg” on body having off white to light pink colour powder inside the capsule.

TemoRel 100 mg hard capsule is a Size “1” hard gelatin capsule with pink colored cap and white colored opaque body, printed in blank ink with “TEMOZOLOMIDE” on cap and “100mg” on body and having

off- white to light pink coloured powder inside the capsule.

TemoRel 250 mg hard capsule is a Size “0” hard gelatin capsule with white colored opaque cap and white colored opaque body, printed in blank ink with “TEMOZOLOMIDE” on cap and “250 mg” on body and having off- white to light pink coloured powder inside the capsule.

- Ingredients

Active ingredient:

The active ingredient is Temozolomide.

- **TemoRel 20mg hard capsules:** Each capsule contains 20mg Temozolomide.
- **TemoRel 100mg hard capsules:** Each capsule contains 100mg Temozolomide.
- **TemoRel 250 mg hard capsules:** Each capsule contains 250 mg temozolomide.

Inactive ingredients:

Capsule content:

Anhydrous lactose, colloidal anhydrous silica, sodium starch glycolate type A, tartaric acid, stearic acid.

Capsule shell:

TemoRel 20 mg hard capsules: gelatin, titanium dioxide (E 171), sodium lauryl sulfate, iron oxide yellow (E 172).

TemoRel 100 mg hard capsules: gelatin, titanium dioxide (E 171), sodium lauryl sulfate, red iron oxide (E 172).

TemoRel 250 mg hard capsules: gelatin, titanium dioxide (E 171), sodium lauryl sulfate.

MAL numbers:

TemoRel 20 mg hard capsules: MAL24046040AZ

TemoRel 100 mg hard capsules: MAL22096013AZ

TemoRel 250 mg hard capsules: MAL22096014AZ

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Manufacturer

Reliance Life Sciences Pvt Ltd.,
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Product Registration Holder

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