

Package leaflet: Information for the user

Temozolomide FAIR-MED 5 mg hard capsules
Temozolomide FAIR-MED 20 mg hard capsules
Temozolomide FAIR-MED 100 mg hard capsules
Temozolomide FAIR-MED 140 mg hard capsules
Temozolomide FAIR-MED 180 mg hard capsules
Temozolomide FAIR-MED 250 mg hard capsules
temozolomide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Temozolomide FAIR-MED is and what it is used for
2. What you need to know before you use Temozolomide FAIR-MED
3. How to use Temozolomide FAIR-MED
4. Possible side effects
5. How to store Temozolomide FAIR-MED
6. Contents of the pack and other information

1. What Temozolomide FAIR-MED is and what it is used for

Temozolomide FAIR-MED contains a medicine called temozolomide. This medicine is an antitumour agent.

Temozolomide FAIR-MED is used for the treatment of specific forms of brain tumours:

- in adults with newly-diagnosed glioblastoma multiforme. Temozolomide FAIR-MED is first used together with radiotherapy (concomitant phase of treatment) and after that alone (monotherapy phase of treatment).
- in children 3 years and older and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma. Temozolomide FAIR-MED is used in these tumours if they return or get worse after standard treatment.

2. What you need to know before you use Temozolomide FAIR-MED

Do not use Temozolomide FAIR-MED

- if you are allergic to temozolomide or any of the other ingredients of this medicine (listed in section 6).
- if you have had an allergic reaction to dacarbazine (an anticancer medicine sometimes called DTIC). Signs of allergic reaction include feeling itchy, breathlessness or wheezing, swelling of the face, lips, tongue or throat.
- if certain kinds of blood cells are severely reduced (myelosuppression), 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Temozolomide FAIR-MED,

- as you should be observed closely for the development of a serious form of chest infection called *Pneumocystis jirovecii* pneumonia (PCP). If you are a newly-diagnosed patient (glioblastoma multiforme) you may be receiving Temozolomide FAIR-MED 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 ever had or might now have a hepatitis B infection. This is because Temozolomide FAIR-MED could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.
- if you have low 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 some cases, it may be necessary to stop treatment with Temozolomide FAIR-MED. Your blood will be tested frequently during treatment to monitor the side effects of Temozolomide FAIR-MED on your blood cells.
- as you may have a small risk of other changes in blood cells, including leukaemia.
- if you have nausea (feeling sick in your stomach) and/or vomiting which are very common side effects of Temozolomide FAIR-MED (see section 4), your doctor may prescribe you a medicine (an anti-emetic) to help prevent vomiting. If you vomit frequently before or during treatment, ask your doctor about the best time to take Temozolomide FAIR-MED 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.
- if you are older than 70 years of age, you might be more prone to infections, bruising or bleeding.
- if you have liver or kidney problems, your dose of Temozolomide FAIR-MED may need to be adjusted.

Children and adolescents

Do not give this medicine to children under the age of 3 years because it has not been studied. There is limited information in patients over 3 years of age who have taken Temozolomide FAIR-MED.

Other medicines and Temozolomide FAIR-MED

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. This is because you must not be treated with Temozolomide FAIR-MED during pregnancy unless clearly indicated by your doctor.

Effective contraceptive precautions must be taken by **both male and female patients** who are taking Temozolomide FAIR-MED (see also “Male fertility” below).

You should stop breast-feeding while receiving treatment with Temozolomide FAIR-MED.

Male fertility

Temozolomide FAIR-MED 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.

Driving and using machines

Temozolomide FAIR-MED may make you feel tired or sleepy. In this case, do not drive or use any tools or machines or cycle until you see how this medicine affects you (see section 4).

Temozolomide FAIR-MED contains lactose

Temozolomide FAIR-MED hard capsules contain lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Temozolomide FAIR-MED

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage and duration of treatment

Your doctor will work out your dose of Temozolomide FAIR-MED. 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 (anti-emetics) to take before and/or after taking Temozolomide FAIR-MED to prevent or control nausea and vomiting.

Patients with newly-diagnosed glioblastoma multiforme:

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

- treatment together with radiotherapy (concomitant phase) first
- followed by treatment with only Temozolomide FAIR-MED (monotherapy phase).

During the concomitant phase, your doctor will start Temozolomide FAIR-MED at a dose of 75 mg/m² (usual dose). You will take this dose every day for 42 days (up to 49 days) in combination with radiotherapy. The Temozolomide FAIR-MED dose may be delayed or stopped, depending on your blood counts and how you tolerate your medicine during the concomitant phase. Once the radiotherapy is completed, you will interrupt treatment for 4 weeks. This will give your body a chance to recover. Then, you will start the monotherapy phase.

During the monotherapy phase, the dose and way you take Temozolomide FAIR-MED will be different. Your doctor will work out your exact dose. There may be up to 6 treatment periods (cycles). Each one lasts 28 days. You will take your new dose of Temozolomide FAIR-MED alone once daily for the first 5 days (“dosing days”) of each cycle. The first dose will be 150 mg/m². Then you will have 23 days without Temozolomide FAIR-MED. This adds up to a 28- day treatment cycle. After Day 28, the next cycle will begin. You will again take Temozolomide FAIR-MED once daily for 5 days followed by 23 days without Temozolomide FAIR-MED. The Temozolomide FAIR-MED dose may be adjusted, delayed or stopped depending on your blood counts and how you tolerate your medicine during each treatment cycle.

Patients with tumours that have returned or worsened (malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma) taking Temozolomide FAIR-MED only:

A treatment cycle with Temozolomide FAIR-MED lasts 28 days.

You will take Temozolomide FAIR-MED alone once daily for the first 5 days. This daily dose depends on whether or not you have received chemotherapy before.

If you have not been previously treated with chemotherapy, your first dose of Temozolomide FAIR-MED will be 200 mg/m² once daily for the first 5 days. If you have been previously treated with chemotherapy, your first dose of Temozolomide FAIR-MED will be 150 mg/m² once daily for the first 5 days.

Then, you will have 23 days without Temozolomide FAIR-MED. This adds up to a 28-day treatment cycle.

After Day 28, the next cycle will begin. You will again receive Temozolomide FAIR-MED once daily for 5 days, followed by 23 days without Temozolomide FAIR-MED.

Before each new treatment cycle, your blood will be tested to see if the Temozolomide FAIR-MED dose needs to be adjusted. Depending on your blood test results, your doctor may adjust your dose for the next cycle.

How to take Temozolomide FAIR-MED

Take your prescribed dose of Temozolomide FAIR-MED once a day, preferably at the same time each day.

Take the capsules on an empty stomach; for example, at least one hour before you plan to eat breakfast. Swallow the capsule(s) whole with a glass of water. Do not open, crush or chew the capsules. If a capsule is damaged, avoid contact of the powder with your skin, eyes or nose. If you accidentally get some in your eyes or nose, flush the area with water.

Depending on the prescribed dose, you may have to take more than one capsule together, eventually with different strengths (content of active substance, in mg). The colour of the capsule cap is different for each strength (see in the table below).

Strength	Colour of the cap
Temozolomide FAIR-MED 5 mg hard capsules	Green
Temozolomide FAIR-MED 20 mg hard capsules	Orange
Temozolomide FAIR-MED 100 mg hard capsules	Purple
Temozolomide FAIR-MED 140 mg hard capsules	Blue
Temozolomide FAIR-MED 180 mg hard capsules	Chocolate brown
Temozolomide FAIR-MED 250 mg hard capsules	White

You should make sure you fully understand and remember the following:

- 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.

Always take Temozolomide FAIR-MED exactly as your doctor has told you. It is very important to check with your doctor or pharmacist if you are not sure. Errors in how you take this medicine may have serious health consequences.

If you take more Temozolomide FAIR-MED than you should

If you accidentally take more Temozolomide FAIR-MED capsules than you were told to, contact your doctor, pharmacist or nurse immediately.

If you forget to take Temozolomide FAIR-MED

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Contact your doctor **immediately** if you have any of the following:

- a severe allergic (hypersensitive) reaction (hives, wheezing or other breathing difficulty),
- uncontrolled bleeding,
- seizures (convulsions),
- fever,
- severe headache that does not go away.

Temozolomide FAIR-MED 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. The reduction in blood cell counts is usually short-lived. In some cases, it may be prolonged and may lead to a very severe form of anaemia (aplastic anaemia). Your doctor will monitor your blood regularly for any changes, and will decide if any specific treatment is needed. In some cases, your Temozolomide FAIR-MED dose will be reduced or treatment stopped.

Side effects from clinical studies:

Temozolomide FAIR-MED in combination treatment with radiotherapy in newly-diagnosed glioblastoma

Patients receiving Temozolomide FAIR-MED in combination with radiotherapy may experience different side effects than patients taking Temozolomide FAIR-MED alone. The following side effects may occur, and may require medical attention.

Very common (may affect more than 1 in 10 people): loss of appetite, headache, constipation (difficulty passing stools), nausea (feeling sick in your stomach), vomiting, rash, hair loss, tiredness.

Common (may affect up to 1 in 10 people): oral infections, wound infection, reduced number of blood cells (neutropenia,

thrombocytopenia, lymphopenia, leukopenia), increased sugar in the blood, loss of weight, change in mental status or alertness, anxiety/depression, 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, shortness of breath, cough, blood clot in the legs, fluid retention, swollen legs, diarrhoea, stomach or abdominal pain, heartburn, upset stomach, difficulty swallowing, dry mouth, skin irritation or redness, dry skin, itching, muscle weakness, painful joints, muscle aches and pains, frequent urination, difficulty with holding your urine, allergic reaction, fever, radiation injury, face swelling, pain, abnormal taste, abnormal liver function tests.

Uncommon (may affect up to 1 in 100 people): flu-like symptoms, red spots under the skin, low potassium level in the blood, weight gain, mood swings, hallucination and memory impairment, partial paralysis, impaired coordination, 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.

Temozolomide FAIR-MED monotherapy in recurrent or progressive glioma

The following side effects may occur, and may require medical attention.

Very common (may affect more than 1 in 10 people): reduced number of blood cells (neutropenia or lymphopenia, thrombocytopenia), loss of appetite, headache, vomiting, nausea (feeling sick in your stomach), constipation (difficulty passing stools).

Common (may affect up to 1 in 10 people): loss of weight, tiredness, dizziness, tingling sensation, shortness of breath, diarrhoea, abdominal pain, upset stomach, rash, itching, hair loss, fever, weakness, shivering, feeling unwell, pain, change in taste.

Uncommon (may affect up to 1 in 100 people): reduced blood cell counts (pancytopenia, anaemia, leukopenia).

Rare (may affect up to 1 in 1,000 people): cough, infections including pneumonia.

Very rare (may affect up to 1 in 10,000 people): skin redness, urticaria (hives), skin eruption, allergic reactions.

Other side effects:

Cases of elevations of liver enzymes have been commonly reported. Cases of increased bilirubin, problems with bile flow (cholestasis), hepatitis and injury to the liver, including fatal liver failure, have been uncommonly reported.

Very rare 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.

Very rare cases of lung side effects have been observed with Temozolomide FAIR-MED. Patients usually present with shortness of breath and cough. Tell your doctor if you notice any of these symptoms.

In very rare cases, patients taking Temozolomide FAIR-MED and medicines like it may have a small risk of developing secondary cancers, including leukaemia.

New or reactivated (recurring) cytomegalovirus infections and reactivated hepatitis B virus infections have been uncommonly reported. Cases of brain infections caused by herpes virus (meningoencephalitis herpetic), including fatal cases, have been uncommonly reported.

Cases of diabetes insipidus have been uncommonly reported. Symptoms of diabetes insipidus include passing a lot of urine and feeling thirsty.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Temozolomide FAIR-MED

Keep this medicine out of the sight and reach of children, preferably in a locked cupboard. Accidental ingestion can be lethal for children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

HDPE Bottle presentation

Store below 30°C

Store in the original bottle in order to protect from moisture.

Keep the bottle tightly closed.

Sachet presentation

5mg, 20mg: Store below 25°C

100mg, 140mg, 180mg and 250mg: Store below 30°C

Tell your pharmacist if you notice any change in the appearance of the capsules.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Temozolomide FAIR-MED contains

- The active substance is temozolomide. Each capsule contains 5 mg temozolomide.
- The active substance is temozolomide. Each capsule contains 20 mg temozolomide.
- The active substance is temozolomide. Each capsule contains 100 mg temozolomide.
- The active substance is temozolomide. Each capsule contains 140 mg temozolomide.
- The active substance is temozolomide. Each capsule contains 180 mg temozolomide.

- The active substance is temozolomide. Each capsule contains 250 mg temozolomide.

- The other ingredients are:

Capsule content

Lactose Anhydrous
Silica, Colloidal Anhydrous
Sodium Starch Glycolate (Type A)
Tartaric Acid
Stearic Acid

(see section 2 "Temozolomide FAIR-MED contains lactose").

Capsule shell, Size 0:

5 mg:

Gelatin,
Titanium dioxide (E 171).
Yellow iron oxide (E 172),
Indigotine – FD&C Blue2 (E132)

20 mg:

Gelatin,
Titanium dioxide (E 171)
Red iron oxide (E 172)
Yellow iron oxide (E 172)

100 mg:

Gelatin,
Titanium dioxide (E 171)
Red iron oxide (E 172)
Indigotine FD&C blue2 (E 132)

140 mg:

Gelatin,
Titanium dioxide (E 171)
Indigotine FD&C blue 2 (E 132)

180 mg:

Gelatin,
Titanium dioxide (E 171)
Red iron oxide (E 172)
Black iron oxide (E 172)
Yellow iron oxide (E 172)

250 mg:

Gelatin,
Titanium dioxide (E 171)

Printing ink

Black Ink:

Shellac

Propylene glycol
Purified water
Sodium ammonia solution
Potassium hydroxide
Black iron oxide (E 172)

What Temozolomide FAIR-MED looks like and contents of the pack

5 mg: The hard gelatin capsules are size 0 and have a green opaque cap/white opaque body with 5 printed in black ink on the body.

20 mg: The hard gelatin capsules are size 0 and have an orange opaque cap /white opaque body with 20 printed in black on the body.

100 mg: The hard gelatin capsules are size 0 and have a purple opaque cap /white opaque body with 100 printed in black on the body

140 mg: The hard gelatin capsules size 0 and have a blue opaque cap /white opaque body with 140 printed in black on the body

180mg: The hard gelatin capsules are size 0 and have a chocolate brown opaque cap /white opaque body with 180 printed in black on the body

250 mg: The hard gelatin capsules are size 0 and have a white opaque cap /white opaque body with 250 printed in black on the body

HDPE Bottle presentation

Child proof container, made from white opaque High Density Polyethylene Bottles with Polypropylene child-proof closure, with polyester coil and dessicant desiccant containing 5 capsules.

Sachet presentation

Sachets composed of paper on linear low density polyethylene (outermost layer), aluminium and ethylene acrylic acid co-polymer (innermost layer). Each sachet contains 1 hard capsule and is dispensed in a cardboard carton. The carton contains 5 or 20 hard capsules, individually sealed in sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

FAIR-MED HEALTHCARE GmbH
Planckstr. 13, 22765, Hamburg
Germany

Manufacturer

FAIR-MED HEALTHCARE GmbH
Maria-Göppert-Straße 3
23562 Lübeck
Germany

EirGen Pharma Ltd.
64/66 Westside Business Park, Old Kilmeaden Road, Waterford,
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands	Temozolomide FAIR-MED 5mg/20mg/100mg/140mg/180mg/250mg, Capsules harde
Cyprus	Temozolomide FAIR-MED 5mg/20mg/100mg/140mg/180mg/250mg hard capsules
Germany	Temozolomid Fair-Med Healthcare 5mg/20mg/100mg/140mg/180mg/250mg Hartkapseln
Denmark	Temozolomid FAIR-MED
Ireland	Temozolomide FAIR-MED 5mg/20mg/100mg/140mg/180mg/250mg hard capsules
Malta	Temozolomide FAIR-MED 5mg/20mg/100mg/140mg/180mg/250mg hard capsules
Poland	Temozolomide FAIR-MED

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