Applicant : Eurolab (Pty) Ltd
Proprietary name : Temintas 5 mg & 20 mg & 100 mg & 250 mg
Dosage form and strength : Gelatin capsule 5 mg & 20 mg & 100 mg & 250 mg
Date of submission : 29 November 2023
Approval date : 08 October 2024

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TEMINTAS 5 mg hard gelatin capsule

TEMINTAS 20 mg hard gelatin capsule

TEMINTAS 100 mg hard gelatin capsule

TEMINTAS 250 mg hard gelatin capsule

Temozolomide

Contains lactose

Read all of this leaflet carefully before you start taking TEMINTAS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- **TEMINTAS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **TEMINTAS** is and what it is used for
2. What you need to know before you take **TEMINTAS**
3. How to take **TEMINTAS**
4. Possible side effects
5. How to store **TEMINTAS**

6. Contents of the pack and other information

1. What TEMINTAS is and what it is used for

TEMINTAS is a chemotherapy medicine.

- **TEMINTAS** is used to treat, certain types of brain tumours and skin Cancer.
- **TEMINTAS** is first used together with radiotherapy and after that alone in newly diagnosed adults.
- **TEMINTAS** is used if these tumours return or get worse after standard treatment.

2. What you need to know before you take TEMINTAS

Do not take TEMINTAS

- if you are hypersensitive (allergic) to temozolomide or any of the other ingredients of TEMINTAS (listed in section 6) or to dacarbazine (DTIC) [another chemotherapy medicine with actions similar to temozolomide].
- If you have severe myelosuppression (decrease in the ability of the bone marrow to produce blood cells like red blood cells, white blood cells or platelets)
- If you are pregnant or breast-feeding (see Pregnancy and Breast-feeding).

Warnings and precautions

Take special care with **TEMINTAS:**

- You should be observed closely for the development of a serious form of chest infection called Pneumocystis carinii pneumonia (PCP). If you are a newly-diagnosed patient (glioblastoma multiforme) you may be receiving **TEMINTAS** 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 severe vomiting, you may require a medicine which will stop this vomiting before your treatment with **TEMINTAS** is started.
- If you have severe liver dysfunction or kidney dysfunction caution should be exercised when you receive TEMINTAS.

- Before you are given TEMINTAS, a complete blood count (blood tests) will be carried out. TEMINTAS will only be used if the blood cell count satisfies certain laboratory parameters. If the cell count falls beyond certain criteria, the dose of the next cycle may be reduced.
- When TEMINTAS is used to treat brain tumour, it should not be given to children under the age of 3 years.
- When TEMINTAS is used to treat skin cancer, it should not be given to children under the age of 18 years.

Other medicines and TEMINTAS

Always tell your health care provider if you are taking any other medicine. (This includes medicines you may have bought without a prescription, including all complementary or traditional medicines.)
Other medicines can affect the way TEMINTAS works and TEMINTAS can affect the way other medicines work.

Please inform your doctor if you are taking:

- valproic acid (medicine used to treat fits),
- other myelosuppressive agents (agents that decrease bone marrow production of blood cells)

TEMINTAS with food and drink

You may take your tablets at least one hour before a meal. The capsules must not be opened or chewed, but must be swallowed whole with a glass of water.

Pregnancy, breastfeeding and fertility

Do not take TEMINTAS if you are pregnant. Contact your doctor immediately. You should not fall pregnant while taking or in the six months after discontinuation of therapy with TEMINTAS.
Do not take TEMINTAS if you are breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Use of **TEMINTAS** in male patients:

- If you are a male patient, you should use effective contraception if you are on therapy with TEMINTAS, and you should not father a child while you are on therapy or for up to 6 months after discontinuation of **TEMINTAS**.
- You may experience irreversible infertility (unable to father a child) due to therapy with **TEMINTAS**, therefore you should seek medical advice on cryoconservation (freezing) of your sperm prior to treatment with **TEMINTAS**.

Driving and using machines

There is a possibility of feeling drowsy when you are given TEMINTAS.

If this happens do not drive or operate any tools or machines.

TEMINTAS contains lactose

If you have lactose intolerance (difficulty digesting the sugar in milk), please inform your doctor.

3. How to take TEMINTAS

Do not share medicines prescribed for you with any other person.

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

TEMINTAS will be prescribed for you by your doctor.

Your doctor will choose the dose that is right for you and your duration of treatment. TEMINTAS will be prescribed in cycles.

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

Treatment in combination with radiotherapy first

- The usual dose is 75 mg/m2 once daily for 42 days if you take TEMINTAS in combination with radiotherapy.

Treatment with TEMINTAS only (adjuvant/monotherapy phase)

- Once the radiotherapy is completed, you will interrupt treatment for 4 weeks.
- The dose and way you take TEMINTAS will be different, your doctor will work out your exact dose. The usual dose is 75 mg/m2 to 200 mg/m2 once daily for 5 days out of a 28 days cycle if you take TEMINTAS as only treatment. There may be up to 6 treatment cycles.

How to take TEMINTAS:

- You should take TEMINTAS exactly as directed by your doctor.
- You should take your capsule on an empty stomach, at least one hour before a meal.
- You may need to take a medicine which stops vomiting prior to or following administration of TEMINTAS.
- If you vomit after taking the dose of TEMINTAS a second dose should not be taken that day. If in doubt check with your doctor.
- Your capsules must not be opened, crushed or chewed, but are to be swallowed whole with a full glass of water. If a capsule becomes damaged, contact of the powder contents with your skin or mucous membranes should be avoided.
- You should continue with TEMINTAS for as long as your doctor has advised.
- Do not take more TEMINTAS than your prescribed dose.

If you have the impression that the effect of TEMINTAS is too strong or too weak, talk to your doctor/oncologist or pharmacist.

If you take more TEMINTAS than you should

- If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately.

If you forget to take TEMINTAS

- If you forget to take TEMINTAS, take your tablets as soon as you remember. Do not take two doses in one day.

4. Possible side effects

TEMINTAS can have side effects.

Not all side effects reported for TEMINTAS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking TEMINTAS, please consult your health care provider for advice.

Please inform you doctor immediately if you experience any of the following side-effects

- difficulty breathing
- allergic reaction such as swelling of your face, lips, tongue or throat or rash
- numbness and tingling or pins and needles on one side of your body
- signs of infection such as fever, chills, or nausea and vomiting

You may experience the following side-effects frequently:

- oral infections, wound infection
- reduced number of blood cells
- easy bruising or bleeding (nosebleeds, bleeding gums)
- constipation, loss of appetite, diarrhoea, abdominal pain, heartburn and taste disturbances.
- increased sugar in the blood
- hair loss, itching, petechiae (red or purple spots on the body)
- pain, generally feeling unwell, weight decrease and shaking.
- anxiety, mood swings, inability to fall asleep or stay asleep

- headache, dizziness, impaired coordination and balance, change in mental status or alertness, forgetfulness, difficulty concentrating, tingling sensations, shaking, difficulty speaking
- abnormal vision, partial loss of vision, double vision
- hearing difficulty
- fast beating, fluttering/pounding heart
- bleeding, bruising, blood clot in the legs, fluid retention, swollen legs
- coughing, shortness of breath
- stomach or abdominal pain, upset stomach, heartburn, difficulty passing stools, vomiting, difficulty swallowing, dry mouth
- muscle damage, muscle weakness, muscle aches and pain
- frequent urination, difficulty withholding your urine
- tiredness, fever, flu-like symptoms, pain, face swelling abnormal taste
- abnormal liver function tests.

The following side-effects may occur less frequently:

- severe allergic reactions and erythema multiforme (redness of the skin)
- an infection known as Pneumocystis carinii pneumonia (PCP)[opportunistic respiratory infections in patients who are immuno-compromised (weakened immune systems) or who have HIV or AIDS]
- secondary malignancies, including myeloid leukaemia (a type of cancer involving the myeloid line of blood cells)
- myelodysplastic syndrome (MDS) [damage to blood forming cells in the bone marrow]
- reduced blood cell counts
- increased levels of a hormone called cortisol causing weight gain and facial puffiness
- low levels of potassium in the blood, high blood sugar, weight gain
- mood swings, hallucination, memory loss
- partial loss of vision, dry or painful eyes

- hearing impairment, infection of the middle ear, ringing in the ears, earache, sensation of spinning dizziness
- palpitations (when you can feel your heart beat)
- high blood pressure, bleeding in the brain, swelling of your legs or hands, blood clot in the lung
- pneumonia, inflammation of your sinuses, bronchitis
- swollen stomach, difficulty controlling your bowel movements, upset stomach, haemorrhoids
- increased sensitivity to sunlight, painful reddening of the skin, skin peeling, increased sweating
- muscle damage, painful joint, back pain, muscle pain
- frequent urination, difficulty in urinating
- absent or heavy menstrual periods, vaginal bleeding, vaginal irritation, breast pain, sexual impotence
- shivering, face swelling, discolouration of the tongue, thirst, tooth disorder

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects you can help provide more information on the safety of TEMINTAS.

5. How to store TEMINTAS

Store in a cool, dry place, at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN

Store in unit carton until before use.

Do not use after the expiry date stated on the carton.

Return all unused TEMINTAS to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g.toilets).

You will not be required to dispose of the unused medicine yourself.

Your healthcare professional will dispose of it in an appropriate manner.

6. Contents of the pack and other information

What TEMINTAS contains

The active substance is temozolomide

The other ingredients are:

- Anhydrous lactose
- Colloidal anhydrous silica
- Sodium starch glycolate (Type A)
- Tartaric acid
- Stearic acid
- Gelatin
- Iron oxide yellow (E172)
- Titanium dioxide (E171)

What TEMINTAS looks like and contents of the pack

- TEMINTAS 5:

Green/White, hard gelatin capsules size '3' imprinted with 'TMZ' on cap & '5' on body, containing white to light pink powder.

Hard gelatin capsules are packed in amber glass bottles of 5 capsules and 20 capsules per bottle, which are packed with a white cotton coil and desiccant disc, and a white opaque polypropylene child resistant closure, in a unit carton.

Hard gelatin capsules are packed in sachets composed of triple laminated foil made of polyethylene, aluminium and poly film. Each sachet contains 1 capsule. Five sachets will be packed in an outer carton.

- **TEMINTAS 20:**

Yellow/ white hard gelatin capsules, size '5' imprinted 'TMZ' on cap & '20' on body, containing white to light pink powder.

Hard gelatin capsules are packed in amber glass bottles of 5 capsules and 20 capsules per bottle, which are packed with a white cotton coil and desiccant disc, and a white opaque polypropylene child resistant closure, in a unit carton.

Hard gelatin capsules are packed in sachets composed of triple laminated foil made of polyethylene, aluminium and poly film. Each sachet contains 1 capsule. Five sachets will be packed in an outer carton.

- **TEMINTAS 100:**

Pink/White hard gelatin capsules, size '3' imprinted 'TMZ' on cap & '100' on body, containing white to light pink powder.

Hard gelatin capsules are packed in amber glass bottles of 5 capsules and 20 capsule per bottle, which are packed with a white cotton coil and desiccant disc, and a white opaque polypropylene child resistant closure, in a unit carton.

Hard gelatin capsules are packed in sachets composed of triple laminated foil made of polyethylene, aluminium and poly film. Each sachet contains 1 capsule. Five sachets will be packed in an outer carton.

- **TEMINTAS 250:**

White/White, hard gelatin capsules size '0' imprinted with 'TMZ' on cap & '250' on body, containing white to light pink powder.

Hard gelatin capsules are packed in amber glass bottles of 5 capsules and 20 capsules per bottle, which are packed with a white cotton coil and desiccant disc, and a white opaque polypropylene child resistant closure, in a unit carton.

Hard gelatin capsules are packed in sachets composed of triple laminated foil made of polyethylene, aluminium and poly film. Each sachet contains 1 capsule. Five sachets will be packed in an outer carton.

Holder of certificate of registration

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