

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TIMUCEN 250 Film-coated tablets

Methyldopa

Sugar free

Read all of this leaflet carefully before you start taking TIMUCEN 250

- 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.
- **TIMUCEN 250** 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 **TIMUCEN 250** is and what it is used for
2. What you need to know before you take **TIMUCEN 250**
3. How to take **TIMUCEN 250**
4. Possible side effects
5. How to store **TIMUCEN 250**
6. Contents of the pack and other information

1. What **TIMUCEN 250** is and what it is used for

TIMUCEN 250 contains methyldopa. Methyldopa belongs to a group of medicines called hypotensives or also known as antihypertensives.

Methyldopa lowers blood pressure and are used in adults and children. Your doctor has prescribed **TIMUCEN 250** to treat essential hypertension, which is a form of high blood pressure that does not have an identifiable cause.

2. What you need to know before you take **TIMUCEN 250**

Do not take **TIMUCEN 250**

- if you are hypersensitive (allergic) to methyldopa or any of the other ingredients of this medicine (listed in section 6);
- if you have kidney or liver problems or have a history of liver disease;
- if you have or ever had depression;
- if you have severe liver problems;
- if you have high blood pressure due to a tumour near your kidney called phaeochromocytoma;
- if you have porphyria (a rare, inherited blood disorder), as **TIMUCEN 250** may worsen it;
- If you are using medication called monoamine oxidase inhibitors (MAOI), used for the treatment of different forms of depression.

Warnings and precautions

Special care should be taken with **TIMUCEN 250**:

- It is recommended that your doctor perform blood tests during the first 6 to 12 weeks of treatment, to check your blood cell counts and liver function, or if you develop an unexplained fever. Therefore, inform your doctor immediately when you develop a fever.
- If you are going to have a blood transfusion, inform your doctor that you are taking **TIMUCEN 250** as it may interfere with a blood test called Coombs' test.
- **TIMUCEN 250** may occasionally cause urine to darken because of the breakdown of the medicine;

- If you are going to be receiving anaesthesia during a procedure or operation, **TIMUCEN 250** may cause severely hypotension (low blood pressure). Your doctor may need to lower the dose of anaesthesia that you would need;

Children

TIMUCEN 250 may be given to children. The same warnings and precautions applicable to adults apply to children.

Other medicines and TIMUCEN 250

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Please inform your healthcare professional if:

- you are currently taking any other medicines to treat high blood pressure. Taking other high blood pressure medicine with **TIMUCEN 250** will increase the blood lowering effects of **TIMUCEN 250**.
- when you have a laboratory test where a urine or blood sample is taken. This is because **TIMUCEN 250** may affect the results of some types of tests.
- you are going to be receiving anaesthesia. See above “**Warnings and precautions**”.
- you are taking medication for depression, called tricyclic antidepressants and monoamine oxidase inhibitors. Taking these medicines with **TIMUCEN 250** may decrease the blood lowering effects of **TIMUCEN 250**.
- you are taking sympathomimetics (medications for managing heart, lung, and eye diseases or allergies), or phenothiazines (used treating depression, nausea and vomiting or other mental illnesses). Taking these medicines with **TIMUCEN 250** may decrease the blood lowering effects of **TIMUCEN 250**.
- you are taking lithium. Taking lithium with **TIMUCEN 250** may lead to lithium toxicity.
- you are taking medications known to potentially harm the liver (hepatotoxic drugs), such as halothane, it's not advisable to combine them.

TIMUCEN 250 with food, drink and/or alcohol

No relevant data are available with regards to interactions between **TIMUCEN 250** and food, drink and/or alcohol.

Pregnancy, breastfeeding and fertility

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 **TIMUCEN 250**.

Pregnancy

The safety of **TIMUCEN 250** in pregnancy has not been established.

Breastfeeding

The safety of **TIMUCEN 250** in lactation has not been established.

Fertility

There are no clinical data available on the effects of **TIMUCEN 250** on human fertility.

Driving and using machines

It is not always possible to predict to what extent **TIMUCEN 250** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **TIMUCEN 250** affects them.

You may feel drowsy or light-headed while taking **TIMUCEN 250**. If this happens do not drive or use any tools or machines.

3. How to take TIMUCEN 250

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

Always take **TIMUCEN 250** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose is one tablet (250 mg) two or three times daily by mouth during the first two days (48 hours). Thereafter, your doctor may change your dose depending on how you respond.

Children

Your doctor will work out the number of tablets. The dose is based on the weight of the child. The usual starting dose is 10 mg for each kg of body weight daily by mouth in divided doses.

If you take more TIMUCEN 250 than you should

Do not exceed the prescribed dose.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TIMUCEN 250

Take your normal dose immediately and continue as prescribed the next day. If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose.

Then go on as before.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking TIMUCEN 250

Do not stop taking **TIMUCEN 250** without talking to your doctor.

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

4. Possible side effects

TIMUCEN 250 can have side effects.

Not all side effects reported for **TIMUCEN 250** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TIMUCEN 250**, please inform your health care provider for advice.

Tell your doctor or health care provider if you notice any of the following:

Frequent side effects:

- Depression, mental changes, nightmares.
- Drowsiness, weakness, dizziness, light-headedness, headache.
- Nasal stuffiness.
- Nausea, dryness of the mouth.
- Changes in sexual function.
- Water retention causing swelling and weight gain.

Less frequent side effects:

- Swelling of the saliva glands.
- Increase in hormones in your blood that causes excess milk production, called hyperprolactinaemia.
- Pins and needles, being unable to move part of your face (Bell's palsy), parkinsonism (symptoms such as tremor, a decrease in body movements with an inability to move your muscles).
- Having movements, you cannot control.
- Chest pain, slow heart rate, existing angina made worse.
- Dizziness due to low blood pressure and light-headedness (particularly when standing up quickly).
- Black or sore tongue, inflammation of the pancreas, stomach upset, diarrhoea, constipation.
- Skin rash or peeling skin.

- Painful and/or swollen joints, muscle pains.
- Breast enlargement, production of milk.
- High levels of urea in the blood (uraemia).

Side effects with unknown frequency:

- Changes in blood cell levels (thrombocytopenia, leucopenia, granulocytopenia, and haemolytic anaemia)
- Fever which may be accompanied by a rise in a type of disease-fighting white blood cells called eosinophils.
- Abnormal liver function tests.
- Liver problems, including jaundice and hepatitis - signs include yellowing of your skin and eyes, sometimes with a fever, pale stools, and dark urine.
- Severe fatigue and joint pain (Lupus-like symptoms).
- Positive Coombs' tests results (a test that checks your blood for antibodies that attack red blood cells) without any evidence of red blood cell breakdown (haemolysis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 **TIMUCEN 250**.

5. How to store TIMUCEN 250

Store all medicines out of reach of children.

Store below 25 °C.

Keep the container tightly closed.

Protect from light and dispense in amber bottles.

Do not use after the expiry date printed on the carton and blister or securitainer.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What TIMUCEN 250 contains

The active ingredient is methyldopa.

The other ingredients are:

- *Tablet core*: Microcrystalline cellulose (Avicel pH 101); Crospovidone CL-M (Type B); Povidone; and Magnesium Stearate.
- *Tablet coating*: Citric Acid Monohydrate; Disodium Edetate; and Opadry Yellow OY-8466, which includes Methocel ES Premium EP, (E464); Titanium Dioxide BP C.I. No. 77891 (E 171); Polyethylene Glycol 400; Quinoline Yellow Aluminium Lake C.I. No. 47005 (E 104); and Iron Oxide Yellow C.I. No. 77492 (E 172).

What TIMUCEN 250 looks like

TIMUCEN 250 are yellow, biconvex film-coated tablets.

Aluminium/PVC/PYDC blister packs or polypropylene securitainer of 56, 84, 100 and 500 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.trinitypharma.co.za