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Patient Information Leaflet
SCHEDULING STATUS
S2

Theophylline 200 GDC, 200 mg tablets

Theophylline
Sugar free

Read all of this leaflet carefully because it contains important information for you

Theophylline 200 GDC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Theophylline 200 GDC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Theophylline 200 GDC with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What Theophylline 200 GDC is and what it is used for
2. What you need to know before you take Theophylline 200 GDC
3. How to take Theophylline 200 GDC
4. Possible side effects
5. How to store Theophylline 200 GDC
6. Contents of the pack and other information

1. What Theophylline 200 GDC is and what it is used for

Theophylline belongs to a group of medicines called bronchodilators. Bronchodilators are used to treat and relieve the symptoms of diseases where the passages in your lungs are blocked. It works by widening the air passages in your lungs which allows you to breathe more easily and feel less tight chested. Theophylline 200 GDC is used for the treatment and prevention of bronchospasm associated with asthma, chronic bronchitis and emphysema.

2. What you need to know before you take Theophylline 200 GDC

Do not take Theophylline 200 GDC:

- If you are hypersensitive (allergic) to theophylline or any of the other ingredients of Theophylline 200 GDC (listed in section 6);
- If you are receiving any other theophylline therapy;
- If you are hypersensitive to products called xanthine derivatives (e.g.: caffeine, theobromine and methylxanthines. These are components of coffee, tea and chocolate) and aminophylline;
- If you have suffered from a heart attack recently;
- If you have acute tachydysrhythmia (fast and/or irregular heartbeat);
- If you have a disease called porphyria which may cause skin problems, chest and stomach pains, nausea and diarrhoea;
- If you are a child and are taking medicines containing ephedrine (e.g. children's cold and cough medicines)
- If you are a child under 2 years old.

Warnings and precautions

Special care should be taken with Theophylline 200 GDC:

- If your asthma symptoms become worse;
- If you are taking medicines used to treat colds or flu (sympathomimetic medicines);
- If you have any heart disease because it can cause other unwanted effects of the heart and influence the theophylline levels in your body;
- If you have high blood pressure because it can cause other side effects of the heart;
- If you have an overactive or underactive thyroid gland because it can influence the elimination of theophylline from your body;
- If you have any liver disease or kidney disease;
- If you are abusing alcohol;
- If you have a chronic obstructive pulmonary disease (COPD: kind of tight chest);
- If your lungs are inflamed, you experience shortness of breath or if you have excess fluid in your lungs (pulmonary oedema);
- If you have a stomach ulcer or suffer from reflux of gastric acid because theophylline can increase gastric acid secretion;
- If you smoke tobacco because it can decrease the elimination of theophylline from your body;
- If you have a high fever, headache and chills that came on suddenly (acute febrile illness) because it can delay the clearance of theophylline;
- If you have a viral infection because it can delay the clearance elimination of theophylline from your body;
- If you have a history of seizures (convulsions);
- if you are taking products called xanthine derivates or xanthine containing beverages (such as tea, coffee, cola, cocoa) because it can influence the level of theophylline in your body;
- If you are more than 55 years old;
- If you are dehydrated (you have lost too much fluid from your body).

Children

Do not give Theophylline 200 GDC to children under 2 years old because they cannot metabolise theophylline sufficiently. For children taking Theophylline 200 GDC tablets, NUELIN LIQUID may be considered as an alternative and more appropriate dosage form.

Other medicines and Theophylline 200 GDC

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

Tell your doctor or pharmacist if you are taking any of the following medicines because they may have to alter the dose of Theophylline 200 GDC that you take:

- Medicines to treat stomach or intestinal ulcers such as cimetidine, nizatidine or ranitidine;
- Medicines to treat high blood pressure such as furosemide, beta-blockers, calcium channel blockers, diltiazem, verapamil, diltiazem;
- Medicines to treat an overactive thyroid gland such as carbimazole;
- Antibiotics such as erythromycin, clarithromycin, ciprofloxacin, enoxacin;
- Medicines to treat worm infections such as thiabendazole;
- Medicines to treat bacterial infections such as imipenem;
- Medicines to treat fungal infections such as fluconazole;
- Medicines to treat gout such as allopurinol or sulfinpyrazone;
- Medicines to treat skin diseases such as corticosteroids;
- Oral contraceptives ("the pill");
- Medicines to treat irregular heart beat and heart conditions such as mexiletine, digoxin or propafenone;
- Medicines to treat depression such as fluvoxamine and viloxazine;
- Tacrine used for the treatment of dementia;
- Medicine for the management of rheumatoid arthritis such as methotrexate;
- Medicine used to improve blood flow and treat small blood vessels such as pentoxifylline;
- Ticlopidine used to reduce the risk of thrombotic stroke;
- A vaccine for preventing flu;
- Medicines to treat alcoholism such as disulfiram;
- Interferon alpha, a medicine used to treat several cancers;
- Medicines to treat tuberculosis such as isoniazid or rifampicin;
- Antiretroviral medicines such as ritonavir;
- Medicines to prevent and treat epileptic seizures such as phenobarbitone, phenytoin, carbamazepine, barbiturates, primidone;
- Aminoglutethimide, used to treat a disease called Cushing's Syndrome;
- St John's Wort (Hypericum perforatum), a herbal remedy used to treat depression;
- Ketamine or halothane, medicines used as an anaesthetic;
- Medicines used to treat mood disorders called lithium;
- Adrenaline and another xanthine called aminophylline which are used to treat asthma or lung disease.

Also tell your doctor or pharmacist if you drink any alcohol or if you smoke tobacco or marijuana.

Pregnancy, breastfeeding and fertility

Theophylline 200 GDC should not be taken if you are pregnant or 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.

Driving and using machinery

Even when taken as prescribed, Theophylline 200 GDC may affect your ability to drive a vehicle, operate machinery or work safely under hazardous conditions. This applies particularly when it is taken in conjunction with alcohol or other medicines liable to impair judgment and motor skills.

It is not always possible to predict to what extent Theophylline 200 GDC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they know how Theophylline 200 GDC affects them.

3. How to take THEOPHYLLINE 200 GDC

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

Always take Theophylline 200 GDC exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults is one Theophylline 200 GDC tablet taken by mouth twice daily (i.e. 12 hourly), to be increased gradually by intervals of 2 to 3 days, if tolerated, to two tablets twice daily (i.e. 12 hourly), if necessary.
The doctor will calculate the specific dose for your child depending on their age and body weight.
The usual dose is:

- 5 to 8 years: 24 mg/kg/24 hours
- 9 to 12 years: 20 mg/kg/24 hours
- 13 to 16 years: 18 mg/kg/24 hours

Theophylline 200 GDC tablets may be halved but should not be crushed or chewed.
You can take Theophylline-SR tablets with or immediately after food so that it does not upset your stomach.
Always take Theophylline-SR tablets regularly, as your doctor has told you to, even if you are not suffering any asthma symptoms.
If you think your asthma is getting worse or if you suffer asthma attacks, please consult your doctor immediately.
Theophylline-SR tablets will not give you relief during an asthma attack.
If you have an asthma attack, please use your relieving inhaler.
Theophylline-SR tablets work best when there is a certain amount of theophylline, the active ingredient, in your blood.
Your doctor may sometimes need to take samples of your blood to check the level of theophylline.
Your doctor will tell you how long your treatment with Theophylline 200 GDC will last. If you have the impression that the effect of Theophylline 200 GDC is too strong or too weak, tell your doctor or pharmacist.

If you take more Theophylline 200 GDC than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.
Taking too much Theophylline 200 GDC can have very serious effects. You may experience the following:

- Nausea, vomiting, stomach pain;
- Lack or loss of appetite for food (anorexia);
- Headache;
- Heart palpitations (heart is beating too fast or skipping beats);
- Irritability, agitation, anxiety;
- Struggling to sleep (insomnia);
- Shortness of breath, rapid pulse or faints;
- Decreased blood pressure, dizziness or light-headedness;
- Insomnia (not being able to sleep);
- Sensory disturbances such as numbness or pins and needles;
- Confusion, delirium (disorientation), wild or changed behaviour;
- Hyperthermia (increased body temperature);
- Dehydration and extreme thirst;
- Seizures.

You will be given symptomatic and supportive care by the hospital following a Theophylline 200 GDC overdose.
Theophylline overdose can potentially be fatal, and patients should be monitored closely.

If you forget to take Theophylline 200 GDC

If you forgot to take your medicine, take it as soon as you remember.
Do not take a double dose to make up for forgotten individual doses.
However, if it is more than 4 hours late, skip the dose that you missed. Take your next dose at the normal time.

4. Possible side effects

Theophylline 200 GDC can have side effects.
Not all side effects reported for Theophylline 200 GDC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Theophylline 200 GDC, please consult your health care provider for advice.
Tell your doctor if you notice any of the following:
Frequent side effects:

- Nausea, vomiting, stomach pain, loss of appetite
- Twitching and tremors (involuntary shaking and spasms)
- Convulsions (seizures)
- Fast, uncomfortable or irregular heartbeat
- Headache
- Difficulty sleeping (insomnia)
- Feeling anxious, irritated, agitated or restless
- Lack or loss of appetite for food
- Stomach irritation
- Worsening of a stomach ulcer
- Heartburn
- Vomiting of blood

Side effects with unknown frequency include:

- Diarrhoea
- Abnormal heart beats and heart rhythm
- Flushing, skin rash
- Irregular breathing or feeling short of breath
- Hair loss
- High blood glucose
- Decreased blood pressure
- Decreased levels of potassium or magnesium in your body
- Excessive urination and/or blood in your urine
- Dehydration and electrolyte imbalance

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 of pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8publications. By Reporting side effects, you can help provide more information on the safety of Theophylline 200 GDC. Alternately you can contact Gulf Drug Company (Pty) Ltd on +31 538 8700. Website: www.gulfdrug.co.za

5. How to store Theophylline 200 GDC

Store all medicines out of reach of children.

- Store at or below 30 °C, in tightly closed containers, in a dry place.
- Blisters should be stored in the original blister pack until required for use.
- Do not use after the expiry date stated on the label or carton.

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 Theophylline 200 GDC contains

- The active ingredient is theophylline.
- The other ingredients are magnesium stearate and guar gum.

What Theophylline 200 GDC looks like and contents of the pack

Theophylline 200 GDC is presented as white, round, biconvex tablets with markings N/L on one side and 200 on the other side.
Theophylline 200 GDC is available in:

- White, opaque, round HDPE bottles, with a white, opaque, round HDPE or PP (Polypropylene) screw cap with induction seal wad, containing 56, 60 and 500 tablets.
- Clear PVC/PVDC film and silver aluminium foil blister packs containing 60 tablets in a carton.

Holder of Certificate of Registration

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