

**RISALAH MAKLUMAT PENGGUNA
MINITEN 25MG TABLETS
CAPTOPRIL 25MG TABLETS**

Apakah isi kandungan risalah ini

- Apakah kegunaan MINITEN®
- Bagaimana MINITEN® berfungsi
- Bagaimana pengambilan MINITEN®
- Semasa menggunakan MINITEN®
- Kesan-kesan sampingan
- Simpanan dan pembuangan MINITEN®
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Kegunaan MINITEN®

- Tekanan yang tinggi
- Kegagalan jantung berfungsi
- Serangan jantung.
- Kegagalan buah pinggang akibat diabetes yang bergantung kepada insulin.

Bagaimana MINITEN® berfungsi

MINITEN® (Captopril) ialah sejenis perencat enzim penukar angiotensin (ACE) yang berfungsi untuk mengembangkan salur darah bagi memudahkan jantung mengepam darah melalui salur darah.

Sebelum mengambil MINITEN®

Bila anda tidak seharusnya ambil:

- Jika anda mengalami alahan terhadap Captopril atau ubat-ubatan lain yang berada dalam kelas yang sama (perencat penukar enzim).
- Semasa mengandung atau menyusukan anak.
- Jika anda juga mengambil sesetengah diuretic (ubat yang digunakan untuk mengurangkan jumlah air dalam badan), garam kalium atau litium, melainkan jika diputuskan oleh doktor anda.

- Dalam kes penyempitan kedua-dua arteri buah pinggang dan apabila hanya mempunyai satu buah pinggang, melainkan jika diputuskan oleh doktor anda.
- Dalam kes hiperkalaemia (kehadiran terlalu banyak kalsium dalam badan), melainkan jika diputuskan oleh doktor anda.

Sebelum mula mengambil

Anda haruslah memberitahu doktor anda jika :

- Mengalami masalah buah pinggang
- Mengalami masalah hati
- Sedang menjalani dialisis
- Mengidap sakit jantung, terutamanya masalah berkaitan injap jantung,
- Mengidap kencing manis,
- Baru-baru ini muntah yang berlebihan atau cirit-birit,
- Sedang menerima terapi immune-suppressant (penahan imunisasi).

Pengambilan bersama ubat-ubatan lain.

Untuk mengelakkan interaksi antara ubat-ubatan, maklumkan kepada doktor atau ahli farmasi anda tentang sebarang ubat lain yang anda sedang ambil terutamanya litium, garam kalium atau diuretik ("ubat kencing manis")

**Cara pengambilan MINITEN®
Jumlah pengambilan**

Iikut nasihat doktor anda.

- Tekanan darah tinggi: dos MINITEN® yang dicadangkan ialah 50 hingga 100mg sehari
- Kegagalan jantung akibat kesesakan: dos permulaan seharusnya rendah. Dos MINITEN® yang disarankan ialah 50 hingga 100mg sehari.
- Serangan jantung: Dos permulaan seharusnya rendah dan dimulakan dalam persekitaran hospital. Dos

MINITEN® yang disarankan pada kebiasaan anda ialah 100mg sehari. Penyakit diabetes buah pinggang: dos MINITEN® yang disarankan pada kebiasaan anda ialah 50 hingga 100mg sehari.

Masa pengambilan

- Tablet MINITEN® boleh diambil sebelum, ketika atau selepas makan dan diambil bersama segelas air.

Tempoh pengambilan

- MINITEN® perlu diambil selagi doktor menetapkannya, walaupun ia itu untuk satu jangka masa yang panjang. Jangan memberhentikan rawatan melainkan doktor menasihatkan anda untuk berbuat demikian.
- Pemeriksaan berkala adalah sangat penting, terutamanya untuk memantau tekanan darah dan keputusan ujian makmal.

Jika terlupa mengambil ubat

Dos yang tertinggal seharusnya diambil sebaik teringat. Jika sudah hampir masa untuk dos seterusnya tinggalkan sahaja dan jangan gandakan dos.

Jika terambil dos berlebihan

Maklumkan kepada doktor atau pergi ke Jabatan Kecemasan terdekat dengan segara.

Kesan paling ketara bagi terlebih dos ialah penurunan tekanan darah. Jika tekanan darah rendah yang serius dapat diperhatikan, pesakit perlu berbaring dengan kaki dinaikkan keatas.

Semasa menggunakan MINITEN®

Perkara yang perlu dilakukan

Beritahu doktor anda jika anda sedang mengambil Miniten:

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- Jika anda akan mendapatkan rawatan penyahpekaan sengatan tebuan atau lebah.
- Jika anda akan menjalani pembedahan membuang kolesterol dari darah menggunakan mesin, (digelar LDL apheresis).
- Beritahu doktor anda sebelum sebarang ujian darah atau air kencing dijalankan kerana tablet MINITEN® boleh menganggu keputusan sesetengah ujian.
- Beritahu doktor atau pakar bius jika anda akan menjalani pembedahan.

Perkara yang perlu diberi perhatian

- Captopril boleh mencetuskan tindak balas alahan terhadap pesakit yang menjalani hemodialysis (proses pembuangan hasil sisa metabolic atau bahan-bahan toksik dari salur darah melalui dialisis). Maklumkan doktor anda terlebih dahulu sebelum menjalani hemodialisis.
- Bagi kes serangan jantung, Captopril perlu dimulakan di dalam persekitaran hospital dibawah penyeliaan ketat doktor.
- Captopril seharusnya digunakan dengan berhati-hati bagi pesakit yang sedang mengikuti diet bebas-garam atau rawatan diuretik yang panjang, serangan jantung akibat kesesakan, atau sirrosis hati (kerosakan sel normal hati dan diganti dengan parut tisu).
- Doktor akan mengubah jumlah dos bagi pesakit yang lebih tua dan juga pesakit yang mengalami masalah buah pinggang, kerosakan hati yang teruk atau diabetes yang bergantung dengan insulin. Doktor anda perlu diberitahu jika keadaan sedemikian berlaku.
- Captopril boleh diberikan kepada kanak-kanak hanya jika

dimulakan di persekitaran hospital dibawah penyeliaan perubatan.

Kesan-kesan sampingan

Seperti semua ubat-ubatan, kesan-kesan sampingan mungkin akan berlaku seperti: Sakit kepala, keletihan, pening, kelesuan, tekanan darah rendah, ruam kulit, gatal-gatal, loya, dan hilang selera makan, sakit perut, perubahan deria rasa, batuk kering dan keputusan ujian makmal yang luar biasa.

Jika anda mengalami kesan-kesan berikut, berhenti mengambil Captopril dan hubungi doktor anda serta merta: Pembengkakan pada muka, bibir, lidah dan/atau kerongkong yang boleh menyebabkan kesukaran untuk bernafas dan menelan.

**Penyimpanan dan pelupusan
MINITEN®**

Penyimpanan: Simpan di suhu tidak melebihi 30°C.

Pelupusan: Jangan gunakan ubat selepas tarikh tamat tempoh seperti yang tertera pada pek. Dapatkan nasihat ahli farmasi tentang cara pelupusan ubat yang tidak diperlukan lagi.

Keterangan produk

MINITEN®

Rupa bentuk

Tablet 25 mg MINITEN® adalah tablet putih berbentuk segi empat, berpalang di dalam pek 20 biji.

Isi kandungan

Bahan aktif:

Captopril 25mg

Bahan tidak aktif:
Microcrystalline cellulose,
Lactose, Pregelatinized starch,
Maize starch & Stearic acid.

MAL No.

MAL08061553A

Pengilang

The United Pharmaceutical Manufacturing Co. Ltd.
P.O.Box 69 Amman 11591,
Jordan

Pemegang Pendaftaran Produk

MEDIDATA SDN BHD

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Tarikh rujukan

Jan 2013

PATIENT INFORMATION LEAFLET
MINITEN 25MG TABLET
Captopril 25mg Tablet

What is in this leaflet

- What is MINITEN® used for
- How MINITEN® works
- Before you take/ How to take MINITEN®
- While you are using MINITEN®
- Side effects
- Storage and Disposal of MINITEN®
- Product Description

What MINITEN® is used for

Miniten is used in the treatment of:

- High blood pressure
- Congestive heart failure
- Heart attack
- Kidney failure in insulin dependent diabetes (diabetic kidney disease).

How MINITEN® works

MINITEN® (Captopril) is an angiotensin converting enzyme (ACE) inhibitor which works by widening the blood vessels, making it easier for the heart to pump blood through them

Before you take MINITEN®

When you must not take it

- If you have allergy to Captopril or to other drugs of the same class (conversion enzyme inhibitor).
- During pregnancy or breastfeeding.
- If you are also taking certain diuretics ("water tablets") Potassium salts or Lithium, unless otherwise decided by your physician.
- In case of stenosis (abnormal narrowing or contraction of a duct or canal) of both renal arteries and when only one kidney is present, unless otherwise decided by your physician.
- In case of hyperkalaemia (high blood levels of potassium which can cause muscle weakness,

twitching or abnormal heart rhythm), unless otherwise decided by your physician.

Before you start to take it

You must tell your doctor is you:

- Suffer from kidney disease,
- Suffer from liver disease,
- Are undergoing dialysis
- Suffer from heart disease, in particular problems with the valves of the heart.
- Have diabetes,
- Have recently suffered from excessive vomiting or diarrhea,
- Are receiving immune-suppressant therapy,

Taking other medicines

To avoid interaction with other drugs, inform your doctor or pharmacist of any other other medicines you are taking, especially Lithium, potassium salts or diuretics.

How to take MINITEN®

How much to take

Follow the directions given by your doctor or pharmacist.

- High blood pressure: The recommended dose of MINITEN® is usually 50 to 100 mg per day.
- Congestive heart problems: The initial dose should be low. The recommended dose of MINITEN® is usually 50 to 100 mg per day.
- Heart attack: The initial dose should be low and initiated in a hospital setting. The recommended dose of MINITEN® is usually 100 mg per day.
- Diabetic kidney disease: The recommended dose of MINITEN® is usually 50 to 100 mg per day.

When to take it

- MINITEN® tablets may be taken before, during or after meals and swallowed with a glass of water.

How long to take it

- MINITEN® must be taken for as long as your doctor prescribed it, even if it is for a very long period of time. DO NOT discontinue treatment unless advised to do so by your doctor.
- Regular medical follow-up is required, especially to monitor blood pressure and laboratory test results.

If you forget to take it

Missed doses should be taken as soon as possible. If it is almost time for the next dose, skip the missed dose. Never double the dose to make up for a missed dose.

If you take too much (overdose)

Inform your doctor or visit the nearest Emergency Department immediately.

The most likely result of an overdose is a drop in blood pressure.

If major hypotension (low blood pressure) is noted, the patient should lie down with raised legs.

While you are using MINITEN®

Things you must do

Tell your doctor that you are taking Miniten:

- If you are to have desensitization treatment for wasp or bee stings.
- If you are about to have treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis)
- Before you have any blood or urine tests as MINITEN® tablets may interfere with the results of some tests.

PATIENT INFORMATION LEAFLET
MINITEN 25MG TABLET
Captopril 25mg Tablet

- If you are to have surgery, inform the doctor and anesthetist that you are under treatment with Captopril.

Things to be careful of

- Captopril may provoke allergic reactions in patients undergoing hemodialysis. Inform your doctor prior to hemodialysis .
- In treatment of heart attack, Captopril must be initiated in a hospital setting under strict supervision of a doctor.
- Captopril should be used with caution in patients with strict salt-free diet or prolonged diuretics treatment , especially in subjects with renal artery stenosis , congestive heart problems which can cause shortness of breath or ankle swelling, or cirrhosis of the liver.
- The doctor will adjust the dose in elderly patients as well as in patients suffering from kidney failure, severe heart failure which can cause shortness of breath or ankle swelling or insulin-dependant diabetes. The doctor should be notified if such conditions are present.
- Captopril may be used in children only if the treatment is initiated in a hospital setting under medical supervision.

Side Effects

As with any drugs, some unpleasant side effects may occur such as: Headache, tiredness, a feeling of dizziness or spinning, malaise (feeling of discomfort), low blood pressure, skin rash, itching, feeling sick, and loss of appetite, gastrointestinal pain, taste changes, dry cough and various abnormalities in the laboratory test results.

If you experience any of the following, stop taking Captopril and immediately contact your doctor:

Swelling of the face, lips, tongue and/or larynx which entail difficulties in breathing or swallowing.

Storage and Disposal of MINITEN®

Storage: Store at temperatures up to 30°C

Disposal: Do not use after the expiry date stated on the pack. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

What it looks like

MINITEN® 25mg Tablets are white square shape crossed tablets in packs of 20tablets.

Ingredients

Active ingredients: Captopril 25mg

Inactive Ingredients: Microcrystalline cellulose, Lactose, Pregelatinized starch, Maize starch & Stearic acid.

MAL No.

MAL08061553A

Manufacturer

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Marketing Authorization Holder

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