

**Pharmaniaga Cetirizine Tablet
10 mg**

(Cetirizine HCl 10 mg)

**Pharmaniaga Cetirizine Oral
Solution 0.1% w/v**

(Cetirizine HCl 1.0 mg)

**Pharmaniaga Cetirizine Oral
Drops 1.0% w/v**

(Cetirizine HCl 10 mg)

Kandungan risalah ini

1. Apakah kegunaan Pharmaniaga Cetirizine
2. Bagaimana Pharmaniaga Cetirizine berfungsi
3. Sebelum pengambilan Pharma-niaga Cetirizine
4. Cara pengambilan Pharma-niaga Cetirizine
5. Semasa pengambilan Pharma-niaga Cetirizine
6. Kesan-kesan sampingan
7. Cara Penyimpanan dan Pelupusan Pharmaniaga Cetirizine
8. Maklumat lanjut
9. Pengilang
10. Pemegang Pendaftaran
11. Tarikh kemaskini RiMUP

**Apakah kegunaan Pharmaniaga
Cetirizine**

Pharmaniaga Cetirizine boleh digunakan:

- untuk melegakan simptom demam alahan pernafasan (rinitis alahan bermusim) dan alahan seperti alahan

terhadap habuk dan haiwan kesayangan (rinitis alahan malar), seperti bersin, gatal-gatal, hidung berair dan tersumbat, mata merah dan berair.

- untuk melegakan bengkak, kemerahan dan gatal pada kulit (simptom urtikaria idiopatik kronik, yang juga diketahui sebagai ruam netel kronik).

**Bagaimana Pharmaniaga Cetiri-
zine berfungsi**

Ubat ini berfungsi dengan cara menghalang kesan bahan yang bernama histamin yang dihasilkan di dalam tubuh. Histamin boleh mengakibatkan gatal-gatal, bersin, hidung berair dan mata berair. Dalam sesetengah kes, bahan ini boleh mengakibatkan saluran udara ke paru-paru tertutup, dengan itu menyukarkan pernafasan.

**Sebelum pengambilan Pharma-
niaga Cetirizine**

Bila tidak boleh mengambil

Jangan ambil Pharmaniaga Cetirizine:

- sekiranya anda diketahui alah (hipersensitif) terhadap bahan aktif Pharmaniaga Cetirizine atau sebarang ramuan lain yang terkandung dalam ubat ini.

- sekiranya anda diketahui alah (hipersensitif) kepada hydroxyzine (berkait rapat dengan bahan aktif ubat lain).

Sebelum mula mengambil

Dapatkan nasihat daripada doktor anda atau ahli farmasi sebelum mengambil ubat anda.

Dapatkan nasihat daripada doktor anda atau ahli farmasi sebelum mengambil ubat ini sekiranya anda hamil atau menyusui bayi.

Jika mengambil ubat-ubat lain

Sila beritahu doktor anda atau ahli farmasi jika anda mengambil atau baru-baru ini mengambil sebarang ubat lain termasuk ubat yang diperolehi tanpa preskripsi.

Pemberian serentak theophylline dan cetirizine boleh mengurangkan penyingkiran cetirizine daripada badan, dengan itu boleh mengakibatkan kemungkinan berlaku ketoksikan cetirizine.

Makanan didapati tidak menjejaskan penyerapan cetirizine dengan ketara. Begitu juga dengan pengambilan sebarang antihistamin, anda disyorkan agar mengelakkan daripada meminum arak semasa mengambil ubat ini.

**Cara pengambilan Pharma-
niaga Cetirizine**

Berapa banyak perlu diambil

Garis panduan ini harus dipatuhi melainkan doktor anda

memberikan arahan berbeza kepada anda mengenai cara pengambilan Pharmaniaga Cetirizine.

Sila ikut semua arahan ini, jika tidak Pharmaniaga Cetirizine mungkin tidak memberikan kesan sepenuhnya.

Pharmaniaga Cetirizine Tablet 10 mg

Dewasa: 1 tablet sekali sehari.

Pharmaniaga Cetirizine Oral Solution 0.1% w/v

Kanak-kanak berusia 6 tahun ke atas: 10mL, sama ada 5mL dua kali sehari atau 10mL sekali sehari.

Pharmaniaga Cetirizine Oral Drops 1.0% w/v

Kanak-kanak berusia di antara 3 hingga 6 tahun: 5mL.

Sekiranya anda merasakan bahawa kesan ubat Pharmaniaga Cetirizine tidak begitu mujarab atau pun terlalu kuat, sila rujuk kepada doktor anda.

Bila perlu diambil

Ubat ini harus diambil sekali sahaja dalam setiap 24 jam. Kekalkan pengambilan setiap dos yang berikutnya pada waktu yang sama dengan dos pertama yang diambil. Doktor anda boleh mengubah aturan pengambilan dos menurut keadaan kesihatan anda. Sila ikut nasihat doktor anda.

Berapa lama perlu diambil

Dos yang ditetapkan amat bergantung pada indikasi penyakit yang anda alami. Sila ikut nasihat doktor anda dan kekalkan pengambilan mengikut panduan dos seperti yang disarankan oleh doktor. Jangan hentikan pengambilan Pharmaniaga Cetirizine tanpa merujuk kepada doktor anda.

Jika terlupa mengambil

Sekiranya anda terlupa mengambil Pharmaniaga Cetirizine, makan ubat tersebut sesegera yang boleh. Ambil dos anda yang berikutnya pada masa yang betul. Jangan ambil dos berganda sebagai ganti dos yang anda terlupa ambil.

Jika mengambil berlebihan (terlebih dos)

Sekiranya anda fikir bahawa anda terlebih ambil dos Pharmaniaga Cetirizine, sila maklumkan kepada doktor anda. Doktor anda akan memutuskan langkah-langkah yang perlu diambil, jika ada.

Setelah terlebih ambil ubat, anda mungkin berasa kegelisahan dan mengalami kerengsaan pada peringkat awalnya, kemudian diikuti oleh rasa mengantuk. Penawar yang khusus bagi cetirizine belum lagi diketahui. Rawatan yang diberikan mengikut simptom dan sebagai sokongan sahaja.

Semasa pengambilan Pharmaniaga Cetirizine

Perkara yang perlu dilakukan

Dapatkan nasihat daripada doktor anda sebelum pengambilan sebarang ubat.

Sebagaimana juga dengan ubat lain, penggunaan Pharmaniaga Cetirizine harus dielakkan oleh wanita hamil.

Penggunaan ubat secara tidak sengaja oleh wanita hamil tidak seharusnya memberi sebarang kesan buruk kepada janin. Namun begitu, pemberian ubat ini harus dihentikan.

Perkara yang tidak boleh dilakukan

Anda tidak sepatutnya mengambil Pharmaniaga Cetirizine semasa menyusui bayi kerana cetirizine boleh meresap masuk ke dalam susu badan.

Perkara yang perlu diawasi

Sekiranya anda berhasrat untuk memandu, mengendalikan mesin atau melakukan tugas lain yang memerlukan perhatian penuh, anda tidak harus mengambil lebih daripada dos yang disarankan dan anda harus mengawasi dengan teliti tindak balas tubuh anda terhadap ubat tersebut.

Sekiranya anda pesakit yang sensitif, anda akan dapati bahawa penggunaan serentak arak atau agen penenang depresi boleh

menjejaskan lagi perhatian anda dan keupayaan anda untuk bertindak balas.

Kesan-kesan sampingan

Sebagaimana ubat-ubatan lain, Pharmaniaga Cetirizine boleh menyebabkan kesan sampingan walaupun tidak pada semua orang.

Pernah dilaporkan berlaku kesan sampingan ringan dan sementara seperti sakit kepala, pening, mengantuk, fikiran terganggu, mulut kering dan ketidakselesaan gastrousus. Keadaan seperti khayal setelah pengambilan Pharmaniaga Cetirizine juga pernah dilaporkan berlaku.

Sekiranya anda fikir anda mengalami sebarang kesan sampingan yang tidak disebutkan dalam risalah ini, sila maklumkan kepada doktor anda atau ahli farmasi.

Cara Penyimpanan dan Pelupusan Pharmaniaga Cetirizine

Penyimpanan

Pastikan semua ubat tidak dapat dilihat dan dicapai oleh kanak-kanak.

Jangan ambil ubat ini sekiranya telah melewati tarikh tamat tempoh yang dicetak pada bungkusannya.

Simpan di tempat yang bersuhu bawah 25°. Ubat ini tidak

memerlukan sebarang keadaan penyimpanan khusus yang lain.

Pelupusan

Ubat tidak harus dilupuskan melalui air buangan atau sisa isi rumah. Dapatkan maklumat daripada ahli farmasi anda mengenai cara yang betul untuk melupuskan ubat yang tidak diperlukan lagi. Langkah-langkah ini dapat membantu melindungi alam sekitar.

Maklumat lanjut

Rupa ubat

Pharmaniaga Cetirizine Tablet 10 mg

Tablet putih berbentuk bujur yang bersalut, rata pada satu sisi dan garisan belahan pada sisi sebelah lagi.

Pharmaniaga Cetirizine Oral Solution 0.1% w/v

Larutan jernih tanpa warna.

Pharmaniaga Cetirizine Oral Drops 1.0% w/v

Larutan jernih tanpa warna.

Ramuan:

Pharmaniaga Cetirizine Tablet 10 mg mengandungi Cetirizine Hydrochloride 10 mg, Glycerin, Propylene Glycol, Sodium Acetate, Sucrose, Methyl Paraben, Grape Flavour,

Purified Water, Citric Acid, Banana Flavour.

Pharmaniaga Cetirizine Oral Solution 0.1% w/v mengandungi Cetirizine Hydrochloride 1.0 mg, Glycerin, Propylene Glycol, Sodium Acetate, Sucrose, Methyl Paraben, Propyl Paraben, Grape Flavour, Purified Water, Citric Acid, Banana Flavour.

Pharmaniaga Cetirizine Oral Drops 1.0% w/v mengandungi Cetirizine Hydrochloride 10 mg, Glycerin, Propylene Glycol, Sodium Acetate, Sodium Saccharin, Sucrose, Methyl Paraben, Propyl Paraben, Grape Flavour, Purified Water

NO. MAL:

Pharmaniaga Cetirizine Tablet 10 mg
MAL20020882A

Pharmaniaga Cetirizine Oral Solution 0.1% w/v
MAL20020881A

Pharmaniaga Cetirizine Oral Drops 1.0% w/v
MAL20020880A

Pengilang:

Pharmaniaga Manufacturing Berhad
(60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Pemegang Pendaftaran:

Pharmaniaga Manufacturing Berhad
(60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Tarikh: 26 Jun 2012

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(Cetirizine HCl 10 mg)
Pharmaniaga Cetirizine Oral
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(Cetirizine HCl 1.0 mg)
Pharmaniaga Cetirizine Oral
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(Cetirizine HCl 10 mg)**

What is in this leaflet

1. What Pharmaniaga Cetirizine is used for
2. How Pharmaniaga Cetirizine works
3. Before you take Pharmaniaga Cetirizine
4. How to take Pharmaniaga Cetirizine
5. While you are taking Pharmaniaga Cetirizine
6. Side effects
7. Storage and Disposal of Pharmaniaga Cetirizine
8. Product Description
9. Manufacturer
10. Marketing Authorisation Holder
11. Date of Revision

What Pharmaniaga Cetirizine is used for

Pharmaniaga Cetirizine is indicated:
- for the relief of symptoms of hay fever (seasonal allergic rhinitis) and allergies such as dust or pet

allergies (perennial allergic rhinitis), such as sneezing, itchy, runny and blocked nose, red and watery eyes.

- for the relief of swelling, redness and itchiness of the skin (symptoms of chronic idiopathic urticaria, which is also known as chronic nettle rash).

How Pharmaniaga Cetirizine works

It works by preventing the effects of a substance called histamine, which is produced in the body. Histamine can cause itching, sneezing, runny nose and watery eyes. In some cases, it can close up the air passage of the lungs and make breathing difficult.

Before you take Pharmaniaga Cetirizine

When you must not take it

Do not take Pharmaniaga Cetirizine:

- if you are known to be allergic (hypersensitive) to the active substance of Pharmaniaga Cetirizine or any of the other ingredients of these medicine.
- if you are known to be allergic (hypersensitive) to hydroxyzine (closely related active substances of other medicines).

Before you start to take it

Check with your doctor or pharmacist before taking your medicine.

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Co-administration of theophylline and cetirizine may decrease clearance of cetirizine resulting possibly cetirizine toxicity.

Food does not noticeably affect the absorption of cetirizine. As it is the case with all antihistamines, it is recommended to avoid consumption of alcohol while taking this medicine.

How to take Pharmaniaga Cetirizine Tablet

How much to take

These guidelines apply unless your doctor has given you different instructions on how to use Pharmaniaga Cetirizine.

Please follow these instructions, otherwise Pharmaniaga

Cetirizine may not be fully effective.

Pharmaniaga Cetirizine Tablet 10 mg

Adults: 1 tablet once daily.

Pharmaniaga Cetirizine Oral Solution 0.1% w/v

Children 6 years old and above: 10mL solution, either 5mL twice daily or 10mL daily.

Pharmaniaga Cetirizine Oral Drops 1.0% w/v

Children aged between 3 to 6 years old: 5mL syrup.

If you feel that the effect of Pharmaniaga Cetirizine is too weak or too strong, please consult your doctor.

When to take it

You should take it once every 24 hours. Stick to the same time as your 1st dose for every subsequent dose. Your doctor may alter the dosing regime according to your health conditions. Please follow your doctor's advice.

How long to take it

The prescription dose very much depends on the indications you have been diagnosed with. Please follow your doctor's advice and stay the dosing regimen as recommended by doctor. Do not stop taking Pharmaniaga Cetirizine without talking to your doctor.

If you forget to take it

If you forget to take Pharmaniaga Cetirizine take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you take too much (overdose)

If you think you have taken an overdose of Pharmaniaga Cetirizine, please inform your doctor. Your doctor will then decide what measures, if any, should be taken.

After an overdose, restlessness and irritability were observed initially and followed by drowsiness. There is no known specific antidote to cetirizine. Treatment is symptomatic and supportive.

While you are using Pharmaniaga Cetirizine

Things you must do

Ask your doctor for advice before taking any medicine.

As with other drugs, use of Pharmaniaga Cetirizine should be avoided by pregnant women.

Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

Things you must not do

You should not take Pharmaniaga Cetirizine during breast-feeding because cetirizine passes into breast milk.

Things to be careful of

If you intend to drive, operate machinery, or perform other tasks that need your full attention, you should not exceed the recommended dose and you should closely observe your response to the drug.

If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Side effects

Like all medicines, Pharmaniaga Cetirizine can cause side effects, although not everybody gets them.

There have been reports of mild and transient side-effects such as headache, dizziness, drowsiness, agitation, dry mouth and gastrointestinal discomfort. The incidence of sedation with Pharmaniaga Cetirizine also was reported.

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

Storage and Disposal of Pharmaniaga Cetirizine Tablet

Storage

Keep all medicines out of the sight and reach of children

Do not take this medicine after the expiry date stamped on the pack.

Store below 25°. This medicine does not require any other special storage conditions.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Pharmaniaga Cetirizine Tablet 10 mg

White oblong film coated tablet, plain on one side and scored on the other side.

Pharmaniaga Cetirizine Oral Solution 0.1% w/v

Clear, colourless solution.

Pharmaniaga Cetirizine Oral Drops 1.0% w/v

Clear, colourless solution.

Ingredients:

Pharmaniaga Cetirizine Tablet 10 mg contains Cetirizine

Hydrochloride 10 mg, Opadry White, Magnesium Stearate, Povidone 30, Starch, Lactose Monohydrate.

Pharmaniaga Cetirizine Oral Solution 0.1% w/v contains Cetirizine Hydrochloride 1.0 mg, Glycerin, Propylene Glycol, Sodium Acetate, Sucrose, Methyl Paraben, Propyl Paraben, Grape Flavour, Purified Water, Citric Acid, Banana Flavour.

Pharmaniaga Cetirizine Oral Drops 1.0% w/v contains Cetirizine Hydrochloride 10 mg, Glycerin, Propylene Glycol, Sodium Acetate, Sodium Saccharin, Sucrose, Methyl Paraben, Propyl Paraben, Grape Flavour, Purified Water

MAL NO:

Pharmaniaga Cetirizine Tablet 10 mg

MAL20020882A

Pharmaniaga Cetirizine Oral Solution 0.1% w/v

MAL20020881A

Pharmaniaga Cetirizine Oral Drops 1.0% w/v

MAL20020880A

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D), 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Marketing Authorisation Holder:

Pharmaniaga Manufacturing Berhad (60016-D), 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Date: 26th June 2012