

Patient Information Leaflet

DHATIFEN TABLET 1mg/DHATIFEN SYRUP 1MG/5ML

Ketotifen Hydrogen Fumarate

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What Dhatifen Tablets 1mg/Dhatifen Syrup 1mg/5ml is used for

Dhatifen is used for the preventive treatment of asthma and the relieving of allergic symptoms like sneezing, running nose or redness in the eyes.

How Dhatifen Tablets 1mg/Dhatifen Syrup 1mg/5ml works

Ketotifen, the active ingredient of Dhatifen, is an anti-histamine and a mast cell stabilizer.

Before you use Dhatifen Tablets 1mg/Dhatifen Syrup 1mg/5ml

- When you must not take it
You should not be taking it if you are taking oral medicines to control your diabetes. Please consult your doctor or pharmacist.
- Before you start to take it

As the action of Dhatifen is preventive, taking the medicine regularly is important.

- Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription and herbal medicines. In particular, inform them if you are using medicine for mood and sleep, antihistamines or consuming alcohol.

How to take Dhatifen Tablets 1mg/Dhatifen Syrup 1mg/5ml

- How much to take
Adult:
1 tablet or 5ml syrup 2 times daily.

Child:
6 months – 3 years:
½ tablet or 2.5ml syrup, 2 times daily.
Over 3 years:
1 tablet or 5ml syrup, 2 times daily.

- When to take it
Always take the medicine exactly as your doctor has told you to. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets or how much syrup to take, and how often. If you are not sure, ask your doctor or pharmacist.
- How long to take it
It may take many weeks to see the results. Please follow the instructions of your doctor or pharmacist and continue taking regularly.

- If you forget to take it
If you forget to take Dhatifen, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.
- If you take too much (overdose)

Please consult a doctor immediately.

While you are using Dhatifen Tablets 1mg/Dhatifen Syrup 1mg/5ml

- Things you must do
You must take this medicine regularly to get maximum benefit from it.
- Things you must not do
If you are on other medicine treating asthma, do not stop them unless instructed by your doctor or pharmacist.
- Things to be careful of
As Dhatifen may make you drowsy, do not drive or operate machinery if you are affected.

Side Effects

Like all medicines, Dhatifen can cause side effects, although not everybody gets them. You may experience sedation, dizziness and / or dry mouth. You may also have increased appetite.

Storage and Disposal of Dhatifen Tablets 1mg/Dhatifen Syrup 1mg/5ml

Storage

Store in a dry place below 30°C.

Disposal

Do not use after the expiry date stated on the label.
Take any unused tablets or syrup back to your pharmacist to be destroyed. Only keep the tablets or syrup if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

- What it looks like
Tablet:
Beige, 8mm diameter, normal convex tablets with score-line and without logo.
Syrup:
Colourless, sweet taste with strawberry flavour.

DHATIFEN TABLET 1mg/DHATIFEN SYRUP 1MG/5ML

Ketotifen Hydrogen Fumarate

- **Ingredients**

Active Ingredient

Ketotifen hydrogen fumarate

equivalent to Ketotifen:

Tablets: 1mg/tab

Syrup: 1mg/5ml

Inactive ingredients

Tablets

Corn starch, Microcrystalline

Cellulose, Povidone 30, Sodium

starch glycolate, Magnesium

stearate, Quinoline Yellow

E104 Alum Lake 30%,

Carmoisine Alum Lake 22-26%

Syrup

Granulated fine white sugar,

Sodium citrate dihydrate, Citric

acid monohydrate, Glycerin,

Sodium

Carboxymethylcellulose,

Strawberry flavour 77876-31,

Purified water, Sodium

Benzoate

- **MAL No.**

For tablets: MAL 19950251A

For syrup: MAL19950333A

Manufacturer

**Drug Houses of Australia Pte.
Ltd.,**

#09-01/02 Haw Par Tiger Balm
Building

No.2 Chia Ping Road,
Singapore 619968.

Marketing Authorization Holder

**Ascent Pharmahealth
Malaysia Sdn Bhd**

Unit 304, Level 3, Uptown 2, 2

Jalan SS21/37, Damansara

Uptown, 47400 Petaling Jaya,

Selangor Darul Ehsan, Malaysia

Date of Revision

09-2011

RiMUP

DHATIFEN TABLET 1mg/DHATIFEN SYRUP 1MG/5ML

Ketotifen Hydrogen Fumarate

Apakah yang ada pada risalah ini

- Apakah kegunaan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml
- Bagaimana Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml berfungsi
- Sebelum mengambil Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml
- Cara menggunakan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml
- Semasa menggunakan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml
- Kesan-kesan sampingan
- Cara penyimpanan dan pelupusan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml
- Maklumat lanjut
- Pengilang
- Pemegang Pendaftaran Produk
- Tarikh kemaskini RiMUP

Apakah kegunaan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml

Dhatifen digunakan untuk rawatan pencegahan asma dan melegakan gejala alahan hidung seperti bersin, selsema atau kemerahan di mata.

Bagaimana Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml berfungsi

Ketotifen, bahan aktif Dhatifen, adalah anti-histamin dan penstabil *mast cell*.

Sebelum mengambil Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml

- Bila tidak boleh mengambil
Anda tidak boleh mengambilnya jika anda mengambil ubat lain untuk mengawal diabetes anda. Sila rujuk doktor atau ahli farmasi.

- Sebelum mula mengambil Dhatifen bertindak sebagai ubat pencegahan, oleh itu mengambil ubat secara berkala adalah penting.

- Jika mengambil ubat-ubat lain

Sila beritahu doktor atau ahli farmasi jika anda mengambil atau baru-baru ini mengambil sebarang ubat-ubatan lain, termasuk yang diperolehi tanpa preskripsi dan ubat herba. Secara khususnya, beritahu jika anda menggunakan ubat untuk mengawal perasaan dan tidur, antihistamin atau minum arak.

Cara menggunakan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml

- Berapa banyak harus diambil
Dewasa:
1 tablet atau sirap 5ml 2 kali sehari.

Kanak-kanak:

6 bulan - 3 tahun:

½ tablet atau sirap 2.5ml, 2 kali sehari.

Lebih 3 tahun:

1 tablet atau sirap 5ml, 2 kali sehari.

- Bila perlu diambil
Selalu ambil tablet seperti yang diberitahu oleh doktor anda. Dos tersebut akan dipamerkan pada label ubat. Periksa label ubat dengan teliti. Ia sepatutnya memberitahu berapa banyak tablet yang anda patut ambil, dan berapa kerap untuk diambil. Jika anda tidak pasti, tanya doctor atau ahli farmasi anda.

- Berapa lama perlu diambil
Ia mungkin mengambil beberapa minggu untuk melihat hasilnya. Sila ikut arahan doktor atau ahli farmasi anda dan terus mengambil dengan kerap.

- Jika terlupa mengambil
Jika anda terlupa untuk mengambil Dhatifen, ambilnya sebaik sahaja anda ingat.

Bagaimanapun, jika ia hampir masa untuk dos seterusnya, abaikan dos tertinggal. Jangan mengambil dos berganda untuk menggantikan dos dilupakan.

- Jika mengambil berlebihan (terlebih dos)

Sila hubungi doktor dengan segera.

Semasa menggunakan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml

- Perkara yang perlu dilakukan

Anda perlu mengambil ubat ini dengan tetap untuk mendapatkan manfaat yang maxima daripadanya.

- Perkara yang tidak boleh dilakukan

Jika anda mengambil ubat lain untuk merawat asma, jangan hentikannya kecuali diarahkan oleh doktor atau ahli farmasi anda.

- Perkara yang perlu diberi perhatian

Dhatifen boleh membuat anda mengantuk, jangan memandu atau mengendalikan jentera jika anda terjejas.

Kesan-kesan sampingan

Seperti semua ubat, Dhatifen boleh menyebabkan kesan sampingan, walaupun tidak semua orang mengalaminya. Anda mungkin merasa mengantuk, pening dan / atau mulut kering. Selera makan anda juga mungkin meningkat.

Cara penyimpanan dan pelupusan Dhatifen Tablet 1mg/Dhatifen Syrup 1mg/5ml

Penyimpanan

Simpan di tempat kering di bawah suhu 30°C.

Pelupusan

Jangan makan ubat itu apabila telah lepas tarikh luputnya. Pulang tablet atau sirup yang belum digunakan kepada ahli

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farmasi anda untuk dilupuskan. Hanya simpan tablet atau sirup jika doktor anda menasihatkannya. Jangan buang ubat tersebut di dalam air atau bersama-sama dengan sampah-sarap rumah. Tindakan ini boleh membantu melindungi alam persekitaran.

Maklumat lanjut

- Rupa dan warna produk

Tablet:

Warna *beige*, 8mm diameter, pil berbentuk cembung dengan garis-skor dan tanpa logo.

Sirap:

Tidak berwarna, rasa manis dengan rasa strawberi.

- Bahan-bahan kandungan

Ramuan aktif

Ketotifen hydrogen fumarate bersamaan dengan Ketotifen:

Setiap Tablet: 1mg

Setiap 5ml Sirap: 1mg

Bahan-bahan tidak aktif

Tablet:

Corn starch, Microcrystalline Cellulose, Povidone 30, Sodium starch glycolate, Magnesium stearate, Quinoline Yellow E104 Alum Lake 30%, Carmoisine Alum Lake 22-26%

Sirup:

Granulated fine white sugar, Sodium citrate dihydrate, Citric acid monohydrate, Glycerin, Sodium Carboxymethylcellulose, Strawberry flavour 77876-31, Purified water, Sodium Benzoate

- Nombor MAL

Untuk tablet: MAL 19950251A

Untuk sirup: MAL 19950333A

Pengilang

Drug Houses of Australia Pte. Ltd.,

#09-01/02 Haw Par Tiger Balm Building

No.2 Chia Ping Road, Singapore 619968.

Pemegang Pendaftaran Produk

Ascent Pharmahealth Malaysia Sdn Bhd

Unit 304, Level 3, Uptown 2, 2 Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor Darul Ehsan, Malaysia

Tarikh kemaskini RiMUP

09-2011