

## MODIM CAPSULE

(Loperamide Hydrochloride)

Risalah Maklumat Ubat Pengguna

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### APAKAH YANG ADA PADA RISALAH INI?

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1. Apakah Kegunaan *MODIM*
2. Bagaimana *MODIM* berfungsi
3. Sebelum mengambil *MODIM*
4. Cara menggunakan *MODIM*
5. Semasa menggunakan *MODIM*
6. Kesan-kesan sampingan
7. Selepas menggunakan *MODIM*
8. Maklumat lanjut
9. Pemegang pendaftaran produk & Pengilang

### Baca seluruh risalah ini sebelum anda mula ambil ubat ini.

- Simpan risalah ini. Anda mungkin perlu membacanya lagi.
- Sekiranya anda perlu maklumat lanjut, sila rujuk doktor atau ahli farmasi anda.
- Ubat ini dipreskripsikan kepada anda. Jangan berikan kepada orang lain. Ini mungkin membahayakan kesihatan mereka walaupun tanda-tandanya adalah sama dengan anda.
- Sekiranya apa-apa kesan sampingan menjadi serius, atau anda perasan apa-apa kesan sampingan yang tidak disenaraikan dalam risalah ini, sila maklumkan doktor atau ahli farmasi anda.

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### 1. APAKAH KEGUNAAN *MODIM*

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*MODIM CAPSULE* mengandungi bahan aktif yang dikenali sebagai *Loperamide hydrochloride*. Ia digunakan untuk merawat cirit-birit ringan dan masalah cirit-birit kronik (berpanjangan).

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### 2. BAGAIMANA *MODIM* BERFUNGSI

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*MODIM CAPSULE* tergolong di dalam kumpulan ubat *Antidiarrheal*. Ia berfungsi untuk melegakan gejala cirit-birit dengan menjadikan tinja lebih padat and kurang kerap.

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### 3. SEBELUM MENGAMBIL *MODIM*

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#### Bila tidak boleh diambil

Anda tidak boleh mengambil *MODIM* sekiranya anda:

- Pernah mengalami alahan terhadap bahan aktif *Loperamide hydrochloride* atau terhadap bahan-bahan lain dalam produk ini.
- Mengandung, atau beranggapan anda telah mengandung.
- Mengalami cirit-birit teruk selepas pengambilan antibiotik.

*Bincang dengan doktor sekiranya anda tidak pasti sama ada anda patut mengambil ubat ini.*

#### Sebelum mula mengambil

Beritahu doktor anda sekiranya anda mengalami alahan terhadap ubat-ubatan lain, makanan, bahan pengawet atau bahan pewarna.

Beritahu doktor anda sekiranya anda:

- Mengalami keradangan usus seperti *ulcerative colitis*.
- Mengalami penyumbatan atau penyekatan pada usus.
- Mengalami kehilangan air berlebihan.

*MODIM CAPSULE* tidak di syorkan untuk kegunaan kanak-kanak di bawah usia 6 tahun.

#### Jika mengambil ubat-ubat lain

Maklumkan kepada doktor atau ahli farmasi sekiranya anda ada mengambil sebarang ubat lain, termasuk ubat-ubat yang didapatkan tanpa preskripsi.

#### Semasa Mengandung

Maklumkan kepada doktor sekiranya anda mengandung, beranggapan anda telah mengandung atau bercadang untuk mengandung. Penggunaan *MODIM* tidak disyorkan semasa mengandung. Bincang dengan doktor anda untuk mengetahui risiko dan manfaat pengambilan *MODIM* semasa mengandung.

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### 4. CARA MENGGUNAKAN *MODIM*

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Sentiasa mengambil *MODIM* sepertimana yang diarahkan oleh doktor atau ahli farmasi

anda. Jika anda tidak pasti, tanya doktor atau ahli farmasi anda.

#### Berapa banyak harus diambil

- *Dewasa dan kanak-kanak berusia 6 tahun ke atas*

Mulakan dengan mengambil 2 kapsul, diikuti dengan 1 kapsul selepas setiap kali cirit-birit. Jangan ambil melebihi 8 kapsul sehari.

#### Bila perlu diambil

Ambil *MODIM* mengikut arahan doktor atau ahli farmasi.

#### Berapa lama perlu diambil

Teruskan pengambilan ubat ini selagi anda diarahkan oleh doktor. Kebiasaannya pengambilan *MODIM* adalah untuk jangka masa pendek dan tidak berpanjangan.

#### Jika terlupa mengambil

Ambil dos anda dengan segera apabila anda ingat dan teruskan mengambil *MODIM* seperti biasa. Jangan ambil dos berganda untuk menggantikan dos yang anda terlupa. Ia boleh mengakibatkan kesan sampingan yang tidak diingini.

#### Jika mengambil berlebihan (terlebih dos)

Jika anda, atau sesiapa telah mengambil ubat ini secara berlebihan, anda hendaklah segera pergi ke Bahagian Rawatan Kecemasan Hospital terdekat atau maklumkan kepada doktor anda. Ini perlu dilakukan walaupun tiada sebarang tanda ketidakselesaian atau keracunan. Bawa bersama bungkusan atau baki ubat yang selebihnya dengan anda.

Antara simptom terlebih dos adalah kepeningan, rasa mengantuk, keletihan dan kurang kepekaan.

*Tanya doktor atau ahli farmasi anda, sekiranya anda mempunyai sebarang pertanyaan lanjut mengenai penggunaan ubat ini.*

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### 5. SEMASA MENGGUNAKAN *MODIM*

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### Perkara yang perlu dilakukan

- Sentiasa ambil *MODIM* mengikut arahan yang diberikan oleh doktor atau ahli farmasi anda. Dapatkan nasihat doktor atau ahli farmasi anda sekiranya anda tidak pasti.
- Beritahu doktor atau ahli farmasi anda sekiranya pada kebelakangan ini anda ada ambil sebarang ubat, termasuk ubat tanpa preskripsi seperti suplemen atau ubat tradisional.
- Beritahu doktor atau ahli farmasi anda sekiranya kesan sampingan menjadi serius atau anda mengalami reaksi lain yang menyebabkan anda berasa tidak sihat.
- Beritahu doktor anda segera sekiranya anda mengandung.
- Jika anda akan mula mengambil ubat baru, ingatkan doktor dan ahli farmasi bahawa anda sedang mengambil *MODIM*.

### Perkara yang tidak boleh dilakukan

- Jangan guna *MODIM* yang telah melebihi tarikh luput yang dicetak pada kotak dan strip ubat.
- Jangan beri ubat ini kepada orang lain, walaupun mereka mempunyai masalah kesihatan yang sama dengan anda.

### Perkara yang perlu diberi perhatian

- **Memandu dan menggunakan mesin**  
Berhati-hati ketika memandu atau menggunakan mesin semasa anda mengambil *MODIM*. *MODIM* mungkin menyebabkan kepeningan atau mengantuk, dapatkan nasihat doktor anda sebelum menjalankan aktiviti-aktiviti seperti ini.

## 6. KESAN-KESAN SAMPINGAN

Semua ubat mempunyai kesan sampingan. *MODIM* mungkin menyebabkan kesan sampingan, tetapi bukan setiap individu akan mengalaminya.

Beritahu doktor atau ahli farmasi anda sekiranya anda mengalami kesan-kesan sampingan seperti berikut:

- Kepeningan
- Kurang kepekaan

- Keletihan
- Sakit abdomen dan ketidakselesaan perut
- Penyumbatan sistem penghadaman disebabkan kelumpuhan otot usus (*Paralytic ileus*)
- Ruam kulit

*Beritahu doktor atau ahli farmasi anda sekiranya kesan sampingan menjadi serius atau anda mengalami reaksi lain yang menyebabkan anda berasa tidak sihat. Kesan-kesan sampingan lain yang tidak disenaraikan mungkin juga akan dialami oleh sesetengah orang.*

## 7. SELEPAS MENGGUNAKAN MODIM

### Penyimpanan

Simpan di tempat sejuk dan kering dibawah suhu 30°C. Simpan dalam bungkus asal untuk melindungi daripada cahaya, haba dan kelembapan.

Jauhi daripada kanak-kanak.

### Pelupusan

Jangan guna *MODIM* yang telah melebihi tarikh luput yang dicetak pada kotak atau strip.

Jika anda diarahkan oleh doktor untuk berhenti mengambil *MODIM*, atau ia telah melebihi tarikh luput, tanya ahli farmasi anda bagaimana untuk mengendalikan baki ubat tersebut.

## 8. MAKLUMAT LANJUT

### Rupa dan warna

*MODIM CAPSULE* adalah dalam kapsul berwarna hijau dengan tulisan 'SPS' berwarna putih.

*MODIM CAPSULE* mengandungi 10 biji kapsul sestrip yang dibungkus dalam pek 50 strip sekotak.

### Bahan-bahan kandungan

Bahan aktif adalah:

Setiap kapsul mengandungi 2mg *Loperamide hydrochloride*.

Bahan-bahan lain:

*Colloidal silicon dioxide, dried corn starch, Lactose, Microcrystalline cellulose, Sodium starch glycolate, Corn starch and Magnesium stearate.*

### Nombor pendaftaran

MAL19921576A

## 9. PEMEGANG PENDAFTARAN PRODUK & PENGILANG

Pemegang Pendaftaran Produk:

IMEKS Pharma Sdn Bhd.

No. 1 & 2, Jalan 6/33B,

MWE Commercial Park,

52000 Kuala Lumpur. Malaysia.

Dikilangkan oleh:

SRIPRASIT PHARMA CO. LTD

619, Charoenrath Road,

Bangkok 10600

Thailand

Tarikh kemaskini: Dis-2011

# MODIM CAPSULE

(Loperamide Hydrochloride)

Patient Information Leaflet

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## WHAT IS IN THIS LEAFLET?

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1. What *MODIM* is used for
2. How *MODIM* works
3. Before you take *MODIM*
4. How to take *MODIM*
5. While you are using *MODIM*
6. Possible side effects
7. After Using *MODIM*
8. Product description
9. Marketing Authorization Holder & Manufacturer

### Read this entire leaflet before you start taking the medication.

- Keep this leaflet. You may need to read again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## 1. WHAT *MODIM* IS USED FOR

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*MODIM CAPSULE* contains the active ingredient *Loperamide hydrochloride*. It is used to treat sudden and short term diarrhea.

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## 2. HOW *MODIM* WORKS

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*MODIM CAPSULE* belongs to the group of medicine called *Antidiarrheal*, which act to relieve symptoms of diarrhea. It works by making the stools more solid and less frequent.

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## 3. BEFORE YOU TAKE *MODIM*

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### When you must not take it

Do not take *MODIM* if you:

- Have allergic reaction to the active ingredient *Loperamide hydrochloride*, or to any other ingredients in this product.
- Are pregnant, or think you are pregnant.
- Have severe diarrhea after taking antibiotics.

*If you are not sure whether you should start taking this medicine, consult your doctor.*

### Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Have inflammatory intestinal condition such as ulcerative colitis.
- Have any obstruction of the intestines
- Suffering from excessive water loss.

*MODIM CAPSULE* is not recommended for children under 6 years of age.

### Taking / using other medicines

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

### Pregnancy

Tell your doctor if you are pregnant; think you are pregnant or planning to become pregnant. *MODIM* is not recommended during pregnancy. Your doctor will discuss the risks and benefits of taking *MODIM* during pregnancy.

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## 4. HOW TO TAKE *MODIM*

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Always take *MODIM* exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

### How much to take

- *Adults and children above 6 years*

Start by taking 2 capsules, followed by 1 capsule after each loose stool and not more than 8 capsules daily.

### When to take it

Take your medicine as directed by your doctor or pharmacist.

### How long to take it

Continue to take your medicines as long as your doctor tells you. *MODIM* is normally required to be taken for short period of time only.

### If you forget to take it

Take your dose as soon as you remember and continue to take it as you would normally. Do not take a double dose to make up for the dose you missed or taking more doses at a time. This may cause unwanted side effects.

### If you take too much (overdose)

If you or anyone else takes too many capsules, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining capsules you have with you.

Dizziness, drowsiness, fatigue and reduced alertness may be observed after an overdose of this medicine.

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

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## 5. WHILE YOU ARE USING *MODIM*

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### Things you must do

- Always take *MODIM* exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you are pregnant, while taking *MODIM*, tell your doctor immediately.

## MODIM CAPSULE

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Patient Information Leaflet

- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking *MODIM*.

### Things you must not do

- Do not use *MODIM* after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.

### Things to be careful of

#### • Driving and using machines

Be careful when driving or operating machineries while you are taking *MODIM*. *MODIM* may cause dizziness and drowsiness in some people. If you experience dizziness or drowsiness, consult your doctor before attempting such activities.

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## 6. POSSIBLE SIDE EFFECTS

All medicines can have side effects. *MODIM* may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects:

- Dizziness
- Irritability
- Fatigue
- Abdominal pain and other gastrointestinal discomfort.
- Dry mouth
- *Paralytic ileus* (obstruction of intestine due to paralysis of the intestinal muscle)
- Skin rashes

*Tell your doctor or pharmacist immediately if you notice the side effect continues or getting serious or anything else that make you fell unwell. Other side effects not listed above may also occur in same people.*

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## 7. AFTER USING MODIM

### Storage

Store in a cool, dry place below 30°C. Store in a well-closed containers to protect from light, heat and moisture.

Keep out of the reach and sight of children.

### Disposal

The expiry date of *MODIM* is printed on the carton and blister. Do not use if after expiry date.

If your doctor tells you to stop taking *MODIM* or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

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## 8. PRODUCT DESCRIPTION

### What it looks like?

*MODIM CAPSULE* is a green- light green color capsule with 'SPS' written in white.

*MODIM CAPSULE* comes in strip of 10 capsules and packed in box of 50 blisters.

### Ingredients

The active ingredient:

Each capsule contains 2mg of *Loperamide hydrochloride*.

The other ingredients are:

*Colloidal silicon dioxide, dried corn starch, Lactose, Microcrystalline cellulose, Sodium starch glycolate, Corn starch and Magnesium stearate.*

### Registration Number

MAL19921576A

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## 9. MARKETING AUTHORISATION HOLDER & MANUFACTURER

Marketing Authorisation Holder:

IMEKS Pharma Sdn Bhd.

No. 1 & 2, Jalan 6/33B,  
MWE Commercial Park,  
52000 Kuala Lumpur. Malaysia.

Manufactured by:

SRIPRASIT PHARMA CO. LTD

619, Charoenrath Road,

Bangkok 10600  
Thailand.

Date of Revision: Dec-2011