

QUETIAPINE WINTHROP TABLET

Quetiapine fumarate

WHAT IS IN THIS LEAFLET:

1. What is Quetiapine Winthrop used for
2. How Quetiapine Winthrop works
3. Before you take Quetiapine Winthrop
4. How to take Quetiapine Winthrop
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1. WHAT IS QUETIAPINE WINTHROP USED FOR

Quetiapine Winthrop can be used to treat several illnesses, such as:

- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Bipolar depression: where you may feel sad all the time or you may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.

Your doctor may continue to prescribe Quetiapine Winthrop even when you are feeling better.

2. HOW QUETIAPINE WINTHROP WORKS

Quetiapine Winthrop belongs to a group of medicines called anti-psychotics. It interacts with a broad spectrum of neurotransmitter receptors in the brain to produce its therapeutic action.

3. BEFORE YOU TAKE QUETIAPINE WINTHROP

When you must not take it

Do not take Quetiapine Winthrop if:

- you are allergic (hypersensitive) to quetiapine or any of the other

ingredients of Quetiapine Winthrop

- you are taking any of the following medicines: protease inhibitors (for HIV infection); azole medicines (for fungal infections); medicines for an infection (like erythromycin or clarithromycin); nefazodone (for depression).

Do not take Quetiapine Winthrop if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Quetiapine Winthrop.

Before you start to take it

Before you take your medicine, tell your doctor if you:

- have or have had any heart problems
- have low blood pressure
- have had a stroke.
- have problems with your liver
- have ever had a fit (seizure)
- have had low levels of white blood cells in the past
- have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Quetiapine Winthrop

Taking other medicines

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

In particular, tell your doctor if you are taking any of the following medicines:

- epilepsy medicines (like phenytoin or carbamazepine)
- rifampicin (for tuberculosis).
- barbiturates (for difficulty sleeping).
- thioridazine (another anti-psychotic medicine).
- medicines for the treatment of fungal infections such as ketoconazole
- certain antibiotics such as erythromycin and clarithromycin

Taking Quetiapine Winthrop with food and drink

- Quetiapine Winthrop can be taken with or without food
- You should avoid alcohol while you are taking Quetiapine Winthrop. This is because the combined effect of Quetiapine Winthrop and alcohol can make you feel sleepy.

4. HOW TO TAKE QUETIAPINE WINTHROP

How much to take

Always take your medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

Your doctor will decide on your starting dose and may gradually increase it depending on your illness and needs.

Schizophrenia

The usual starting dose is 25mg twice daily. The dose is gradually increased to a target dose range of 300mg to 400mg daily, given in 2 or 3 times a day.

Mania

Quetiapine Winthrop should be administered twice daily. Therapy is started with 100mg daily on the first day of treatment, and gradually increased to the target dose. The usual effective dose is 400 to 800mg per day.

Bipolar depression

Quetiapine Winthrop should be administered once daily at bedtime. Quetiapine Winthrop is initiated at 50mg on the first day of therapy, and gradually increased to the target dose.

Elderly people

If you are elderly your doctor may give you a lower dose.

When to take it

Take Quetiapine Winthrop as instructed by your doctor.

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How long to take it

Do not stop taking Quetiapine Winthrop unless instructed by your doctor.

If you forget to take it

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

If you take too much

If you take more Quetiapine Winthrop than prescribed by your doctor, you may feel sleepy, feel faint or dizzy and have palpitations (a pounding heart beat). Contact your doctor or nearest hospital straight away. Take the Quetiapine Winthrop tablets with you.

5. WHILE YOU ARE USING QUETIAPINE WINTHROP

Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you experience:

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called “neuroleptic malignant syndrome”). Immediate medical treatment may be needed.
- Uncontrollable movements, mainly of your face or tongue.

These conditions can be caused by this type of medicine.

Things you must not do

Do not stop taking the medicine even if you feel better unless your doctor told you so.

If you suddenly stop taking Quetiapine Winthrop, you may be unable to sleep (insomnia), you may feel nauseous, or you may experience headache, diarrhoea, vomiting, dizziness or irritability.

Things to be careful of

Pregnancy and lactation

If you are pregnant, trying to get pregnant, or breast-feeding, talk to your doctor before taking Quetiapine Winthrop.

The following symptoms may occur in newborn babies of mothers that have used Quetiapine Winthrop in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding.

If your baby develops any of these symptoms you may need to contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Your tablets may make you feel sleepy. Do not drive or use any tools or machines until you know how the tablets affect you.

6. SIDE EFFECTS

Like all medicines, Quetiapine Winthrop can cause side effects, although not everybody gets them.

The most commonly reported undesirable effects with quetiapine are drowsiness, dizziness, dry mouth, mild weakness, constipation, rapid heartbeat (tachycardia), low blood pressure when standing causing dizziness, and indigestion.

As with other antipsychotic medicines, weight gain, fainting, neuroleptic malignant syndrome (characterized by a combination of high fever, sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat), decreased white blood cell count, and swelling especially the lower limbs, have been associated with quetiapine.

A list of side effects is given as below:

Very common: $\geq 1/10$

Common: $\geq 1/100$, $< 1/10$

Uncommon: $\geq 1/1,000$, $< 1/100$

Rare: $\geq 1/10,000$, $< 1/1,000$

Very rare: $< 1/10,000$, including isolated cases

Blood and lymphatic system disorders

Common: decreased white blood cells

Uncommon: increase of a type of white blood cells called eosinophils in blood

Very rare: decrease in white blood cells called neutrophils

Immune system disorders

Uncommon: hypersensitivity

Metabolism and nutrition disorders

Very rare: high blood sugar level, diabetes

Nervous system disorders

Very common: dizziness, drowsiness, headache

Common: fainting

Uncommon: seizures

Very rare: Uncontrollable movements, mainly of the face or tongue (tardive dyskinesia)

Heart disorders

Common: rapid heartbeat, abnormal or irregular heart rhythm

Vascular disorders

Common: low blood pressure upon standing up (this may make you feel dizzy or faint)

Respiratory disorders

Common: nasal congestion (rhinitis)

Gastrointestinal disorders

Common: dry mouth, constipation, indigestion

Liver disorders

Rare: jaundice

Very rare: hepatitis

Skin and subcutaneous tissue disorders

Very rare: swelling of mucous membrane (angioedema), serious skin reaction known as Stevens-Johnson syndrome

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Reproductive system disorders

Rare: a long-lasting and painful erection (priapism)

General disorders

Common: mild weakness, swelling especially the lower limbs (peripheral oedema)

Rare: neuroleptic malignant syndrome (a combination of high fever, sweating, stiff muscles, feeling very drowsy or faint, large increase in blood pressure or heartbeat)

Investigations

Common: weight gain, increase in liver enzymes (ALT, AST)

Uncommon: elevation in an enzyme called gamma-GT, elevations in serum triglyceride levels, elevations in total cholesterol

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

7. STORAGE AND DISPOSAL OF QUETIAPINE WINTHROP

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date.

Store below 25°C in the original package in order to protect from moisture.

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.

8. PRODUCT DESCRIPTION

What it looks like

Quetiapine Winthrop 100mg Tablet

Yellow coloured, round, biconvex film-coated tablet with a break line on one side

Quetiapine 200mg Tablet

White, round, biconvex film-coated tablets

Ingredients

Active substance

Each Quetiapine Winthrop 100mg Tablet contains 115.13 quetiapine fumarate equivalent to 100mg quetiapine.

Each Quetiapine Winthrop 200mg Tablet contains 230.26mg quetiapine fumarate equivalent to 200mg quetiapine.

Other ingredients

Anhydrous calcium hydrogen phosphate, lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate, Opadry Yellow (Quetiapine Winthrop 100mg Tablet), Opadry White (Quetiapine Winthrop 200mg Tablet)

MAL NO.

Quetiapine Winthrop 100mg Tablet
MAL10100023ACR

Quetiapine Winthrop 200mg Tablet
MAL10100024ACR

MANUFACTURER

Matrix Laboratories Limited.
Plot No. F-4 and F-12,
Malegaon M.I.D.C, Sinnar, Nashik,
422113 Maharashtra, India

DATE OF REVISION

September 2012
(based on PI September 2011)

MARKETING AUTHORISATION HOLDER

Winthrop Pharmaceuticals (M) Sdn.
Bhd.
8th Floor, PNB Damansara
No. 19, Lorong Dungun,
Damansara Heights 50490
Kuala Lumpur, Malaysia.

TABLET QUETIAPINE WINTHROP

Quetiapine fumarate

APAKAH YANG ADA PADA RISALAH INI:

1. Apa kegunaan Quetiapine Winthrop
2. Bagaimana Quetiapine Winthrop berfungsi
3. Sebelum anda mengambil Quetiapine Winthrop
4. Cara menggunakan Quetiapine Winthrop
5. Semasa menggunakan Quetiapine Winthrop
6. Kesan-kesan sampingan
7. Cara penyimpanan dan pelupusan Quetiapine Winthrop
8. Maklumat lanjut

1. APA KEGUNAAN QUETIAPINE WINTHROP

Quetiapine Winthrop boleh digunakan untuk merawat beberapa penyakit seperti:

- *Schizophrenia*: di mana anda mungkin mendengar atau merasa sesuatu yang tidak wujud, percaya sesuatu yang tidak benar, atau berasa amat curiga, cemas, keliru, bersalah, tegang atau murung.
- *Mania*: di mana anda mungkin merasa sangat ghairah, gembira, gelisah, bersemangat atau hiperaktif, atau pertimbangan terjejas, termasuk bertindakan agresif atau menimbulkan gangguan.
- Kemurungan jenis *Bipolar*: di mana anda mungkin merasa sedih sepanjang masa, atau anda mungkin berasa murung, bersalah, tidak bertenaga, kehilangan selera atau tidak dapat tidur.

Doktor anda mungkin teruskan rawatan Quetiapine Winthrop walaupun anda berasa lebih baik.

2. BAGAIMANA QUETIAPINE WINTHROP BERFUNGSI

Quetiapine Winthrop tergolong dalam kumpulan ubat-ubatan yang dikenali sebagai *anti-psychotic*. Ia berinteraksi dengan banyak jenis reseptor neurotransmitter dalam otak untuk menghasilkan tindakan terapeutiknya.

3. SEBELUM ANDA MENGAMBIL QUETIAPINE WINTHROP

Bila tidak boleh mengambil

Jangan mengambil Quetiapine Winthrop jika:

- anda alah (hipersensitif) kepada quetiapine atau mana-mana bahan kandungan lain
- anda mengambil mana-mana ubat-ubatan berikut:
protease inhibitor (untuk jangkitan HIV); ubat jenis *azole* (untuk jangkitan kulat); ubat-ubatan untuk jangkitan (seperti *erythromycin* atau *clarithromycin*); *nefazodone* (untuk kemurungan)

Jangan mengambil Quetiapine Winthrop jika mana-mana di berkenaan anda. Jika anda tidak pasti, berbincang dengan doktor atau ahli farmasi anda sebelum mengambil Quetiapine Winthrop.

Sebelum mula mengambil

Sebelum anda mengambil ubat ini, beritahu doktor anda jika anda:

- sedang mengalami atau pernah mempunyai sebarang masalah jantung
- mempunyai tekanan darah rendah
- pernah mengalami strok
- mempunyai masalah hati
- pernah mengalamai sawan
- pernah mempunyai tahap sel darah putih yang rendah
- ada diabetes atau mempunyai risiko mendapat diabetes. Jika ya, doktor anda mungkin akan memeriksa paras gula darah anda semasa anda mengambil Quetiapine Winthrop

Jika mengambil ubat-ubat lain

Beritahu doktor atau ahli farmasi jika anda mengambil atau baru-baru ini telah mengambil apa-apa ubatan lain, termasuk ubat-ubatan yang diperolehi tanpa preskripsi.

Khususnya, beritahu doktor anda jika anda mengambil mana-mana ubat berikut:

- ubat epilepsi (seperti *phenytoin* atau *carbamazepine*)

- *rifampicin* (untuk tuberkulosis)
- *barbiturate* (untuk kesukaran tidur)
- *thioridazine* (sejenis ubat anti-psikotik lain)
- ubat-ubatan untuk rawatan jangkitan kulat seperti *ketoconazole*
- antibiotik tertentu seperti *erythromycin* dan *clarithromycin*

Mengambil Quetiapine Winthrop dengan makanan dan minuman

- Quetiapine Winthrop boleh diambil dengan atau tanpa makanan
- Anda harus mengelakkan alkohol semasa anda mengambil Quetiapine Winthrop. Ini kerana kesan gabungan Quetiapine Winthrop dan alkohol boleh menyebabkan anda berasa mengantuk.

4. CARA MENGGUNAKAN QUETIAPINE WINTHROP

Berapa banyak harus diambil

Sentiasa mengambil ubat anda seperti yang diberitahu oleh doktor anda. Anda harus menyemak dengan doktor anda jika anda tidak pasti.

Doktor anda akan menentukan dos permulaan anda, dan meningkatkan dos anda secara beransur-ansur bergantung kepada penyakit dan keperluan anda.

Schizophrenia

Dos permulaan biasa adalah 25mg dua kali sehari. Dos ini akan ditingkatkan secara beransur-ansur kepada dos sasaran iaitu 300mg hingga 400mg sehari, di mana ia diberikan dalam 2 atau 3 kali sehari.

Mania

Quetiapine Winthrop harus diberi dua kali sehari. Terapi dimulakan dengan 100mg sehari pada hari pertama, dan dos ditingkatkan secara beransur-ansur kepada dos sasaran. Dos berkesan yang biasa adalah 400mg hingga 800mg sehari.

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Kemurungan jenis Bipolar

Quetiapine Winthrop harus diberi sekali sehari sebelum tidur. Terapi Quetiapine Winthrop dimulakan dengan 50mg pada hari pertama, dan dos akan ditingkatkan secara beransur-ansur kepada dos sasaran.

Warga tua

Jika anda warga tua, doktor anda mungkin memberi anda dos yang lebih rendah.

Bila perlu diambil

Ambil Quetiapine seperti yang diarahkan oleh doktor anda.

Berapa lama perlu diambil

Jangan berhenti mengambil Quetiapine Winthrop melainkan jika diarah oleh doktor anda.

Jika terlupa untuk mengambil

Jika anda terlupa mengambil ubat, ambil ubat sebaik sahaja anda ingat. Jika ia hampir masa untuk mengambil dos seterusnya, tunggu sehingga masa untuk dos kemudian. Jangan ambil dos berganda untuk menggantikan dos yang terlupa

Jika mengambil berlebihan (terlebih dos)

Jika anda mengambil lebih Quetiapine Winthrop daripada yang ditetapkan oleh doktor anda, anda mungkin berasa mengantuk, rasa nak pingsan atau pening dan mempunyai denyutan jantung yang berdebar-debar. Hubungi doktor anda atau hospital terdekat dengan segera. Bawa tablet Quetiapine Winthrop anda bersama.

5. SEMASA MENGGUNAKAN QUETIAPINE WINTHROP

Perkara yang perlu dilakukan

Ambil ubat anda seperti yang diberitahu oleh doktor anda.

Beritahu doktor anda segera jika anda mengalami:

- Kombinasi demam, kekejangan otot teruk, berpeluh atau kesedaran terjejas (dikenali sebagai “*neuroleptic malignant*

syndrome”). Rawatan perubatan segera mungkin diperlukan.

- pergerakan yang tidak terkawal, terutamanya pada muka atau lidah anda.

Gejala-gejala ini boleh disebabkan oleh ubat jenis ini.

Perkara yang tidak boleh dilakukan

Jangan berhenti mengambil ubat ini walaupun anda berasa lebih baik, kecuali dinasihatkan oleh doktor anda untuk berbuat demikian.

Jika anda tiba-tiba berhenti mengambil Quetiapine Winthrop, anda mungkin tidak dapat tidur (*insomnia*), berasa loya, atau anda mungkin mengalami sakit kepala, cirit-birit, muntah-muntah, pening atau keresahan.

Perkara yang perlu diberi perhatian

Mengandung dan menyusu bayi

Jika anda hamil, sedang cuba untuk hamil, atau sedang menyusukan bayi, berbincang dengan doktor anda sebelum mengambil Quetiapine Winthrop.

Gejala berikut mungkin berlaku kepada bayi yang baru dilahirkan oleh ibu yang menggunakan Quetiapine Winthrop dalam trimester terakhir (tiga bulan terakhir kehamilan): menggeletar, kekejangan otot dan/atau rasa lemah, mengantuk, keresahan, masalah bernafas dan kesukaran untuk makan.

Jika bayi anda mengalami mana-mana gejala ini anda perlu menghubungi doktor anda.

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

Memandu dan menggunakan mesin

Ubat anda boleh membuatkan anda mengantuk. Jangan memandu atau mengguna apa-apa peralatan atau mesin sehingga anda tahu bagaimana tablet ini mempengaruhi anda.

6. KESAN-KESAN SAMPINGAN

Seperti semua ubat, Quetiapine Winthrop boleh menyebabkan kesan-kesan sampingan, walaupun tidak semua orang mendapatnya.

Kesan sampingan yang paling kerap dilaporkan dengan quetiapine adalah mengantuk, pening, mulut kering, kelemahan ringan, sembelit, denyutan jantung yang cepat (*tachycardia*), tekanan darah rendah apabila berdiri dan menyebabkan pening kepala, dan ketakcernaan.

Seperti ubat *antipsychotic* lain, peningkatan berat badan, pingsan, *neuroleptic malignant syndrome* (yang ciri-cirinya termasuk kombinasi demam panas, berpeluh, kekejangan otot, rasa sangat mengantuk atau pingsan, peningkatan tekanan darah atau denyutan jantung), penurunan paras sel darah putih, dan bengkak terutamanya pada kaki, telah dikaitkan dengan penggunaan quetiapine.

Senarai kesan sampingan adalah seperti yang berikut:

Sangat biasa: $\geq 1/10$

Biasa: $\geq 1/100, <1/10$

Tidak biasa: $\geq 1/1,000, <1/100$

Jarang: $\geq 1/10,000, <1/1,000$

Sangat jarang: $<1/10,000$, termasuk kes-kes asing

Gangguan darah dan sistem limfa

Biasa: penurunan sel-sel darah putih

Tidak biasa: peningkatan sel darah putih yang dikenali sebagai eosinofil dalam darah

Sangat jarang: penurunan sel-sel darah putih yang dipanggil neutrofil

Gangguan sistem imun

Tidak biasa: hipersensitiviti

Gangguan metabolisme dan pemakanan

Sangat jarang: paras gula darah tinggi, diabetes

Gangguan sistem saraf

Sangat biasa: pening, mengantuk, sakit kepala

Biasa: pingsan

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Tidak biasa: sawan

Sangat jarang: pergerakan di luar kawal, terutamanya pada muka atau lidah (*tardive dyskinesia*)

Gangguan jantung

Biasa: denyutan jantung cepat, rentakan jantung yang tidak normal atau tidak teratur

Gangguan vaskular

Biasa: tekanan darah rendah apabila berdiri (ini mungkin membuatkan anda berasa pening atau pingsan)

Gangguan sistem pernafasan

Biasa: kesesakan hidung (rinitis)

Gangguan sistem penghadaman

Biasa: mulut kering, sembelit, ketakcernaan

Gangguan hati

Jarang: jaundis

Sangat jarang: hepatitis

Gangguan kulit dan tisu subkutaneus

Sangat jarang: bengkak membran mukus (*angioedema*), tindak balas kulit serius yang dikenali sebagai *Stevens-Johnson Syndrome*

Sistem gangguan pembiakan

Jarang: ereksi yang berpanjangan dan menyakitkan (*priapism*)

Gangguan am

Biasa: kelemahan ringan, bengkak terutamanya pada kaki (*peripheral oedema*)

Jarang: *neuroleptic malignant syndrome* (kombinasi demam tinggi, berpeluh, ketegangan otot, berasa sangat mengantuk atau pingsan, peningkatan besar dalam tekanan darah atau denyutan jantung)

Ujian makmal

Biasa: peningkatan berat badan, peningkatan enzim hati (ALT, AST)

Tidak biasa: peningkatan enzim yang dikenali sebagai gamma-GT, peningkatan paras trigliserida serum, peningkatan jumlah kolesterol

Jika mana-mana kesan sampingan menjadi serius, atau jika anda mendapati sebarang kesan sampingan yang tidak disenaraikan dalam risalah ini, sila beritahu doktor anda atau ahli farmasi.

7. CARA PENYIMPANAN DAN PELUPUSAN QUETIAPINE WINTHROP

Jauhkan daripada jangkauan dan penglihatan kanak-kanak.

Jangan menggunakan ubat ini selepas tarikh luput.

Simpan di bawah 25°C dalam pakej asal untuk melindunginya daripada kelembapan.

Ubat-ubatan tidak harus dilupuskan melalui air kumbahan atau buangan isi rumah. Tanya ahli farmasi anda tentang cara untuk melupuskan ubat-ubatan yang tidak lagi diperlukan. Langkah ini akan membantu melindungi alam sekitar.

8. MAKLUMAT LANJUT

Rupa dan warna produk

Tablet Quetiapine Winthrop 100mg

Tablet berwarna kuning, berbentuk bulat dan bikonveks, bersalut filem dan bergarisan di sebelah tablet

Tablet Quetiapine Winthrop 200mg

Tablet berwarna putih, berbentuk bulat dan bikonveks, dan bersalut filem

Bahan-bahan kandungan

Bahan aktif

Setiap tablet Quetiapine Winthrop 100mg mengandungi 115.13mg quetiapine fumarate bersamaan 100mg quetiapine.

Setiap tablet Quetiapine Winthrop 200mg mengandungi 230.26mg quetiapine fumarate bersamaan 200mg quetiapine.

Bahan-bahan lain

Anhydrous calcium hydrogen phosphate, lactose monohydrate, microcrystalline cellulose, sodium

starch glycolate, povidone, magnesium stearate, Opadry Yellow (Tablet Quetiapine Winthrop 100mg), Opadry White (Tablet Quetiapine Winthrop 200mg)

MAL NO.

Quetiapine Winthrop 100mg Tablet
MAL10100023ACR

Quetiapine Winthrop 200mg Tablet
MAL10100024ACR

PENGILANG

Matrix Laboratories Limited.
Plot No. F-4 and F-12,
Malegaon M.I.D.C, Sinnar, Nashik,
422113 Maharashtra, India

TARIKH KEMASKINI RIMUP

September 2012

(berdasarkan PI Sept 2011)

PEMEGANG PENDAFTARAN

Winthrop Pharmaceuticals (M) Sdn.
Bhd.

8th Floor, PNB Damansara
No. 19, Lorong Dungun,
Damansara Heights 50490
Kuala Lumpur, Malaysia.