

LABEDATE TABLET 100 mg and 200 mg®

LABETALOL HYDROCHLORIDE TABLET 100 mg and 200 mg

What is in this leaflet:

1. What Labedate Tablet 100 mg and 200 mg is used for
2. How Labedate Tablet 100 mg and 200 mg works
3. Before you use Labedate Tablet 100 mg and 200 mg
4. How to take Labedate Tablet 100 mg and 200 mg
5. While you are using Labedate Tablet 100 mg and 200 mg
6. Side Effects
7. How to store and dispose
8. Product description

What Labedate Tablet 100 mg and 200 mg is used for

Labedate Tablet 100 mg and 200 mg is used to:

1. Treat severe chest pain due to lack of oxygen supply of heart muscle, generally due to obstruction or spasm of heart blood vessel.
2. Treat high blood pressure when used alone or in combination with other high blood pressure medication.

How Labedate Tablet 100 mg and 200 mg works

Labedate Tablet 100 mg and 200 mg block beta receptor that are found in heart. This reduces the action of adrenaline and noradrenaline on the heart, causing it to beat more slowly and with less force, in turn, this reduces the pressure at which the blood is pumped out of the heart and around the body, which helps to reduce blood pressure.

Labedate Tablet 100 mg and 200 mg action in slowing the rate and force of the heartbeat also reduces the energy used by the heart to pump blood around the body. This reduce the heart's need for oxygen, which mean can be used for severe chest pain.

Before you use Labedate Tablet 100 mg and 200 mg

Labedate Tablet 100 mg and 200 mg should not be used in condition of allergic to any ingredient of the tablet, and during pregnancy and breastfeeding.

Before start using Labedate Tablet 100 mg and 200 mg tell your doctor or pharmacist if you are taking other medications, or have diabetes or other health problem.

Cimetidine may increase the bioavailability of labetalol and care is required in the oral dosing of the latter.

How to take Labedate Tablet 100 mg and 200 mg

How much to take

Always take the dose exactly as your doctor has told you.

Adult dose:

The usual starting dose is 100 to 200 mg twice daily. Your doctor may change this dose depending how you respond to the medicine.

Elderly dose:

Elderly patients may need smaller doses. The initial dose of 50 mg twice daily is recommended.

Paediatric dose:

Dosage has not been established.

When to take it

Take Labedate Tablet 100 mg and 200 mg after meals.

How long to take it

To properly control your blood pressure, Labedate Tablet 100 mg and 200 mg must be taken every day. Continue taking the medicine as long as your doctor recommends it.

If you forget to take it

If you miss a dose of Labedate Tablet 100 mg and 200 mg, take it as soon as possible. Unless if nearly time for next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

If you take too much (overdose)

If you have taken more than the prescribed dose, contact your doctor or pharmacist. Overdose symptoms are nausea, vomiting, dizziness, lightheadedness, faintness and very slow heart beat.

While you are using Labedate Tablet 100 mg and 200 mg

1. Immediately stop taking the medicine if a skin rash or any other allergic reaction occurs.
2. If you become pregnant while taking the medicine, tell your doctor immediately.
3. Do not stop taking the medicine without advice your doctor.
4. Do not drive or operate machinery if dizziness or tiredness occurs after taking the medicines.

Side Effects

Side effects of Labedate Tablet 100 mg and 200 mg such as slow heart rate, breathing difficulty and/or wheezing, heart failure, mental depression, skin rashes, allergic reaction, abnormal heart beat, back pain or joint pain, chest pain, confusion, hallucinations, liver damage, decrease number of white blood cells and withdrawal reaction. Transient scalp tingling may occur, usually at beginning and withdrawal of treatment.

How to store and dispose

Storage

Keep container tightly closed in a dry place, below 25°C. Protect from light. Keep out of the reach of children..

Disposal

Do not dispose the medicine into wastewater or household garbage. Ask your pharmacist how to dispose of medicines that are no longer required.

Product Description

What it looks like?

Labedate Tablet 100 mg is round and orange coloured film coated tablet. The pack sizes are: Plastic Container of 500 and 1000 tablets (for Tender or Export only).

Labedate Tablet 200 mg is round and orange coloured film coated tablet. The pack sizes are: Plastic Container of 500 and 1000 tablets (for Tender or Export only).

Ingredients

The active substance is labedate hydrochloride either 100 mg and 200 mg per tablet.

The other ingredients of Labedate Tablet 100 mg and 200 mg are aerosil, lactose, sodium starch glycolate, corn starch, talc powder, povidone K-30, magnesium stearate, titanium dioxide, hydroxy methyl cellulose, sunset yellow Al lake, isopropyl alcohol, propylene glycol, microcrystalline cellulose.

Registration Numbers:

Labedate Tablet 100 mg:

MAL20041095A

Labedate Tablet 200 mg:

MAL20041096A

Manufactured by:

Idaman Pharma Manufacturing Sdn Bhd (661901-P)

Lot 24, Bakar Arang Industrial Estate, Sungai Petani, Kedah, Malaysia.

Date of revision:

Marketing Authorisation Holder

September 21th, 2011

IDAMAN PHARMA MANUFACTURING SDN BHD

LABEDATE TABLET 100 mg and 200 mg®

LABETALOL HYDROCHLORIDE TABLET 100 mg and 200 mg

Apakah yang ada pada risalah ini:

1. Apakah kegunaan Labedate Tablet 100 mg dan 200 mg
2. Bagaimana Labedate Tablet 100 mg dan 200 mg berfungsi
3. Sebelum mengambil Labedate Tablet 100 mg dan 200 mg
4. Cara pengambilan Labedate Tablet 100 mg dan 200 mg
5. Semasa menggunakan Labedate Tablet 100 mg dan 200 mg
6. Kesan-kesan sampingan
7. Cara penyimpanan dan pelupusan
8. Deskripsi produk

Apakah kegunaan Labedate Tablet 100 mg dan 200 mg

Labedate Tablet 100 mg dan 200 mg digunakan untuk:

1. Mengubati sakit dada yang teruk disebabkan kekurangan bekalan oksigen dari otot jantung, secara amnya disebabkan oleh halangan atau kekejangan salur darah jantung.
2. Mengubati tekanan darah tinggi apabila digunakan secara bersendirian atau digabungkan dengan lain-lain ubat tekanan darah tinggi.

Bagaimana Labedate Tablet 100 mg dan 200 mg berfungsi

Labedate Tablet 100 mg dan 200 mg memblok reseptor beta yang terdapat di jantung. Ini akan mengurangkan tindakan adrenalin dan noradrenalin jantung, menyebabkan denyut jantung lebih perlahan dan dengan kuasa yang kurang, ini akan mengurangkan tekanan darah yang dipam keluar dari jantung dan ke seluruh tubuh, yang membantu untuk mengurangkan tekanan darah.

Labedate Tablet 100 mg dan 200 mg bertindak memperlakan kadar dan kuasa denyutan jantung juga mengurangkan tenaga yang digunakan oleh jantung untuk mengepam darah ke seluruh tubuh. Ini mengurangkan keperluan jantung untuk oksigen, yang bermakna boleh digunakan untuk sakit dada yang teruk.

Sebelum mengambil Labedate Tablet 100 mg dan 200 mg

Labedate Tablet 100 mg dan 200 mg tidak harus digunakan dalam keadaan alah kepada mana-mana bahan pil, mengandungi dan dalam waktu menyusu.

Tarikh semakan:

Sebelum mula menggunakan Labedate Tablet 100 mg dan 200 mg maklumkan doktor atau ahli farmasi anda jika anda mengambil ubat-ubatan lain, menghadapi kencing manis atau masalah kesihatan yang lain.

Cimetidine boleh meningkatkan bioavailabiliti-labetalol dan perhatian diperlukan dalam dos oral yang kedua.

Cara pengambilan Labedate Tablet 100 mg dan 200 mg

Berapa banyak untuk diambil

Ambil dos mengikut arahan doktor kepada anda.

Dos dewasa:

Dos permulaan yang biasa adalah 100 hingga 200 mg dua kali sehari. Doktor boleh menukar dos ini bergantung kepada tindak balas anda terhadap ubat.

Dos Warga Tua:

Pesakit warga tua mungkin memerlukan dos yang lebih kecil. Dos awal 50 mg dua kali sehari adalah disyorkan.

Dos kanak-kanak:

Dos belum diwujudkan.

Bila ubat diambil

Ambil ubat ini selepas makan.

Berapa lama ubat diambil

Untuk mengawal tekanan darah anda, ambil Labedate Tablet 100 mg dan 200 mg setiap hari. Teruskan mengambil ubat selagi doktor anda mencadangkan.

Jika anda lupa mengambil ubat

Jika anda terlewat mengambil dos Labedate Tablet 100 mg dan 200 mg, ambil ubat secepat mungkin. Jika hampir masa untuk dos berikutnya, lewatkan dos tersebut dan kembali ke jadual dos rutin. Jangan mengambil 2 dos sekaligus.

Jika anda mengambil ubat terlalu banyak

Jika anda telah mengambil lebih daripada dos yang ditetapkan, sila hubungi doktor atau ahli farmasi. Gejala dos yang berlebihan adalah rasa loya, muntah-muntah, pening, rasa ringan kepala, rasa hendak pitam dan denyutan jantung sangat lambat.

Semasa menggunakan Labedate Tablet 100 mg dan 200 mg

1. Berhenti mengambil ubat serta merta jika ruam kulit atau apa-apa reaksi alahan lain berlaku.
2. Jika anda hamil ketika mengambil ubat, beritahu doktor anda dengan segera.
3. Jangan berhenti mengambil ubat tanpa nasihat doktor anda.

4. Jangan memandu atau mengendalikan jentera jika berlaku pening atau keletihan selepas pengambilan ubat.

Kesan-kesan sampingan

Kesan-kesan sampingan Labedate Tablet 100 mg dan 200 mg seperti kadar denyut jantung perlahan, sesak nafas dan/atau berdehit, kegagalan jantung, kemurungan mental, mengurangkan ruam kulit, reaksi alahan, rentak jantung yang tidak normal, sakit belakang atau sakit sendi, sakit dada, kekeliruan, halusinasi, kerosakan hati, mengurangkan bilangan sel darah putih dan tindak balas penarikan balik rawatan. Rasa cucuk kulit kepala yang mungkin berlaku, biasanya pada semasa awal dan sementara waktu penarikan balik rawatan.

Cara penyimpanan dan pelupusan

Penyimpanan

Simpan ke dalam bekas yang tertutup rapat dan diletak ditempat yang kering, dibawah suhu 25°C. Jauhi dari cahaya dan kanak-kanak.

Pelupusan

Jangan buang ubat ke dalam longkang dan tong sampah. Bertanyakan kepada ahli farmasi anda cara membuang ubat yang tidak diperlukan lagi.

Diskripsi produk

Rupa dan warna tablet

Labedate Tablet 100 mg tablet berbentuk bulat dan bersalut filem berwarna oren. Saiz pek: Bekas plastik sebanyak 500 dan 1000 tablet (untuk Tender atau Eksport sahaja). Labedate Tablet 200 mg tablet berbentuk bulat dan bersalut filem berwarna oren. Saiz pek: Bekas plastik sebanyak 500 dan 1000 tablet (untuk Tender atau Eksport sahaja).

Bahan-bahan

Bahan aktif hydrochloride labedate sama ada 100 mg dan 200 mg per tablet. Bahan-bahan lain Labedate Tablet 100 mg dan 200 mg adalah aerosil, laktosa, 'sodium starch glycolate', kanji jagung, serbuk talkum, 'povidone' K-30, magnesium stearat, titanium dioksida, hidroxy metil selulosa, 'sunset yellow Al lake', 'isopropyl alcohol', 'propylene glycol', 'microcrystalline cellulose'.

Nombor Pendaftaran:

Labedate Tablet 100 mg: MAL20041095A
Labedate Tablet 200 mg: MAL20041096A

Dikilangkan oleh:

Idaman Pharma Manufacturing Sdn Bhd (661901-P)
Lot 24, Bakar Arang Industrial Estate, Sungai Petani, Kedah, Malaysia.

Pemegang Kuasa Pemasaran