

APAKAH YANG ADA PADA RISALAH INI

Risalah ini menjawab beberapa soalan umum tentang Bisohehexal. Ia tidak mengandungi semua maklumat mengenai Bisohehexal. Risalah ini hanyalah sebagai rujukan, ia tidak menggantikan nasihat daripada doktor/ahli farmasi. Sila baca dan fahami seluruh kandungan risalah ini sebelum anda mula mengambil ubat anda. Ubat ini adalah untuk anda, jangan berikannya kepada orang lain walaupun mereka mempunyai simptom yang sama seperti anda. Jika anda mempunyai sebarang soalan mengenai ubat ini, sila tanya doktor / ahli farmasi anda. Simpan risalah ini, anda mungkin perlu membacanya lagi.

1. APAKAH KEGUNAAN BISOHEXAL

Bisohehexal digunakan dalam rawatan:

1. Tekanan darah tinggi
2. Sakit dada (*angina*)
3. Kegagalan jantung (biasanya digunakan bersama ubat-ubatan lain)

Sila rujuk kepada doktor sekiranya anda mempunyai sebarang soalan mengenai tujuan ubat ini dipreskripsikan kepada anda. Doktor anda mungkin memberikan ubat ini kepada anda untuk sebab-sebab yang lain.

2. BAGAIMANA BISOHEXAL BERFUNGSI

Bisoprolol fumarate tergolong dalam kumpulan ubat yang dikenali sebagai *beta-blockers*. Ia berfungsi dengan mempengaruhi tindak balas badan terhadap rangsangan saraf, terutamanya di jantung. Ia mengurangkan keperluan darah dan oksigen oleh jantung dan dengan itu mengurangkan beban kerja jantung. Bisohehexal juga memperlambatkan kadar degupan jantung anda, dan membolehkan jantung berfungsi dengan lebih efisien. Bisohehexal boleh membantu mengurangkan episod kegagalan jantung yang memerlukan pesakit dimasukkan ke dalam wad dan juga mengurangkan risiko kematian secara mendadak.

3. SEBELUM MENGAMBIL BISOHEXAL

Jangan ambil ubat ini sekiranya:

- 1) Anda mempunyai alahan terhadap bahan aktif, bisoprolol fumarate atau bahan lain dalam formulasi ini atau jenis ubat yang sama.
- 2) Anda mengalami atau pernah mengalami gejala-gejala berikut:
 - Kegagalan jantung akut
 - Kejutan cardiogenik, masalah serius jantung yang menyebabkan tekanan darah rendah.
 - Masalah jantung dimana kadar degupan jantung menjadi lambat atau ritma jantung terganggu.
 - Hipotensi, tekanan darah rendah
 - Masalah asma atau penyakit paru-paru terhalang kronik (*chronic obstructive lung disease*), yang mengganggu penafasan.
 - *Peripheral arterial occlusive disease*: masalah peredaran darah berkurang disebabkan penghalangan salur darah yang menyebabkan pesakit rasa sakit atau kebas terutamanya pada tangan dan kaki
 - Sindrom Raynaud, yang menyebabkan rasa kebas pada jari, tangan dan kaki apabila sejuk.
 - Terdapat ketumbuhan di kelenjar adrenal yang tidak dirawat (*phaeochromocytoma*)
 - Tahap asid dalam darah berlebihan.

Sekiranya anda tidak pasti samada anda perlu mengambil ubat ini, sila berbincang dengan doktor anda.

Sebelum anda mula mengambil ubat ini
Sila maklumkan kepada doktor anda sekiranya mempunyai alahan terhadap ubat-ubatan tertentu, makanan, bahan pengawet atau bahan pewarna

Maklumkan kepada doktor anda sekiranya anda:

- Akan menjalani pembedahan yang menggunakan anesthesia
- Asma, masalah pernafasan atau masalah paru-paru yang lain.
- Sakit dada (*angina*)
- Kencing manis
- Sebarang alahan
- hiperthyroidisme, kelenjar tiroid yang terlampau aktif.

- masalah pada salur darah yang mengurangkan peredaran darah ke tangan dan kaki.
- Masalah ginjal
- Masalah hati
- Ketumbuhan pada kelenjar adrenal (*phaeochromocytoma*)
- Rawatan desensitasi
- Semasa berpuasa
- Sedang atau pernah mengalami psoriasis

Mengambil ubat lain

Maklumkan kepada doktor anda sekiranya anda mengambil ubat lain, termasuk ubatan yang didapatkan tanpa preskripsi. Ubat-ubat ini mungkin berinteraksi dengan Bisohehexal atau mungkin mempengaruhi kesan ubat ini. Anda mungkin perlu mengubah dos atau pengambilan ubat-ubat tertentu dan berhati-hati semasa mengambil sesetengah ubat, doktor atau ahli farmasi anda mempunyai lebih maklumat tentang ubat-ubat yang berikut:

- *calcium antagonists*, ubat yang digunakan untuk merawat tekanan darah tinggi dan *angina* seperti *diltiazem*, verapamil
- ubat untuk gangguan ritma jantung seperti *flecainide*, *amiodarone*, *disopyramide*, *lidocaine*
- *clonidine*, ubat untuk rawatan penyakit darah tinggi
- *beta-blockers* lain, termasuklah ubat penitis mata
- ubat yang bertindak ke atas sistem saraf parasimpatetik seperti asetilkolina dan nikotin.
- insulin dan ubat lain untuk penyakit kencing manis
- ubat anestesia yang digunakan semasa pembedahan
- digoxin, ubat untuk kegagalan jantung
- Ubat anti-inflamasi bukan steroid (NSAIDs) seperti *ibuprofen*
- Ubat beta-simpatomimetik seperti *dobutamine* dan *isoprenaline*
- Noradrenalin dan adrenalin
- Ubat anti-hipertensi lain
- ubat antidepresi trisiklik (cth: *amitripyline*)
- barbiturate (cth: *phenobarbital*) untuk rawatan penyakit epilepsi
- *phenothiazine* (cth: *chlorpromazine*) ubat untuk penyakit psikosis.
- *Rifampicin*, sejenis antibiotik.

- *Mefloquine*, untuk rawatan malaria
- *Monoamine oxidase inhibitors*, ubat untuk rawatan kemurungan, contohnya *phenelzine* dan *tranylcypromine*

Semasa mengandung dan menyusu bayi

Sila maklumkan kepada doktor anda sekiranya anda hamil atau merancang untuk hamil atau sedang menyusu. Doktor anda akan berbincang dengan anda mengenai risiko dan kebaikan yang terlibat. Seperti semua ubat *beta blockers*, anda tidak disarankan mengambil *Bisohexal* semasa menyusu.

4. CARA MENGGUNAKAN BISOHEXAL

Ambil ubat ini seperti yang diarahkan oleh doktor anda.

Berapa banyak harus diambil Tekanan darah tinggi (Hypertensi)

Biasanya 5mg sehingga 10mg sekali sehari. Dos lebih tinggi boleh dipreskripsikan kepada sesetengah pesakit. Untuk tekanan darah tinggi yang ringan, 2.5mg adalah memadai. *BisoHEXAL* mungkin akan digunakan bersama ubat anti hipertensi lain.

Sakit dada atau angina

5mg hingga 10mg sekali sehari.

Kegagalan jantung

Dos permulaan biasa adalah 1.25mg sekali sehari dan akan ditambah perlahan-lahan mengikut respons pesakit. Dos pengekalan adalah 10mg sekali sehari. *BisoHEXAL* mungkin akan digunakan bersama ubat anti hipertensi lain.

Bagaimana ubat diambil

Telan ubat dengan sedikit air. Sekiranya anda perlu membahagikan tablet, letak ubat pada permukaan yang keras dengan muka garis pembelahan pada sebelah atas. Tekan pada tengah-tengah tablet dengan ibu jari anda untuk membahagikan tablet kepada dua atau empat bahagian.

Bila perlu diambil

BisoHEXAL boleh diambil sebelum atau selepas makan pada sebelah pagi.

Berapa lama perlu diambil

Ambil ubat ini selagi diarahkan oleh doktor anda. Ubat ini membantu untuk

mengawal keadaan anda tetapi bukan untuk menyembuhkannya. Jangan berhenti mengambil ubat ini dengan tiba-tiba.

Jika terlupa mengambil

Jika anda lupa satu dos, ambil sejeurus anda teringat, tetapi sekiranya hampir masa untuk dos seterusnya, anda bolehlah cuma mengambil dos seterusnya. Jangan sesekali mengambil dos berganda untuk menggantikan dos yang terlupa. Sekiranya anda tidak pasti, tanya doktor atau ahli farmasi anda.

Jika mengambil berlebihan (terlebih dos)

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

Tanda-tanda terlebih dos termasuklah pening, kadar degupan jantung sangat rendah, kesukaran bernafas, tekanan darah sangat rendah.

5. SEMASA MENGGUNAKAN BISOHEXAL

Perkara yang perlu dilakukan

- Sekiranya anda hamil semasa mengambil *Bisohexal*, beritahu doktor anda segera.
- Sekiranya anda bercadang mengambil ubat baru, ingatkan doktor dan ahli farmasi anda bahawa anda sedang mengambil *Bisohexal*
- Maklumkan kepada doktor, doktor gigi dan ahli farmasi anda yang anda sedang mengambil ubat ini
- Sekiranya anda bercadang untuk menjalani pembedahan, maklumkan kepada pakar bedah/doktor bius bahawa anda sedang mengambil ubat ini. *Bisohexal* mungkin mempengaruhi kesan ubat lain yang digunakan semasa pembedahan
- Sekiranya anda merancang untuk menjalani ujian darah, beritahu doktor anda bahawa anda sedang mengambil *Bisohexal*. Ia mungkin mengganggu keputusan sesetengah ujian makmal.
- Pastikan anda menjalani rawatan susulan untuk memeriksa

perkembangan anda. Doktor anda mungkin akan memeriksa mata, tiroid, tahap lipid dan glukosa darah anda dari semasa ke semasa untuk memastikan keberkesanan ubat dan memastikan tiada kesan sampingan.

- Sila maklumkan kepada doktor anda sekiranya anda tidak mengambil ubat anda seperti yang diarahkan untuk sebab-sebab tertentu. Doktor anda mungkin akan menukar ubat anda sekiranya mendapati ubat anda tidak berkesan untuk anda.

Perkara yang tidak boleh dilakukan

- Jangan berikan ubat ini kepada orang lain, walaupun mereka mengalami keadaan yang sama dengan anda.
- Jangan berhenti mengambil *Bisohexal* atau mengurangkan dos tanpa izin doktor anda.

Perkara yang perlu diberi perhatian

- Sekiranya anda sedang menerima rawatan untuk penyakit kencing manis, sila pastikan tahap gula darah anda diperiksa selalu dan laporkan sebarang perubahan kepada doktor anda.
- *Bisohexal* mungkin akan mengganggu pengawalan penyakit kencing manis anda. Ia mungkin akan mengaburi simptom-simptom darah gula rendah (hypoglycemia), seperti kadar degupan jantung bertambah cepat.
- *Bisohexal* boleh menyebabkan keadaan hypoglycemia berlarutan. Dos ubat kencing manis anda termasuk insulin mungkin perlu diubah.
- Berhati-hati sekiranya anda mengambil ubat ini dalam keadaan puasa, sila rujuk kepada doktor dan ahli farmasi anda untuk sebarang pertanyaan.
- *Bisohexal* boleh menyebabkan kepeningan atau pitam pada sesetengah orang, terutama selepas dos pertama. Sekiranya anda mengalami simptom-simptom ini, jangan memandu kereta, mengendalikan mesin, atau melakukan perkara yang mungkin membahayakan anda.
- Sekiranya anda pitam, pening atau pingsan semasa anda bangun, cuba bangun dengan perlahan-lahan, ini boleh membantu badan anda menyesuaikan diri dengan perubahan posisi dan tekanan darah.

Sekiranya masalah ini berlarutan, cuba bincang dengan doktor anda.

6. KESAN-KESAN SAMPINGAN

Seperti semua ubat-ubatan, *Bisohexal* boleh menyebabkan kesan sampingan, walaupun bukan semua orang akan mengalaminya. Kesan-kesan sampingan berikut mungkin berlaku dengan penggunaan *Bisohexal*.

Biasa berlaku:

- Tangan atau kaki berasa sejuk atau bebas
- Letih, lesu, vertigo (pening, hilang keseimbangan), sakit kepala
- Loya, muntah, cirit-birit, sembelit
- Peningkatan tahap trigliserida dan paras gula dalam darah atau air kencing
- Gangguan keseimbangan cecair dan elektrolit badan
- Peningkatan keasidan dalam darah (*metabolic acidosis*)

Jarang berlaku:

- Otot lemah atau kejang
- Kadar degupan jantung perlahan, degupan jantung tidak tetap, kegagalan jantung bertambah buruk
- Gangguan tidur, kemurungan
- Kesukaran bernafas
- Paras kreatinin dan urea serum meningkat
- Hilang selera makan, sakit abdomen
- *Orthostatic hypotension*, rasa pening atau pengan semasa pertukaran posisi mendadak.

Sangat jarang berlaku:

- Mimpi ngeri, halusinasi
- Reaksi alahan seperti ruam, kemerahan, gatal, sensitif terhadap cahaya, perubahan warna kulit
- Peningkatan paras enzim hati, hepatitis, jaundis
- impotensi
- Masalah pendengaran
- Rinitis alergi
- Mata kering, masalah penglihatan
- Bilangan sel darah merah, putih dan platetlet berkurangan
- Mata merah (konjuktivitis)
- Sakit dada
- Masalah kulit (psoriasis, keguguran rambut)
- Radang pada pankreas (*Pancreatitis*)

Maklumkan kepada doktor anda sekiranya anda mendapati kesan-kesan

sampingan lain. Sesetengah pesakit mungkin mengalami kesan-kesan sampingan yang tidak disenaraikan.

7. CARA PENYIMPANAN DAN PELUPUSAN *BISOHEXAL*

Cara penyimpanan

Simpan ubat dalam bungkusan asal. Simpan di tempat sejuk (bawah 25°C) dan kering. Jauhi daripada kepanasan, cahaya dan kelembapan yang berlebihan. Jangan tinggalkan ubat anda di dalam kereta. Jauhi daripada kanak-kanak.

Pelupusan

Ubat-ubatan tidak sepatutnya dibuang seperti biasa. Tanya doktor atau ahli farmasi untuk mengetahui cara pelupusan.

8. MAKLUMAT LANJUT

BisoHEXAL® 2.5 mg Film Coated Tablet: Tablet berwarna putih, berbentuk bulat, dengan salah satu permukaan bertanda "BIS 2.5".

BisoHEXAL® 5.0 mg Film Coated Tablet: Tablet berwarna kuning, berbentuk bulat, dengan salah satu permukaan bertanda "BIS5".

Bahan aktif: bisoprolol fumarate
Bahan lain: calcium hydrogen phosphate, cellulose, maize starch, croscarmellose sodium, silica (colloidal anhydrous), magnesium stearate, lactose monohydrate, titanium dioxide, hydroxypropylmethylcellulose, polyethylene glycol.

BisoHEXAL 5mg Film-coated Tablet juga mengandungi 'yellow ferric oxide'

Pembungkusan:

BisoHEXAL 2.5mg Film-coated Tablet: Pek blister 10 biji yang dibungkus dalam 20, 28, 30, 50, 60, 100 tablets sekotak

BisoHEXAL 5mg Film-coated Tablet: Pek blister 10 biji yang dibungkus dalam 30, 50, 60 dan 100 tablet sekotak.

No. Pendaftaran:

BisoHEXAL 2.5mg Film-coated Tablet: MAL09122028A

BisoHEXAL 5mg Film-coated Tablet: MAL09111737A

9. PENGILANG

Dikilangkan oleh:

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben, Germany

Untuk:

Hexal AG
Industriestraße 25,
83607 Holzkirchen,
Germany.

10. PEMEGANG PENDAFTARAN

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

Tarikh kemaskini:

October 2011

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about BisoHEXAL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this entire leaflet carefully before you start to take your medicine. This medicine is for you. Never give it to other people even if their condition appears to be the same as yours. If you have any questions about this medicine ask your pharmacist. Keep this leaflet, you may need to read it again.

1. WHAT IS BisoHEXAL USED FOR

BisoHEXAL is used to treat:

1. high blood pressure
2. chest pain (angina)
3. heart failure (usually used in combination with other medicines)

Ask your doctor if you have any questions about why this medicine was prescribed for you. Your doctor may have prescribed it for another reason.

2. HOW BisoHEXAL WORKS

Bisoprolol fumarate belongs to a group of medicines called beta-blockers. It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. **BisoHEXAL** also slows your heart rate, which in turn increases the efficiency of your heart. **BisoHEXAL** can help to reduce the number of heart failure episodes needing hospital admission and also the risk of sudden death.

3. BEFORE YOU TAKE BisoHEXAL

Do not take this medicine if

- 1) You are hypersensitive to the active ingredient, bisoprolol fumarate or any ingredients in the formulation or any other similar medicines.
- 2) Do not take this medicine if you have or have had any of the following medical conditions:
 - acute heart failure

- cardiogenic shock, a serious heart condition causing low blood pressure
- heart conditions where the electrical activity controlling your heart rate does not work properly, causing a very slow heart rate or uneven heart beating
- hypotension, low blood pressure
- severe asthma or chronic obstructive lung disease
- late stages of peripheral arterial occlusive disease (reduced blood flow due to obstruction in blood vessels, causing numbness or weakness, especially in the limbs)
- Raynaud's syndrome, a condition causing numbness, tingling and colour change in fingers and toes when exposed to the cold
- untreated phaeochromocytoma, a rare tumour of the adrenal gland
- metabolic acidosis, when there is too much acid in the blood.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start taking this medicine

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

Tell your doctor if you have:

- to undergo surgery which involves using anesthesia
- asthma, breathing difficulty or other lung problems
- Prinzmetal angina or variant angina
- diabetes
- any allergic conditions
- hyperthyroidism, an over active thyroid gland
- any blood vessel disorder causing poor circulation in the arms and legs
- kidney problems
- liver problems
- phaeochromocytoma, a rare tumour of the adrenal gland
- desensitizing therapy
- During strict fasting
- Psoriasis or history of psoriasis

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription. These medicines may be affected by

BisoHEXAL, or may affect how well it works. You may need different amount of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking these medicine listed below:

- calcium antagonists, medicines used to treat high blood pressure and angina such as diltiazem, verapamil
- anti-arrhythmic drugs used to treat irregular or abnormal heartbeat such as flecainide, amiodarone, disopyramide, lidocaine
- clonidine, a medicine used to treat high blood pressure
- other beta-blockers, including eye drops
- drugs that act on the parasympathetic nervous system such as acetylcholine and nicotine
- insulin and oral drugs for diabetes
- anaesthetic agents used in surgery
- digoxin, a medicine used to treat heart failure
- Non-steroidal anti inflammatory drugs (NSAIDs) eg. ibuprofen
- Beta-sympathomimetic drug, eg dobutamine and isoprenaline
- Noradrenaline and adrenaline
- Other antihypertensives
- tricyclic antidepressants (eg: amitriptyline)
- barbiturates, (eg: phenobarbital) medicines used to treat epilepsy
- phenothiazine (eg: chlorpromazine) a type of medicine used to treat psychoses
- rifampicin, an antibiotic
- mefloquine, a medicine used to treat malaria
- monoamine oxidase inhibitors, medicines used to treat depression such as phenelzine, tranylcypromine

Pregnancy and lactation

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor will discuss with you the risks and benefits involved. Like most beta-blocker medicines, **BisoHEXAL** is not recommended while you are breastfeeding.

4. HOW TO TAKE BisoHEXAL

Take your medication exactly as directed by your doctor.

How much to take:

High blood pressure (hypertension)

Usually 5mg to 10mg. Higher dose may be prescribed on individual basis. For mild forms of hypertension, 2.5mg may be sufficient. **BisoHEXAL** may be used alone or with other antihypertensive.

Chest pain (Coronary Heart Disease-angina pectoris)

5mg to 10mg per day.

Heart failure

The usual starting dose is 1.25mg once daily and adjusted up according to patients response. The usual dose for maintenance therapy is 10mg once daily. **BisoHEXAL** may be used together with other antihypertensive.

How to take:

Swallow the tablets with a glass of water. If you need to break the tablet, place the tablet on a hard flat surface with the scored side at the top. Press with your thumb in the middle of the tablet to break into halves or quarters.

When to take

BisoHEXAL can be taken before or after meal preferably in the morning.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is very important that you do not stop taking this medicine suddenly.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

If you take too much

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

Symptoms of an overdose may include dizziness, very slow heart rate, difficulty in breathing or very low blood pressure.

5. WHILE YOU ARE USING BisoHEXAL

Things you must do

- If you become pregnant while taking this medicine, tell your doctor immediately.
 - If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **BisoHEXAL**.
 - Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
 - If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
 - If you are about to have any blood tests tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
 - Keep all of your doctor's appointments so that your progress can be checked. Your doctor may check your eyes, thyroid, lipid and blood glucose levels from time to time to make sure the medicine is working and to prevent unwanted side effects.
 - Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Your doctor may think it is not working effectively and change your treatment unnecessarily.
- ### ***Things you must not do***
- Do not give your medicine to anyone else, even if they have the same condition as you.
 - Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

- If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.
- **BisoHEXAL** may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heart beat.

- **BisoHEXAL** may make hypoglycaemia last longer. Your dose of diabetic medicines, including insulin, may need to be changed.
- Take this medicine with caution under strict fasting conditions. Ask your doctor or pharmacist to answer any questions you may have.
- Be careful driving or operating machinery until you know how **BisoHEXAL** affects you. This medicine may cause dizziness or light headedness in some people, especially after the first dose. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

6. POSSIBLE SIDE EFFECTS

Like all medicines, **BisoHEXAL** can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common:

- coldness or numbness in the hands or feet
- tiredness, exhaustion, vertigo (dizziness, loss of balance), headache
- nausea, vomiting, diarrhoea, constipation
- increase in triglyceride, sugar level (blood or urine)
- disturbance of fluid and electrolytes
- increase in blood acidity (metabolic acidosis)

Uncommon:

- muscular weakness or cramps
- slow heart beat, irregular heartbeat, aggravation of heart failure.
- sleep disorders, depression
- breathing difficulties
- increase in serum creatinine and urea
- loss of appetite, abdominal pain
- orthostatic hypotension, feeling dizzy or fainting during sudden change of position.

Rare and isolated cases:

- nightmare, hallucinations
- hypersensitivity reactions: such as rash, redness, skin discolouration, itching, hives, sensitive to light
- increase in liver enzymes, hepatitis, jaundice
- impotence
- difficulty in hearing
- allergic rhinitis
- eye dryness, visual disturbance
- decrease in blood cells count (white blood cells, platelets)
- conjunctivitis
- chest pain
- skin reactions (psoriasis, hair loss)
- pancreatitis, inflammation of pancreas

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

7. HOW TO STORE *BisoHEXAL*

Storage

Keep medicines in original packaging. Store in a cool (below 25°C), dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car. Keep all medicines out of the reach of children.

Disposal

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines.

8. PRODUCT DESCRIPTION

BisoHEXAL® 2.5 mg Film Coated Tablet: White coloured, round, snap tab film-coated tablets, divisible into two parts with a one-sided embossment "BIS 2.5".

BisoHEXAL® 5.0 mg Film Coated Tablet: Yellow coloured, round, snap tab film-coated tablets, divisible into four parts with a one-sided embossment "BIS5".

Active ingredient: bisoprolol fumarate

Other ingredients: calcium hydrogen phosphate, cellulose, maize starch, croscarmellose sodium, silica, magnesium stearate, lactose monohydrate, titanium dioxide, hydroxypropylmethylcellulose, polyethylene glycol.

BisoHEXAL 5mg Film-coated Tablet also contains yellow ferric oxide

Packing

BisoHEXAL 2.5mg Film-coated Tablet: Blisters of 10 tablets packed in 20, 28, 30, 50, 60 and 100 film coated tablets per box.

BisoHEXAL 5mg Film-coated Tablet: Blisters of 10 tablets packed in 30, 50, 60 and 100 film coated tablets per box

Registration No

BisoHEXAL 2.5mg Film-coated Tablet: MAL09122028A

BisoHEXAL 5mg Film-coated Tablet: MAL09111737A

9. MANUFACTURER

Manufactured by

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben, Germany

For

Hexal AG
Industriestraße 25,
83607 Holzkirchen,
Germany.

10. MARKETING AUTHORIZATION HOLDER

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

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