MONICOR 60 mg SR

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:
MONICOR 60 mg SR slow release tablets

COMPOSITION:
Active ingredients:
Each slow release tablet contains 60 mg isosorbide-5-mononitrate.

Inactive ingredients:
Carnauba wax, ferric oxide, hydroxypropylmethylcellulose, macrogol, magnesium stearate, silica anhydrous colloidal, stearic acid, talc, titanium dioxide.
MONICOR 60 mg SR also contains sugar (lactose monohydrate 38,167 mg per tablet). (see WARNINGS and SPECIAL PRECAUTIONS).

PHARMACOLOGICAL CLASSIFICATION:
A 7.1.4 Vasodilators – coronary and other medicines used in angina pectoris.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Isosorbide-5-mononitrate is an active metabolite of isosorbide dinitrate. It relaxes vascular smooth muscle, producing vasodilation of both the arteries and veins (predominantly in the veins). This effect is dose-dependent. Low plasma concentrations lead to venous dilatation, resulting in peripheral pooling of blood, decreased venous return and reduction in left ventricular end-diastolic pressure (preload).
High plasma concentrations also dilate the arteries, reducing systemic vascular resistance and arterial pressure, leading to a reduction in cardiac afterload.
Isosorbide-5-mononitrate may also have a direct dilatory effect on the coronary arteries. By reducing the end diastolic pressure and volume, isosorbide-5-mononitrate lowers the intramural pressure, thereby leading to an improvement in the subendocardial blood flow. The net effect is therefore a reduced workload of the heart and an improved oxygen supply/demand balance in the myocardium.

Pharmacokinetic properties:
Isosorbide-5-mononitrate is almost completely absorbed, though it does not undergo first pass metabolism in the liver, elimination takes place primarily in the liver by denitration and conjugation. The elimination half-life is about 5 hours, volume of distribution is 0,6 L/kg and total clearance is approximately 115 mL/minute. The metabolites of isosorbide-5-mononitrate are excreted mainly via the kidneys. Only about 2 % of the isosorbide-5-mononitrate dose ingested is excreted unchanged in the urine.
Impaired liver or kidney function does not have a major influence on the pharmacokinetics of isosorbide-5-mononitrate. MONICOR 60 mg SR is a slow release formulation of isosorbide-5-mononitrate. The active substance is released independently of pH over a 10-hour period. The absorption phase of MONICOR 60 mg SR is prolonged and the duration of effect is extended. After repeated per oral administration with 60 mg once daily, a maximal plasma concentration (of about 3000 nmol/L) is achieved after around four hours.
The plasma concentration then steadily falls to around 500 nmol/L at the end of the dosage interval (which is twenty-four hours after dose intake). Absorption is not significantly affected by food intake.

INDICATIONS:
MONICOR 60 mg SR is indicated for the prophylactic treatment of angina pectoris.

CONTRAINDICATIONS:
- hypersensitivity to any of the ingredients
- severe hypotension, hypovolaemia, marked anaemia, heart failure due to obstruction (including constrictive pericarditis), or raised intracranial pressure due to head trauma or cerebral haemorrhage
- patients with angle closure glaucoma as MONICOR 60 mg SR may increase intra-ocular pressure
- sildenafil and other phosphodiesterase type 5 inhibitors (PDE5) must not be given with MONICOR 60 mg SR (see INTERACTIONS).

WARNINGS and SPECIAL PRECAUTIONS:
Caution should be observed in patients with severe cerebral arteriosclerosis and hypotension (see CONTRAINDICATIONS). MONICOR 60 mg SR tablets are not indicated for the relief of acute anginal attacks. Sublingual or buccal nitroglycerin tablets should be used in these situations (see DOSAGE AND DIRECTIONS FOR USE).
MONICOR 60 mg SR may increase intra-ocular pressure in patients with angle closure glaucoma, (see CONTRAINDICATIONS). It should be used with caution in patients with severely impaired renal or hepatic function, hypothyroidism, malnutrition or hypothermia.
MONICOR 60 mg SR contains lactose. Patients with rare hereditary problems or a history of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take MONICOR 60 mg SR.

Effects on ability to drive and use machinery:
MONICOR 60 mg SR may cause drowsiness and impair your ability to drive and use machinery. Caution is advised while performing these tasks, especially if other blood pressure lowering medications are taken at the same time.

INTERACTIONS:
The hypotensive effects of MONICOR 60 mg SR may be enhanced by alcohol, and by vasodilators and other medicines with hypotensive actions.
Concomitant administration with sildenafil and other phosphodiesterase type 5 inhibitors (PDE5) can potentiate the effect of MONICOR 60 mg SR with the potential result of serious adverse effects such as hypotension, syncope or myocardial infarction.

PREGNANCY AND LACTATION:
The safety of MONICOR 60 mg SR during pregnancy and lactation has not been established.
It is not known whether MONICOR 60 mg SR is secreted in human milk.

DOSAGE AND DIRECTIONS FOR USE:
The recommended dosage is 60 mg daily (one tablet), in the morning.
This dosage may be increased to 120 mg (two tablets), once daily in the morning.
Treatment may be initiated with 30 mg (half a tablet) for the first two to four days, to minimize the possibility of headache. MONICOR 60 mg SR tablets may be broken in half, but should not be chewed or crushed and should be taken with half a glass of water.
MONICOR 60 mg SR may be used effectively in monotherapy as well as in combination with chronic beta-blocker therapy.

NOTE:
MONICOR 60 mg SR tablets are not indicated for the relief of acute anginal attacks. Sublingual or buccal nitroglycerin tablets should be used in these situations (see WARNINGS and SPECIAL PRECAUTIONS).
Tablets are divisible but should not be chewed or crushed.

SIDE EFFECTS:

System Organ Class	Frequency	Undesirable effects
Blood and the lymphatic system disorders	*Less frequent*	Methaemoglobinaemia
Nervous system disorders	*Frequent*	Dizziness, restlessness
Eye disorders	*Less frequent*	Blurred vision
Cardiac disorders	*Frequent* *Less frequent*	Tachycardia Bradycardia
Vascular disorders	*Frequent* *Less frequent*	Hypotension, syncope, headache Severe or prolonged headache
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Impairment of respiration
Gastro-intestinal disorders	*Frequent* *Less frequent*	Nausea Vomiting, diarrhoea
Skin and subcutaneous tissue disorders	*Frequent* *Less frequent*	Flushing of the face Cyanosis, rash, pruritus
Musculoskeletal, connective tissue and bone disorders	*Less frequent*	Myalgia

Note that the following side effects generally disappear with continued treatment:
- headache which occurs when treatment has just been started
- hypotension which may manifest as dizziness and nausea.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Symptoms of overdosage are pulsing headache, excitation, flushing, cold perspiration, nausea, vomiting, vertigo, syncope, tachycardia and hypotension.
Treatment should include induction of emesis and the use of activated charcoal.
If the patient presents with pronounced hypotension, they should be placed in the supine position with legs raised and if necessary intravenous fluid can be administered.
Treatment is symptomatic and supportive.

IDENTIFICATION:
Cream oval tablets, half-scored on both sides, marked with “60” on one side.

PRESENTATION:
White polypropylene securitainers containing 30 tablets. MONICOR 60 mg SR is also packed in hard silver-coloured aluminium foil/ clear transparent PVC/ PVDC/ film blister strips of 3 X 10 tablets inside an outer carton.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Keep well closed. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
A37/ 7.1.4/ 0340

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Pharma Dynamics (PTY) LTD
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pharma dynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
MONICOR 60 mg SR slow release tablets.

Read all of this leaflet carefully before you start using MONICOR 60 mg SR:
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- MONICOR 60 mg SR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MONICOR 60 mg SR CONTAINS:
The active ingredient is isosorbide-5-mononitrate. Each tablet contains 60 mg isosorbide-5-mononitrate.
In addition, MONICOR 60 mg SR contains the following inactive ingredients: Carnauba wax, ferric oxide, hydroxypropylmethylcellulose, macrogol, magnesium stearate, silica anhydrous colloidal, stearic acid, talc, titanium dioxide.
MONICOR 60 mg SR also contains sugar (lactose monohydrate 38,167 mg per tablet) (see "Important information about some of the ingredients of MONICOR 60 mg SR").

2. WHAT MONICOR 60 mg SR IS USED FOR:
MONICOR 60 mg SR is prescribed by doctors for the preventative treatment of angina pectoris, a condition characterised by frequent and intense pain in the chest.

3. BEFORE YOU USE MONICOR 60 mg SR:
Do not take MONICOR 60 mg SR:
- if you are hypersensitive (allergic) to isosorbide-5-mononitrate, organic nitrate type medications or any of the other ingredients of (see "WHAT MONICOR 60 mg SR CONTAINS")
- if you have very low blood pressure, a low amount of blood in the body, a clear reduction in the amount of red blood cells in the body, a weak heart due to blockage of your heart arteries or increased pressure in the skull due to head injury or bleeding in the brain
- if you have angle closure glaucoma (increased pressure in the eye/eyes); as MONICOR 60 mg SR may increase the pressure in the eye further
- if you are also taking sildenafil, a medicine used to treat a man who cannot get or keep a hard, erect penis suitable for sexual activity, or other similarly acting medicines (see "Using other medicines with MONICOR 60 mg SR")
- for the relief of sudden attacks of angina pectoris. Your doctor will prescribe sublingual (under the tongue) nitroglycerin tablets to be used in these situations (see "HOW TO USE MONICOR 60 mg SR").

Take special care with MONICOR 60 mg SR:
- if you have severe cerebral arteriosclerosis (hardening and/or thickening of the walls of the smaller arteries of the brain) or severe low blood pressure (see "Do not take MONICOR 60 mg SR")
- you are undernourished, have severely weakened kidney or liver function, decreased function of the thyroid gland or have a low body temperature
- if you have angle closure glaucoma (increased pressure in the eye/eyes); as MONICOR 60 mg SR may increase the pressure in the eye further (see "Do not take MONICOR 60 mg SR").

Taking MONICOR 60 mg SR with food or drink:
- MONICOR 60 mg SR can be taken with or without food
- MONICOR 60 mg SR tablets can be broken into two, but should not be chewed or crushed and should be taken with half a glass of water.

Pregnancy and breastfeeding:
- DO NOT use MONICOR 60 mg SR if you are pregnant, suspect that you are pregnant or are breastfeeding, as the safety of MONICOR 60 mg SR in pregnancy and breastfeeding is not known
- if you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MONICOR 60 mg SR.

Driving and using machinery:
- MONICOR 60 mg SR may impair your ability to drive and use machinery. Take care if you feel dizzy, tired, or drowsy while using MONICOR 60 mg SR, especially if other blood-pressure lowering medications are taken at the same time.

Important information about some of the ingredients of MONICOR 60 mg SR:
- MONICOR 60 mg SR contains lactose. Please consult your doctor if you know or suspect that you are lactose intolerant before taking MONICOR 60 mg SR.

Using other medicines with MONICOR 60 mg SR:
- always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)
- if you intend taking alcohol or other medicines that cause widening of the blood vessels, these may cause excessive lowering of blood pressure.

If you are taking:
- sildenafil and other medicines used to treat a man who cannot get or keep a hard, erect penis suitable for sexual activity,
- other antihypertensive agents (medicines used for high blood pressure),
- alcohol,

please consult your doctor, pharmacist or other healthcare professional for advice.
Not all medicines that may interact with MONICOR 60 mg SR are listed above.

4. HOW TO USE MONICOR 60 mg SR:
Do not share medicines prescribed for you with any other person.
Always take MONICOR 60 mg SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Take one MONICOR 60 mg SR tablet daily, in the morning. This dosage may be increased to two MONICOR 60 mg SR tablets once daily, in the morning. Treatment may be started with a half MONICOR 60 mg SR tablet daily, in the morning for the first two to four days to decrease the possibility of headache. MONICOR 60 mg SR tablets may be broken in half, but should not be chewed or crushed and should be taken with half a glass of water.
Your doctor will tell you how long your treatment with MONICOR 60 mg SR will last. Do not stop treatment early because your condition may worsen.
If you have the impression that the effect of MONICOR 60 mg SR is too strong or too weak, talk to your doctor or pharmacist.
MONICOR 60 mg SR may be used on its own or in combination with other medicines to control angina pectoris.

NOTE:
MONICOR 60 mg SR tablets are not to be used for the relief of sudden attacks of angina pectoris.

If you take more MONICOR 60 mg SR than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take your MONICOR 60 mg SR:
Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:
MONICOR 60 mg SR can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MONICOR 60 mg SR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MONICOR 60 mg SR and tell your doctor immediately or go to the causality department at your nearest hospital:
- rash or itchiness
- fainting spells
- flushing of the face.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MONICOR 60 mg SR. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- rapid and irregular heartbeat, headache, difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
- vomiting, blurred vision, severe or prolonged headache; muscle pain, a runny tummy
- a blood disorder that causes a bluish discolouration of the skin, tiredness, dizziness, low blood pressure, nausea, restlessness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

The following side effects may not need medical attention and may go away during treatment:
- headache or low blood pressure which is often experienced as dizziness and nausea.

6. STORING AND DISPOSING OF MONICOR 60 mg SR:
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Store in the original container.
- Protect from light.
- Keep the container tightly closed.
- Do not use after the expiry date printed on the label/blister or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF MONICOR 60 mg SR:
MONICOR 60 mg SR tablets are packed in a white plastic securitainer containing 30 tablets.
MONICOR 60 mg SR is also packed in hard silver-coloured aluminium foil and clear transparent PVC/PVDC film blister strips of 3 X 10 tablets inside an outer carton.

8. IDENTIFICATION OF MONICOR 60 mg SR:
MONICOR 60 mg SR tablets are cream coloured, oval tablets, half-scored on both sides, marked with "60" on one side.

9. REGISTRATION NUMBER:
A37/7.1.4/ 0340

10. NAME AND ADDRESS OF REGISTRATION HOLDER:
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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:
MONICOR 60 mg SR stadig-vrystellende tablette.

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om MONICOR 60 mg SR te gebruik:
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, of u apteker.
- MONICOR 60 mg SR is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

1. WAT MONICOR 60 mg SR BEVAT:
Die aktiewe bestanddeel is isosorbied-5-mononitraat. Elke tablet bevat 60 mg isosorbied-5-mononitraat.
Bykomend, bevat MONICOR 60 mg SR die volgende onaktiewe bestanddele: anhidriese kolloidale silika, hidroksiepropielmetielsellulose, karnouba waks, makrogol, magnesiumstearaat, stariensuur, talk, titaandioksied en ysteroksied.
MONICOR 60 mg SR bevat suiker (laktosemonohidraat 38,167 mg per tablet) (kyk "Belangrike inligting omtrent sommige van die bestanddele van MONICOR 60 mg SR").

2. WAARVOOR MONICOR 60 mg SR GEBRUIK WORD:
MONICOR 60 mg SR word deur dokters voorgeskryf, vir die voorkomende behandeling van angina pectoris, 'n toestand wat gekenmerk word deur gereelde en intense pyn in die bors.

3. VOORDAT U MONICOR 60 mg SR GEBRUIK:
Moet nie MONICOR 60 mg SR neem:
- indien u hipersensitief (allergies) is vir isosorbied-5-mononitraat, organiese nitraat-tipe medikasie, of enige van die ander bestanddele van (sien "WAT MONICOR 60 mg SR BEVAT")
- indien u baie lae bloeddruk, 'n lae bloedvolume in die liggaam, 'n beduidende verlaging in die hoeveelheid rooibloedselle in die liggaam, 'n swak hart, weens die blokkasie van u hart-arteries, of 'n druktoename in die skedel, weens 'n hoofbesering, of bloeding in die brein, het nie
- indien u hoeksluiting gloukoom het nie (drukverhoging in die oog/oë); aangesien MONICOR 60 mg SR die oogdruk verder mag verhoog
- indien u ook sildenafil neem nie, 'n medisyne wat deur 'n man gebruik word om 'n harde, regop penis, geskik vir seksuele aktiwiteit, te bewerkstellig, of ander soortgelyke medisyne (sien "Die neem van ander medisyne saam met MONICOR 60 mg SR")
- vir die verligting van skielike aanvalle van angina pectoris. U dokter sal sublinguale (onder die tong) nitrogliserientablette voorskryf, om tydens hierdie situasies te gebruik (kyk "HOE OM MONICOR 60 mg SR TE GEBRUIK").

Neem spesiale sorg met MONICOR 60 mg SR:
- indien u erge serebrale arteriosklerose (verharding en/of verdikking van die wande van kleiner arteries van die brein), of erge lae bloeddruk het (kyk "Moet nie MONICOR 60 mg SR neem")
- indien u ondervoed is, erge, verswakte nier-, of lewerfunksie het, verminderde tiroïedklierfunksie het, of 'n lae liggaamstemperatuur het
- indien u hoeksluiting gloukoom het (verhoogde druk in die oog/oë); aangesien MONICOR 60 mg SR die oogdruk verder mag verhoog (kyk "Moet nie MONICOR 60 mg SR neem").

Die neem van MONICOR 60 mg SR saam met kos en drinkgoed:
- MONICOR 60 mg SR kan saam met, of sonder kos, geneem word
- MONICOR 60 mg SR tablette kan gehalveer word, maar moet nie gekou, of fyngemaak word nie en moet saam met 'n halwe glas water geneem word.

Swangerskap en borsvoeding:
- MOET NIE MONICOR 60 mg SR gebruik, indien u swanger is, vermoed dat u swanger is, of borsvoed nie, aangesien die veiligheid van MONICOR 60 mg SR tydens swangerskap en borsvoeding nie bekend is nie
- indien u swanger is, of u baba borsvoed, raadpleeg asseblief u dokter, apteker, of ander professionele gesondheidsorgverskaffer vir advies, voordat u MONICOR 60 mg SR neem.

Bestuur en die hantering van masjinerie:
- MONICOR 60 mg SR mag u vermoë om te bestuur en masjinerie te hanteer, beïnvloed. Wees versigtig, indien u duiselig, moeg, of lomerig voel terwyl u MONICOR 60 mg SR gebruik, veral indien ander bloeddruk-verlagende medikasies op dieselfde tydstip geneem word.

Belangrike inligting omtrent sommige van die bestanddele van MONICOR 60 mg SR:
- MONICOR 60 mg SR bevat laktose. Raadpleeg asseblief u dokter, indien u weet, of vermoed, dat u laktose-onverdraagsaam is voordat MONICOR 60 mg SR geneem word.

Die gebruik van ander medisyne saam met MONICOR 60 mg SR:
- vertel altyd u professionele gesondheidsorgverskaffer indien u enige ander medisyne neem. (Hierdie sluit aanvullende, of tradisionele medisyne in)
- indien u beplan om alkohol te gebruik, of ander medisyne neem, wat die verwyding van bloedvate veroorsaak, mag hierdie middels oormatige verlaging van bloeddruk veroorsaak.

Indien u die volgende neem:
- sildenafil en ander medisyne, wat gebruik word om 'n man te behandel, wie nie 'n harde, regop penis (geskik vir seksuele aktiwiteit), kan verkry, of behou nie,
- ander antihipertensiewe middels (medisyne wat gebruik word vir hoë bloeddruk),
- alkohol,

raadpleeg u dokter, apteker of ander professionele gesondheidsorgverskaffer vir advies. Nie all medisyne wat moontlik met MONICOR 60 mg SR wisselwerkend reageer, is gelys hierbo nie.

4. HOE OM MONICOR 60 mg SR TE GEBRUIK:
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem MONICOR 60 mg SR altyd presies soos deur u dokter voorgeskryf is, U moet u dokter, of apteker raadpleeg, indien u onseker is.
Neem een MONICOR 60 mg SR tablet daagliks, in die oggend. Hierdie dosis mag verhoog word na twee MONICOR 60 mg SR tablette, een keer daagliks, in die oggend. Behandeling mag begin word met 'n halwe MONICOR 60 mg SR tablet daagliks, in die oggend, vir die eerste twee tot vier dae, om die moontlikheid van 'n hoofpyn, te verlaag.
MONICOR 60 mg SR tablette mag halveer word, maar moet nie gekou, of fyngemaak word nie en moet saam met 'n halwe glas water geneem word.
U dokter sal u vertel vir hoe lank u behandeling met MONICOR 60 mg SR sal voortduur. Moet nie behandeling vroeg staak nie, aangesien u toestand mag versleg.
Indien u onder die indruk is dat die uitwerking van MONICOR 60 mg SR té sterk, of té swak is, praat met u dokter, of apteker.
MONICOR 60 mg SR mag alleen, of in kombinasie met ander medisyne gebruik word, om angina pectoris te beheer.

OPMERKING:
MONICOR 60 mg SR tablette word nie gebruik vir die verligting van skielike aanvalle van angina pectoris nie.

Indien u meer MONICOR 60 mg SR neem as wat u behoort:
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal, of gifbeheersentrum. Neem hierdie inligtingsblad en die res van die oorblywende tablette saam met u, sodat die dokter sal weet wat u geneem het.

Indien u vergeet om u MONICOR 60 mg SR te neem:
Moet nie 'n dubbel dosis neem, om op te maak vir die vergete, individuele dosisse nie.

5. MOONTLIKE NEWE-EFFEKTE:
MONICOR 60 mg SR kan newe-effekte hê. Nie alle newe-effekte wat aangemeld is vir hierdie medisyne, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, terwyl u MONICOR 60 mg SR neem, raadpleeg asseblief u dokter, apteker, of ander professionele gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van MONICOR 60 mg SR en vertel u dokter onmiddellik, of gaan na die ongevalle afdeling by u naaste hospitaal:
- uitslag of gejeuk
- tydelike floute
- gesigsblosing.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie vir MONICOR 60 mg SR gehad het. U mag dringende mediese aandag benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- vinnige en onreëlmatige hartklop, hoofpyn, moeilike asemhaling.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
- braking, versteurde visie, erge of voortdurende hoofpyn; spierpyn, 'n loopmaag
- 'n bloedversteuring, wat 'n blouerige verkleuring van die vel, moegheid, duiseligheid, lae bloeddruk, naarheid en rusteloosheid, veroorsaak.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter, of apteker.

Die volgende newe-effekte mag nie mediese aandag benodig nie en mag verdwyn tydens behandeling:
- Hoofpyn of lae bloeddruk, wat dikwels ervaar word as duiseligheid en naarheid.

6. BEWARING EN WEGDOENING VAN MONICOR 60 mg SR:
- BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
- Bewaar teen of benede 25 °C.
- Bewaar in die oorspronklike houer.
- Beskerm teen lig.
- Hou die houer dig geseël..
- Moet nie gebruik na die vervaldatum, wat op die etiket/stulpstrook, of kartonhouer gedruk is nie.
- Neem alle ongebruikte medisyne na u apteker terug.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette), weggooi nie.

7. AANBIEDING VAN MONICOR 60 mg SR:
MONICOR 60 mg SR tablette word verpak in 'n wit, veilige, plastiese, houer, wat 30 tablette bevat.
MONICOR 60 mg SR word ook verpak in harde, silwerkleurige, aluminiumfoelie en helder, deurskynende PVC/PVDC film stulpstroke van 3 X 10 tablette, binne-in 'n buitenste kartonhouer.

8. IDENTIFIKASIE VAN MONICOR 60 mg SR:
MONICOR 60 mg SR tablette is roomkleurige, ovaal tablette, gegroef in die helfte aan beide kante en gemerk met "60" aan een kant.

9. REGISTRASIENOMMER:
A37/7.1.4/ 0340

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER:
PHARMA DYNAMICS (EDMS) BPK.
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