

Monicor SR 60 mg

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

Monicor SR 60 mg SLOW RELEASE TABLETS

COMPOSITION:

Each slow release tablet contains 60 mg Isosorbide-5-mononitrate.

PHARMACOLOGICAL CLASSIFICATION:

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

PHARMACOLOGICAL ACTION:

Isosorbide-5-mononitrate is an active metabolite of isosorbide dinitrate. It relaxes vascular smooth muscle, producing vasodilation of both the arteries and veins (predominantly). 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 dilates 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.

Pharmacokinetics:

The elimination half-life is about 5 hours. Only about 2% of isosorbide-5-mononitrate is excreted unchanged in the urine. **Monicor SR 60 mg** 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 SR 60 mg** is prolonged and the duration of effect is extended.

INDICATIONS:

Prophylactic treatment of angina pectoris.

CONTRA-INDICATIONS:

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 SR 60 mg** may increase intra-ocular pressure.

Sildenafil and other phosphodiesterase type 5 inhibitors (PDE5) must not be given **Monicor SR 60 mg** (see Interactions).

WARNINGS:

Caution should be observed in patients with severe cerebral arteriosclerosis and hypotension (See Contra-indications).

INTERACTIONS:

The hypotensive effects of **Monicor SR 60 mg** 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 SR 60 mg** with the potential result of serious adverse effects such as hypotension, syncope or myocardial infarction.

PREGNANCY AND LACTATION:

The safety during pregnancy and lactation has not been established.

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 SR 60 mg** tablets may be broken in half, but should not be chewed or crushed and should be taken with half a glass of water.

NOTE:

Monicor SR 60 mg tablets are not indicated for the relief of acute anginal attacks. Sublingual or buccal nitroglycerin tablets should be used in these situations.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Cardio-vascular disorders:

Incidence more frequent: Tachycardia; hypotension; syncope; headache

Incidence less frequent: Severe or prolonged headache; bradycardia

Nervous system disorders:

Incidence more frequent: Dizziness; restlessness

Gastro-intestinal disorders:

Incidence more frequent: Vomiting

Skin disorders:

Incidence more frequent: Flushing of the face

Incidence less frequent: Cyanosis

Eye disorders:

Incidence less frequent: Blurred vision

Other disorders:

Incidence less frequent: Methaemoglobinaemia; impairment of respiration

Precautions:

Monicor SR 60 mg, may increase intra-ocular pressure in patients with angle-closure glaucoma (see Contra-indications). It should be used with caution in patients with severely impaired renal or hepatic function, hypothyroidism, malnutrition or hypothermia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See Side-effects and Special Precautions.

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.

STORAGE INSTRUCTIONS:

Store below 25°C. Keep well closed. Protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

37/7.1.4/0340

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Marketed by **PHARMA DYNAMICS (PTY) LTD** for:

CompuPharm (Pty) Ltd

476 Kings Highway

Lynnwood

Pretoria

DATE AND PUBLICATION OF THE PACKAGE INSERT:

17 January 2005

Monicor SR 60 mg

SKEDULERINGSSTATUS:

S3

EIENDOMSNAAM EN DOSEERVORM:

Monicor SR 60 mg STADIGE -VRYSTELLINGSTABLETTE

SAMESTELLING:

Elke stadige-vrystellingstablet bevat 60 mg Isosorbied-5-mononitraat.

FARMAKOLOGIESE KLASSIFISERING:

A 7.1.4 Vasodilatoriese middels - koronêre en ander medisyne wat in angina pectoris gebruik word.

FARMAKOLOGIESE WERKING:

Isosorbied-5-mononitraat is 'n aktiewe metaboliet van isosorbied-dinitraat. Dit verslap vaskulêre gladde spier, om vasodilasie van beide die arterieë en venes (hoofsaaklik) te veroorsaak. Hierdie effek is dosis-afhanklik. Lae plasmakonsentrasies lei tot veneuse dilatering, wat perifere poeling van bloed, verlaagde veneuse terugvoer en 'n vermindering in linker ventrikulêre end-diastoliese druk (voorbelading), veroorsaak. Hoë plasmakonsentrasies dilateer ook die arterieë waardeur sistemiese vaskulêre weerstand en arteriële druk verlaag word wat dan 'n vermindering in kardiaal nabelading tot gevolg het. Isosorbied-5-mononitraat mag ook 'n direkte dilatasie effek op die koronêre arterieë uitoefen. Deur verlaging van die end-diastoliese druk en volume, verlaag isosorbied-5-mononitraat die intramurale druk, wat tot 'n verbetering in die sub-endokardiale bloedvloei lei. Die netto effek is dus 'n laer werkbelading op die hart en 'n verbeterde suurstofverskaffing/-aanvraag ewewig in die miokardium.

Farmakokinetika:

Die eliminasië halfleeftyd is ongeveer 5 uur. Slegs ongeveer 2% van isosorbied-5-mononitraat word onveranderd in die urine uitgeskei. **Monicor SR 60 mg** is 'n stadige-vrystellingsformulering van isosorbied-5-mononitraat. Die aktiewe stof word onafhanklik van pH oor 'n tydperk van 10 uur vrygestel. Die absorpsiefase van **Monicor SR 60 mg** word verleng en die duur van die effek word uitgerek.

INDIKASIES:

Profilaktiese behandeling van angina pectoris.

KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enigeen van die bestanddele.

Ernstige hipotensie, hipovolemie, uitgesproke anemie, hartversaking as gevolg van obstruksie (insluitend konstriktiewe perikarditis), of verhoogde intrakraniale druk as gevolg van trauma van die kop of serebrale bloeding.

Pasiënte met geslote-hoek-gloukoom omdat **Monicor SR 60 mg** intra-okulêre druk mag verhoog.

Sildenafil en ander fosfodiësterase-tipe-5-inhibeerders (FDE5) moet nie saam met **Monicor SR 60 mg** toegedien word nie (sien Interaksies).

WAARSKUWINGS:

Omsigtigheid moet uitgeoefen word by pasiënte met ernstige serebrale arteriosklerose en hipotensie (Sien Kontra-indikasies).

INTERAKSIES:

Die hipotensiewe uitwerkings van **Monicor SR 60 mg** mag deur alkohol, en deur vasodilators en ander medisyne met hipotensiewe uitwerkings, versterk word.

Gelyktydige toediening saam met sildenafil en ander fosfodiësterase-tipe-5-inhibeerders (FDE5) kan moontlik die effek van **Monicor SR 60 mg** versterk

met die potensiële resultaat van ernstige nadelige uitwerkings soos hipotensie, sinkopee of miokardiale infarksie.

SWANGERSKAP EN LAKTASIE:

Die veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

DOSERING EN GEBRUIKSAANWYSINGS:

Die aanbevole dosering is 60 mg daaglik (een tablet), in die oggend. Hierdie dosering kan tot 120 mg (twee tablette), een keer daaglik in die oggend, verhoog word. Behandeling kan met 30 mg ('n halwe tablet) vir die eerste twee tot vier dae begin word om die moontlikheid van hoofpyn tot 'n minimum te beperk. **Monicor SR 60 mg** tablette kan in die helfte gebreek word, maar dit moet nie gekou of vergruis word nie, en behoort met 'n halwe glas water geneem te word.

LET WEL:

Monicor SR 60 mg tablette word nie aangedui vir die verligting van akute angina aanvalle nie. Sublinguale of bukkale nitrogliserientablette moet in sulke situasies geneem word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Neuwe-effekte:

Kardiovaskulêre versteurings:

Voorkoms meer frekwent: Tagikardie; hipotensie; sinkopee; hoofpyn

Voorkoms minder frekwent: Ernstige of langdurige hoofpyn; bradikardie

Senusisteemversteurings:

Voorkoms meer frekwent: Duiseligheid; rusteloosheid

Gastroïntestinale versteurings:

Voorkoms meer frekwent: Braking

Velversteurings:

Voorkoms meer frekwent: Blossing van die gesig

Voorkoms minder frekwent: Sianose

Oogversteurings:

Voorkoms minder frekwent: Versteurde visie

Ander versteurings:

Voorkoms minder frekwent: Methemoglobinemie; belemmering van asemhaling

Voorsorgmaatreëls:

Monicor SR 60 mg mag die intra-okulêre druk in pasiënte met geslote-hoek gloukoom verhoog (sien Kontra-indikasies). Dit moet met omsigtigheid gebruik word in pasiënte met ernstige inkorting van nier- of lewerfunksie, hipotiroïedisme, wanvoeding of hipotermie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sien Newe-effekte en Spesiale Voorsorgmaatreëls.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Roomkleurige ovaal tablette, half-gekeep op beide kante en gemerk met "60" aan die een kant.

AANBIEDING:

Wit polipropileen sekurihouers wat 30 tablette bevat.

BERGINGSAAWYSINGS:

Bewaar onder 25°C. Maak houer dig toe. Beskerm teen lig.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

37/7.1.4/0340

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT
VAN REGISTRASIE:**

Bemark deur **PHARMA DYNAMICS (EDMS) BPK** vir:

CompuPharm (Edms) Bpk

Kings Highway 476

Lynnwood

Pretoria

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17 Januarie 2005