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MCC046TW06PE-03
30/06/2015
148x300 - 148x31 - 50gr

Progor Capsule 120 mg
Progor Capsule 180 mg

DCI: Diltiazem Hydrochloride

COMPOSITION

Progor 120 mg:
Diltiazem hydrochloride 120mg-Sucrose Stearate-Microcrystalline cellulose-Magnesium stearate-Talc-Titanium dioxide-Hypromellose-Polysorbate 80-Polyacrylate dispersion 30%-Simeticone emulsion q.s. ad capsul. una.-Gelatine-Titanium dioxide

Progor 180 mg:
Diltiazem hydrochloride 180mg-Sucrose stearate-Microcrystalline cellulose-Magnesium stearate-Talc-Titanium dioxide-Hypromellose-Polysorbate 80-Polyacrylate dispersion 30%-Simeticone emulsion q.s. ad capsul. una.-Gelatine-Titanium dioxide

PHARMACEUTICAL FORM AND OTHER PACKAGES

Capsules containing slow-release minigranules and packed in a thermoformed card-pack. Boxes of 28 capsules and unit-doses of 120 mg, 180 mg, 240 mg, 300 mg and 360 mg of diltiazem hydrochloride per capsule.

PHARMACOTHERAPEUTIC GROUP

Anti-hypertensive.

OWNER OF REGISTRATION, MANUFACTURER

Owner of registration	Manufacturer
SMB LABORATOIRES S.A. Rue de la Pastorale 26-28 1080 BRUSSELS	SMB Technology. S.A. Rue du Parc Industriel, 39 B-6900 MARCHE EN FAMENNE, Belgium

INDICATED IN

The treatment of slight to moderate arterial hypertension.

CASES WHERE USE OF THE DRUG MUST BE AVOIDED

- irregular heartbeat, especially when heart rate is lower than 50 beats/min.
- heart disease, with or without lung congestion
- heart attack, with complications
- lung congestion (not associated with congestive heart failure)
- low blood pressure;
- stroke;
- unstable angina pectoris;
- digitalis intoxication;
- hypersensitivity to diltiazem.

SPECIAL PRECAUTIONS

Treatment with **PROGOR** should be started under strict medical supervision, particularly if β-blockers are being taken or the patient has a heart disorder, as well as elderly patients and those with kidney and lung disease.

Special medical supervision is required if the patient is being treated with cyclosporin.

In cases of general anaesthesia, the anaesthetist must be informed about that this drug is being taken.

The capsules may fail to release all their content in case of diarrhoea.

INTERACTIONS WITH OTHER DRUGS OR FOOD

Many interactions may occur when **PROGOR** is combined with other drugs and particularly with those which act on the blood circulation and the heart, due to addition either of similar therapeutic effects or undesired effects. Interactions may occur, in particular, with the following substances: dantrolene, amiodarone, anti-depressants, neuroleptics, lithium, rifampicin, vitamin D, calcium salts, triazolam, nifedipine, digoxin, digitoxin, imipramine, α-blockers such as prazosin, carbamazepine, cyclosporin, theophylline, phenytoine, H_2-antagonists, nitrocompounds and anaesthetics.

USE DURING PREGNANCY AND BREAST-FEEDING

PROGOR should not be used by women who are or may be pregnant. If it is essential to use **PROGOR** during a period of breast-feeding, the infant should be fed in another way.

DRIVING A VEHICLE AND USE OF MACHINERY

Caution is required, particularly in the early stages of treatment, in case of changes of treatment or the consumption of alcohol due to the possibility of tiredness and dizziness. Treatment with **PROGOR** requires regular medical supervision.

HOW TO USE IT AND IN WHAT QUANTITY?

One capsule per day, to be taken before or during a meal, at approximately the same time every day.
The capsule should not be chewed, but swallowed whole while drinking a glass of water.

Adults:
Initial dose: 180 mg/day
Maintenance dose: 240 mg to 360 mg/day
Maximum dose: 360 mg/day

Elderly people and patients with kidney or liver disorders;
Initial dose: 120 mg/day

Children:
The safety and efficacy of the drug for children have not been established.

Route and mode of administration

The **PROGOR** capsules are administered orally.

MEASURES IN CASE OF EXCESSIVE DOSES

The signs of intoxication as a result of excessive doses range from falling blood pressure to acute fatigue and exhaustion.
The patient should be hospitalised immediately.

UNDESIRED EFFECTS

Certain undesired effects may lead to the treatment being stopped: cardiac problems, rash, swelling of the lower limbs.

In patients with high blood pressure, undesirable effects are usually infrequent and temporary.

The following events have been reported by decreasing incidents: swelling of the lower limbs, headache, flushes, fatigue, palpitations, discomfort, digestive problems, dry mouth, nausea, vomiting, diarrhoea, constipation and rashes.

In rare cases of irregular heartbeat, hypotension and syncope have been experienced.

Isolated cases of hallucinations, depression, insomnia, hyperglycemia and impotence have been reported.

Experience has shown that skin rashes are usually localised and disappear when the treatment is stopped.

A moderate and transitory increase in hepatic transaminase has been observed at the start of the treatment. Isolated cases of clinical hepatitis, which regress once the treatment is stopped, have been reported.

Dizziness, itching of the skin or mucous membranes, nervousness, pain in the joints and muscles, sensitivity to sunlight, hypotension, swelling of the gums and male breasts have been observed.

STORAGE

PROGOR capsules should be stored at a temperature of less than 25°C and protected from moisture.
Stability: check that the validity date shown on the packaging after the letters "EX" has not been exceeded; the 6 figures shown designate the month (1st day) and the year after which the product will be out of date.
Example: EX. : 09-2001: expiry date on 1 September 2001.
Keep out of the reach of children.

LAST UPDATE OF THIS NOTICE

9 December 1997.

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保樂康 緩釋膠囊120公絲
Progor Capsule 120 mg

衛署藥輸字第023001號

保樂康 緩釋膠囊180公絲
Progor Capsule 180 mg

衛署藥輸字第022997號

主成份： Diltiazem Hydrochloride

成份：

Progor 120 mg
Diltiazem hydrochloride 120mg-Sucrose Stearate-Microcrystalline cellulose-Povidone-Magnesium stearate-Talc-Titanium dioxide-Hypromellose-Polysorbate 80-Polyacrylate dispersion 30%-Simeticone emulsion q.s. ad capsul. Una.-Gelatine-Titanium dioxide

Progor 180 mg
Diltiazem hydrochloride 180mg-Sucrose Stearate-Microcrystalline cellulose-Povidone Magnesium stearate-Talc-Titanium dioxide-Hypromellose-Polysorbate 80-Polyacrylate dispersion 30%-Simeticone emulsion q.s. ad capsul. Una.-Gelatine-Titanium dioxide

劑型與包裝
本品爲微粒緩釋膠囊，每盒28顆，PTP片裝，每顆含Diltiazem 120毫克及180毫克。

藥理
抗高血壓

適應症
高血壓

下列疾患應避免使用本品：
- 心跳不規則，尤其是心跳速率低於50次／分
- 心臟疾患，無論有無肺充血
- 伴有併發症之心臟發作
- 肺部充血（與充血性心臟衰竭無關）
- 低血壓
- 中風
- 不穩定性心絞痛
- 毛地黃中毒
- 對Diltiazem過敏者

注意事項：
- 使用Progor治療，對於正使用β-Blocker之患者、心臟病患、老年患者及其併有肝腎疾患者應注意監控。
- 如果患者已使用Cyclosporin治療者，尤其需要特別監督使用。
- 如果是全身麻醉時，需通知麻醉師患者服用本藥。
- 如果腹瀉，可能會影響本膠囊所有內容物完整釋出。
- 與其他藥物或食物交互作用
  當Progor與其他藥物併用，尤其是與作用於血液循環與心臟藥物併用時，因爲類似療效或副作用的加強，需注意交互作用可能會發生，尤其是合併下列藥物：dantrolene, amiodarone, 抗憂鬱劑, neuroleptic, 鋰製劑, rifampicin, 維他命D, 鈣鹽, triazolam, nifedipine, digoxin, digitoxin, imipramine, alpha-拮抗劑（例如prazosin）, carbamazepine, cyclosporin, theophylline, phenytoine, H2-拮抗劑, nitrocompounds與麻醉劑。
- 懷孕期與哺乳期使用
  Progor不建議用於懷孕或即將懷孕的婦女。如果哺乳期還是必須使用Progor治療，應改以他法餵食嬰兒
- 開車與機器操作
  須小心使用，尤其是治療初期；如果需要改變治療或需要使用含酒精成份製劑，都須要定期監督Progor之治療。

用法與用量
成人：
起始用量：每天180mg
維持用量：每天240mg-360mg
最高用量：每天360mg

老年或伴有肝腎疾患之患者
起始用量：每天120mg

孩童：
幼兒使用之安全性及有效性，尚待建立。

每天一次，飯前或飯中服用，每次用藥間隔24小時。
不可咬碎膠囊，應以足夠之開水吞服藥品。

過量使用之處理
過量使用所導致的中毒症狀，有可能從血壓降低至急性疲倦與虛脫，病患應立即住院。

副作用
若下列副作用發生，必須立即停藥：心臟問題、發疹、下肢腫脹，這些特殊副作用通常是不會發生的或祇是暫時性的出現在高血壓病人身上。

偶有下列症狀發生：下肢腫脹、頭痛、臉部潮紅、疲倦、心悸、不適、消化問題、口乾、噁心、嘔吐、下瀉、便祕與皮膚發疹。

極少患者會有心跳不規則、低血壓與昏厥、幻覺、憂鬱、失眠、血糖過高與陽萎。

曾有皮膚局部發疹病例，於停止治療後，症狀即會消失。

治療初期，曾有肝臟氨基轉移酵素暫時性增加的情形。極少有病例出現肝炎報告，於停止治療後症狀消退。

曾有眩暈、皮膚或黏膜發炎、神經質、關節與肌肉疼痛、光敏感、低血壓、牙齦腫脹與男性乳房症等報告。

保存
Progor應避濕保存於25℃以下。
本藥應存放於兒童無法取拿之處

製造廠：SMB Technology. S.A.
廠　址：Rue du Parc Industriel, 39
B-6900 MARCHE EN FAMENNE, Belgium

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