MCC083TW-03
05.10.2005
148x300-148x31:50gr

MCC085TW-03
05.10.2005
148x300-Plano:50gr

善寧持續性藥效膠囊 200公絲/400公絲

衛署藥輸字第019624號
衛署藥輸字第019567號
本藥須由醫師處方使用

XANTHIUM 200mg/400mg(Theophylline)

品　　名：XANTHIUM 200mg/400mg
主要成份：Theophylline Monohydrate(As Theophylline Anhydrous 200mg/400mg)
組　　成：
XANTHIUM 200
Theophylline.=200 mg Anhydric.-Microcry stalline Cellulose-Polyvidon.-Sucros.Stearas-Polyvidon-Polymeris.Methacrylat.-Titan.Dioxid.-Magnes.Stearas-Polymeris.Acrylat.Siccum-Polysorbat.80-Simeticon.Emulsio Siccum-Gelatin.-Titan. Dioxid.q.s.pro Caps.Gel.una.
XANTHIUM 400mg
Theophylline.=400 mg Anhydric.-Microsry stalline Cellulose-Polyvidon.-Sucros.Stearas-Polyvidon.-Polymeris.Methacrylat.-Titan.Dioxid.-Magnes.Stearas-Polymeris.Acrylat.Siccum-Polysorbat.80-Simeticon.Emulsio Siccum-Gelatin.-Titan. Dioxid.q.s.pro Caps.Gel.una.
包裝及外觀：
XANTHIUM 200 每盒60顆膠囊，每顆膠囊含theophylline anhyrous 200mg，密封單顆包裝，口服使用
XANTHIUM 400 每盒60顆膠囊，每顆膠囊含theophylline anhyrous 400mg，密封單顆包裝，口服使用
治療分類：長效支氣管擴張劑
適 應 症：氣喘及支氣管痙攣

禁　　忌：
- 6歲以下兒童
- 對theophylline,aminophylline或其他Xanthines類(theobromine,caffeine)過敏
- 對製劑中賦型劑過敏者

注意事項：
- 服用時勿打開或咀嚼或壓碎膠囊內微細顆粒
- 未與醫師諮商不得任意增減劑量
- 心臟病、肝衰竭、肺臟疾病、腎衰竭、急性病毒感染、有甲狀腺疾病、頭痛、胃十二指腸潰瘍或老年人反覆性潰瘍患者需慎用
- 避免在氣喘發作已服用Theophylline成份藥劑時再增加處方的膠囊劑量
- 癲癇患者要小心使用
- 若正在服用St.John's wort (Hypericu perforatum)藥物，在開始服用Xanthium前應先停藥
- 若要同時服用St.John's wort藥物及Xanthium時，應先詢問過醫師，因爲Xanthium劑量也許需要改變。

醫療人員資訊：因爲治療劑量範圍窄，緊急時病患在靜脈注射theophylline後，再以長效型Theophylline治療，可能會很快達到毒性值。必須考慮到使用過量的危險性，緊急時必需用beta-擬交感神經作用劑治療，因爲theophylline代謝的個體差異性，劑量必需依照不良反應或血中濃度來調整

配伍禁忌：到目前爲止並無物理化學上之配伍禁忌

與藥物或食品之交互作用：
- 與吸入性擬交感神經作用劑併用可降低兩者藥量，因而減少副作用發生的風險
- Theophylline與digitalis併用可能會增加心臟方面的作用
- 有些藥物會降低Theophylline的代謝，而引起毒性反應，因此併用下列藥物時需降低Theophylline的劑量：
  - 抗生素類藥品(erythromycin,troleandomycin,lincomycin, clindamycin),
  - 抗潰瘍藥品及制酸劑(cimetidine,aluminium gels),
  - β-阻斷劑類藥品(propranolo,labetalol,alprenolol,oxprenolol),
  - 其他藥品(viloxazine,diltiazem,interferon alpha-2a, ticlopidine, fluvoxamine,disulfiram,ranitidine).
- 有些藥物會增加Theophylline的代謝時間，因此需要增加theophylline的劑量：
  鎮靜安眠及抗癲癇類藥品(barbiturates, phenytoin, carbamazepine....)Aminoglutethimide
- 病患如有抽煙應告知醫師，theophylline的劑量可能需要增加。若病患已戒菸亦應通知醫師，因爲Theophylline的劑量可能需要降低。
- theophylline和有些抗憂鬱劑(lithium carbonate)併服，抗憂鬱劑(lithiumcarbonate)的劑量需增加
- Theophylline不建議和ephedrine，amphetamine類藥品併用因爲會增加副作用
- Quinolenes,口服避孕藥,tacrine,verapamil and the 抗流行性感冒疫苗會增加theophylline的濃度
- Rifampicin會降低theophylline的濃度
- 服用St.John's wort(Hypericum perforatum)相關藥物時應避免與Theophylline併服，這交互作用主要是由於某些肝的酵素作用
- Theophylline和benzodiazepines.的藥理作是相互拮抗的
- Furosemide可能會降低或增加theophylline的濃度
- 同時服用adenosine and Theophylline會停止adenosine的電流生理反應
- 過度攝取caffeine(超過6to10杯咖啡)會抑制Theophylline的代謝
- 油膩的飲食會增加theophylline的吸收，高碳水化合物的飲食會降低theophylline的吸收
- 使用theophylline時，若併服葡萄柚汁，應注意可能產生的藥物交互作用
- 與上述所提藥物併服時應告知醫師，醫師必須要調整劑量

懷孕及授乳婦：
除醫師處方外，不建議在懷孕及授乳時服用Theophylline。
懷孕末期服用Theophylline會造成新生兒噁心、餵食困難、易怒。
授乳期間服用，會造成新生兒興奮、易怒和失眠。
開車及機械操作能力的影響：到目前爲止並無禁忌

劑量：遵照醫生處方是必要的，醫師會因病人的個體差異，來調整theophyline的量。

年齡	無水茶鹼劑量 mg/kg/day*	每天投予總劑量 mg/day
6-9歲	20 mg/kg/day	400mg
9-12歲	18mg/kg/day	400-600mg
12-16歲	16 mg/kg/day	600-800g
17歲以上	10 mg/kg/day	600-1000mg
老人	6-8 mg/kg/day	400-600mg

*過重病患，劑量應依標準體重換算。

- Xanthium膠囊劑建議以每日單次給藥方式投予。醫師處方之每日總劑量(單粒或多粒膠囊)應間隔24小時投予，給藥時間應固定在每天的相同時刻(早上或晚上)。
- 如醫師認爲每日給藥二次爲宜，應於早上及晚上間隔十二小時服用，並固定於用餐前或用餐後，不可打開膠囊，亦不可咀嚼或壓碎內容物。

服用方式：XANTHIUM膠囊口服投予

過量處理：
服用過量theophylline會有下列症狀：
消化系統不適（噁心、嘔吐、胃痛、腹瀉、吐血），神經干擾（過度興奮、心神不寧、神經質、混亂狀況），心臟不適（心悸、心律不整、低血壓或高血壓），更嚴重的中毒會導致抽搐。過量使用的風險最常發生在老年人、肝臟疾病、心臟病或持續發燒患者。若有上述症狀應告知醫師，判斷可能爲中毒時，必須送醫治療。Theophylline中毒時的治療，可藉由胃排空或使用活性碳治療；抽搐得以鎮靜劑（例如：靜脈注射diazepam5-10 mg，小孩靜脈注射0.1~0.2mg/kg）治療；氧氣處理，維持血壓，治療脫水（保持電解質平衡）和血液灌注（hemoperfusion）。
若theophylline超過下列濃度，hemoperfusion治療是必要的：
- 40-60 μg/ml（對已治療病人）
- 80 μg/ml（對尚未治療之病人）
- 50 μg/ml（在超過60歲或有心臟或肝臟衰竭病人）

血液透析和血液灌注同樣有效

副作用：
以下反應通常爲過量導致的：
- 消化系統：噁心、胃痛、嘔吐、腹瀉、食慾不振、吐血、胃十二指腸潰瘍
- 中樞神經系統：失眠、神經質、頭痛、易怒、顫抖、抽搐
- 內分泌/代謝異常：低鈣、高血醣、低磷酸鹽、低鎂、抑制尿液分泌荷爾蒙分泌，油脂異常、（porphyria）毗咯紫質沉著病。
- 心血管異常：心律不整、低血壓或高血壓、心悸、紅斑
- 呼吸道：呼吸加速、呼吸停止、respiratory、alcalosis.
- 潛在過敏反應：蕁麻疹、搔癢併有血小板減少及出血傾向
- 較少發生的：接觸性皮膚炎，伴隨支氣管痙攣的剝落性紅皮症

若您有仿單中未提及的副作用發生時，請聯絡您的醫師或藥師

儲存：
- XANTHIUM應儲存在25℃下
- 過期品不得再使用
- 效期標示範例Exp 08/2002意思爲效期爲2002年8月1日
- 存放於小孩不易拿取之處

製造廠：
SMB TECHNOLOGY S.A.
39 Rue Du Parc Industriel 6900,Marche-En-Famenne,Belgium

藥商：
天義企業股份有限公司
臺北市復興南路一段129號5樓
TEL:(02)2752-3235

XANTHIUM 200　XANTHIUM 400

NAME OF THE MEDICINAL PRODUCT
XANTHIUM 200 Capsule
XANTHIUM 400 Capsule
INN : Theophylline monohydrate

COMPOSITION
XANTHIUM 200
Theophyllin. = 200 mg anhydric. - microcrystalline cellulose - Polyvidon. -Sucros. stearas - Polyvidon. - Polymeris. methacrylat.- Titan. dioxid.- Magnes. stearas - Polymeris. acrylat. siccum Polysorbat. 80 - Simeticon. emulsio siccum - Gelatin.- Titan. dioxid. q.s.pro caps.gel. una.

XANTHIUM 400

Theophyllin. = 400 mg anhydric. - microcrystalline cellulose - Polyvidon. -Sucros. stearas - Polyvidon. - Polymeris. methacrylat. - Titan. dioxid.-Magnes. stearas - Polymeris. acrylat. siccum Polysorbat. 80 - Simeticon.emulsio siccum - Gelatin. - Titan. dioxid. q.s.pro caps. gel. una.

PHARMACEUTICAL FORMS AND OTHER PRESENTATIONS

XANTHIUM 200

Box of 60 capsules and Unit-dose of 200 mg of anhydrous theophylline, packaged in thermoformed strip packs.

XANTHIUM 400

Box of 60 capsules and Unit-dose of 400 mg of anhydrous theophylline, packaged in thermoformed strip packs.Oral administration.

PHARMACOTHERAPEUTICAL GROUP

Long acting bronchodilator.

REGISTRATION HOLDER AND MANUFACTURER

REGISTRATION HOLDER :
LABORATOIRES SMB S.A.
rue de la Pastorale, 26-28
B-1080 BRUXELLES

MANUFACTURER :
SMB TECHNOLOGY S.A.
rue du Parc Industriel, 39
B-6900 MARCHE-EN-FAMENNE

INDICATED IN

Treatment and prevention of bronchospasms (spasmodic contraction of the bronchus) associated with asthma, chronic bronchitis, and emphysema (destruction of the alveoli of the lung wall).This drugis not indicated in the treatment of acute asthmatic crisis.In case of an acute crisis, your physician should indicate more appropriate drugs.

CONTRAINDICATIONS

Children under 6 years old.
Allergy to theophylline, aminophylline or other xanthines(theobromine, caffeine).
Hypersensitivity to one excipient of the preparation.

SPECIAL PRECAUTIONS

Do not open the capsules and do not crunch the microgranules inside the capsules.
Do not take a stronger dose without prescription from your physician.
Use with caution in case of heart disease, liver failure, lung disease, renal failure, acute virosis, thyroid troubles,headaches and gastro-duodenal ulcer or progressive ulcer in elderly patients.
In case of asthmatic crisis, the administration of any other drugs containing theophylline and the increase of the prescribed quantity of capsules should be avoided.
Use with caution in case of epilepsy.
If you are taking a product or a drug containing St. John's wort (Hypericu perforatum), you should stop taking it BEFORE starting a treatment with XANTHIUM.
If you are simultaneously treated with a drug or a product containing St. John's wort (Hypericum perforatum) and XANTHIUM, you should not stop taking St. John's wort beforeconsulting your physician because this decision might require a change in the posology of XANTHIUM.

INFORMATIONS TO MEDICAL STAFF

Because of the narrowness of the therapeutical range, patients treated with long acting theophylline might quickly reach a toxic level after an intravenous injection of theophylline in case of acute crisis.
This danger of overdose must be taken into account. Crisis should be treated with a Beta-sympathomimetic substance.Because of the significant interindividual variations of the theophylline metabolism, doses must be changed according to undesired reactions and (or) blood levels.

INCOMPATIBILITIES

No physico-chemical incompatibility is known up to now.

INTERACTIONS WITH OTHER DRUGS OR FOODSTUFFS

The association with sympathomimetic substances by inhalation reduces the posology of both substances and therefore reduces the risk of undesired effects.
Theophylline might increase cardiac effects if in association with digitalic drugs.
Some drugs might reduce the time of elimination of theophylline and therefore might provoke the appearance of toxic levels.

That is why the following drugs shall require a decreasein the theophylline dosages :

- Antibiotics (erythromycin, troleandomycin, lincomycin, clindamycin),
- Antiulceratives and antacids (cimetidine, aluminium gels),
- b-blockers (propranolol, labetalol, alprenolol, oxprenolol),
- Other drugs (viloxazine, diltiazem, interferon alpha-2a, ticlopidine, luvoxamine, disulfiram, ranitidine).

Other drugs increase the time of elimination of theophylline and therefore require an increase in the dosages :

- Hypnotics and anti-epileptics (barbiturates, phenytoin, carbamazepine ...)
- Aminoglutethimide
- A patient should inform his/her physician if he/she is a regular smoker becausein that case, the dosage might be increased. He/She must also inform him/her about his/her decision of giving up smoking because theophylline dosages shall be reduced.
- The dosages of some antidepressants (lithium carbonate) will be increased with theophylline.

The association of theophylline with ephedrine and amphetamine -like anorexiants is not recommended because the undesired effects of those substances add up.

- Quinolones, oral contraceptives, tacrine, verapamil and the antiflu vaccine might provoke an increase of the theophylline level.
- Rifampicine might provoke a decrease of the theophyllinelevel.
- An interaction has been observed between St. John's wort (Hypericum perforatum) and the substance contained in XANTHIUM. This interaction should be due to an action on some enzymes of the liver.

The intake of a drug or product with St. John's wort (Hypericum perforatum) must be avoided with XANTHIUM.
-Theophylline is an antagonist of the pharmacologic action of benzodiazepines.
Furosemide might provoke a decrease or an increase of the theophylline levels.
Simultaneous administration of adenosine and theophylline mightstop the electrophysiologic effects of adenosine.
-An excessive consumption of caffeine (more than 6 to 10 cups ofcoffee) might inhibit the metabolism of theophylline.
-A fatty meal might increase the absorption of theophylline and a meal with many carbohydrates might decrease its absorption.
In all cases of simultaneous administration of theophylline with one of the above-mentioned drugs, the physician will be informed and will adapt the dosage.

USE IN CASE OF PREGNANCY AND BREAST-FEEDING

Except on advice by your physician, it is not recommended to take theophylline during pregnancy and breast-feeding. The intake of theophylline during the end of pregnancy can cause to the newborn symptoms such as nausea, feeding difficulties, irritability. Intake during breast-feeding may cause to the newborn symptoms such as irritability, excitability, and insomnia.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No contraindication is known up to now.

DOSAGE

It is necessary to follow the treatment prescribed by your physician because each patient receives a treatment adapted to his/her personal case. The physician will decide of the quantity of theophylline in the blood. The doses usually recommended in adults and children above 6 years old are outlined in the following table :

Age groups	Dosage of anhydrous theophylline in mg/kg/day*	Dosage of anhydrous theophylline in mg/day	Dosage strength and number of XANTHIUM capsules per day		
			200 mg	300 mg	400 mg
6 to 9 years	20 mg/kg/day	400 mg	2	-	or 1
9 to 12 years	8 mg/kg/day	400 to 600 mg			
		400 mg	2	-	or 1
		500 mg	1+	1	
		600 mg	-	2	-
12 to 16 years	16 mg/kg/day	600 to 800 mg			
		600 mg	-	2	-
		700 mg	-	1+	1
		800 mg	-	-	2
above 17 years old	10 mg/kg/day	600 to 1000 mg			
		600 mg	-	2	-
		700 mg	-	1+	1
		800 mg	-	-	2
		900 mg	-	3	-
		1000mg	-	2+	1
Elderly patients	6 to 8 mg/kg/day	400 to 600 mg			
		400 mg	2	-	or 1
		500 mg	1+	1	-
		600 mg	-	2	-

*** In overweight patients, ideal body weight should be used to calculate dosages.**

If XANTHIUM is administered in one daily dose, the prescribed capsules are to be taken orally at one time, in the morning or in the evening, at the same time of the day with or without accompanying.

If the physician thinks that it is better to give the drug twice a day, the capsules will be taken in the morning and in the evening with an interval of 12 hours and in the same conditions regarding the meals.
In all ways of administration, do not open the capsules and do not crunch or crush their content.

ADMINISTRATION

XANTHIUM capsules are taken orally.

OVERDOSAGE

The intake of excess theophylline can produce the follow ingsymptoms: digestive disorders (nausea,vomiting, stomach pain, diarrhea, blood vomiting),nervous troubles (excessive excitation, restlessness, nervousness, confusion), cardiac disorders (palpitation, rhythmic troubles, hypotension or hypertension).
A more severe intoxication can cause convulsions. The risk of overdose is most frequent in the case of elderly people and in the case of persons with liver disorders, heart deficiency or prolonged fever.
The physician should be informed if one of these troubles appears.
If it seems to be an intoxication, it might be necessary to go to hospital.

Theophylline intoxication will be treated by gastric emptying or by using activated charcoal ; sedatives (diazepam, for example, 5-10 mg in I.V. (children 0.1 to 0.2 mg/kg in intravenous injection) will be administered in case of convulsions ; oxygenation, keeping of blood pressure, treatment of dehydration(keeping of the hydroelectrolytic balance), hemoperfusion with resins.

A hemoperfusion is necessary if theophylline levels are above :

- 40 to 60 mg/ml in a patient already treated,
- 80 mg/ml in a non treated patient,
- 50 mg/ml in a patient above 60 years old or in case of cardiac or hepatic failure.

A hemodialysis is as efficient as a hemoperfusion.

UNDESIRED EFFECTS

Those effects are often due to overdose and can be the following :

- gastrointestinal troubles : nausea, stomach pain, vomiting, diarrhea, absence of appetite,blood vomiting, peptic and esophageal ulcer ;troubles of the central nervous system : insomnia, nervousness,
- headaches, irritability, tremor, convulsions ;
- endocrinal/metabolic troubles : hypokalemia, hyperglycemia, hypophosphatemia, hypomagnesemia, secretion of antidiuretic hormones, lipidic abnormalities, porphyria ;
- cardio-vascular troubles: rythmic troubles, hypotension or hypertension, palpitations, red spots ;
- respiratory troubles: breath acceleration, breath stopping, respiratory alcalosis potential allergic reaction: urticaria, pruritus with thrombocytopenia and bleeding tendencies.

Less often, contact dermatitis, exfoliative erythrodermia with bronchospasm.

If you notice undesired effects that are not mentioned in this leaflet, please inform your physician or pharmacist.

STORAGE

XANTHIUM should be stored at temperature below 25°C.
Do not use beyond the expiry date indicated on the sales pack.
Example : Exp 08/2002 means that the expiry date is 1st August 2002.
Keep out of the reach of children

DATE OF THE LAST UPDATE OF THE LEAFLET

2nd May 2002.