014533-02

“理奧” 必瑞錠

Burinex® Tablets 1 mg

衛署藥輸字第 005176 號

【成　　份】每錠含Bumetanide 1mg

【性　　質】“理奧” 必瑞錠是一種高限能之利尿劑，作用快，而且作用時間短，口服幾乎全部被吸收，30分鐘內發生利尿作用，1-2小時內達高峰療效，口服1mg之劑量，其利尿作用3小時內完成，因其作用短，故不會影響病人的日常生活，並可依據病人的需要間而服藥。
本品之利尿作用與劑量多寡有關。某些病人使用低劑量不會發生反應，但對高劑量則有反應。"理奧"必瑞主要作用於亨利氏踦的上升支，於近曲細尿管亦有作用。

【適 應 症】水腫、利尿
本藥限由醫師處方使用

【用法、用量】每日一錠。
於反拗(refractory)病人可逐漸增加劑量直至獲得滿意的效果。極少數病人每天須要超過4mg，高劑量之治療應考慮每天服用2次。
小孩：每天每公斤體重0.03--0.06mg。
老年人：依據病人的反應而調整劑量，某些病人每天0.5mg即夠。

【禁 忌 症】任何顯著的增加血尿素或尿少症或嚴重進行性腎疾病病人於治療期間發生無尿症應停止使用。
肝昏迷病人應禁用，嚴重電解質缺乏之病人應特別注意。
因本品可減少鋰之清除力而導致高鋰血清濃度，故不可與鋰鹽一起給藥。

【注意事項】本品與其他利尿劑一樣，會引起電解質障礙。肝硬化和服用digitalis的病人應特別注意低鉀血症之發生。故需定期控制人之血清電解質。糖尿病和疑有潛在性糖尿病人亦應定期控制尿和血糖，本品可加強抗高血壓藥物之作用。
孕婦：雖然於動物尚未發現致畸形之作用，懷孕首三個月仍應避免使用。

【副 作 用】副作用少，長期使用可能會引起電解質平衡之改變而形成低鉀血症和低氯鹼血症。此種情況下可補充氯化鉀。某些病人被發現有無微狀的高尿酸血症。嚴重慢性腎功能衰竭病人之加強治療可能引起肌肉痙攣或疼痛，一但停藥即可消失。
極少數病例有皮膚疹、顆粒性白血球缺症、血小板減少及腹部不適之報告。耳毒性非常少見。

【過量之處理】恢復血液溶積，維持血壓和改正電解質障礙。

【包　　裝】錠劑：2--1000 錠盒裝。

國外許可證持有者及產品釋出廠：LEO Pharmaceutical Products
地　址：55 Industriparken DK-2750 Ballerup, Denmark
製造廠：Laboratoires LEO, S.A
廠　址：39 Route de Chartres, F-28500 Vernouillet, France
藥　商：禾利行股份有限公司
地　址：台北市敦化北路311號

Overseas license holder and site of batch release:
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LEO

Burinex®

Short-acting diuretic

TABLETS:
Bumetanide 1 mg.

PROPERTIES:
Burinex® is a potent high-ceiling diuretic with a rapid onset and a short duration of action. After oral administration, Burinex® is almost totally absorbed and the diuresis begins within 30 minutes with a peak effect between 1 and 2 hours. After a dose of 1 mg the diuretic effect is virtually complete in 3 hours. This short action minimizes disturbances in the patient's daily routine and allows an individual timing of the diuresis according to the needs of the patient.
Burinex® has been shown to exert its major effect in the ascending limb of the loop of Henle, but it may also have an additional action in the proximal tubule.
Clinical investigations have shown that Burinex® is reliably effective and well tolerated.

INDICATIONS:
Burinex® is indicated whenever diuretic therapy is required in the treatment of oedema e.g. associated with congestive heart failure, cirrhosis of the liver, renal diseases including the nephrotic syndrome. Acute pulmonary oedema, drug-induced fluid retention, and drug poisoning that can be treated by forced diuresis. Hypertension.

DOSAGE:
Orally: 1 mg daily.
In refractory cases the dose can be increased gradually till a satisfactory response has been obtained. Rarely will it be necessary to exceed a dose of 4 mg daily.
In high dose therapy consideration should be given to a twice daily dosing.
Children: The dose is calculated on the basis of 0.03–0.06 mg/kg daily.
Elderly: Adjust dosage according to response; a dose of 0.5 mg daily may be sufficient in some elderly patients.

CONTRA-INDICATIONS:
Although Burinex® can be used to induce diuresis in renal insufficiency, any marked increase in blood urea or the development of oliguria or anuria during treatment of severe progressing renal disease are indications for stopping treatment with Burinex®. Burinex® is contraindicated in hepatic coma and care should be taken in states of severe electrolyte depletion.
As with other diuretics, Burinex® should not be administered concurrently with lithium salts. Diuretics can reduce lithium clearance resulting in high serum levels of lithium.

PRECAUTIONS:
The precautions to be taken with Burinex® – as with other diuretics – are mainly those associated with electrolyte disturbances. Patients with hepatic cirrhosis and patients on digitalis therapy are particularly susceptible to changes in the serum potassium levels. Periodic control of serum electrolytes is, therefore, advisable. Similarly, periodic control of urine and blood glucose is advisable in patients with diabetes and patients suspected of latent diabetes.
Burinex® may potentiate the effect of antihypertensive drugs.

PREGNANCY:
The general principle that drug treatment should be avoided in the 1st trimester of pregnancy is also valid for Burinex® although no teratogenic effects have been observed in animal experiments.

SIDE-EFFECTS:
The incidence of reported side-effects is low. Long-term treatment may provoke changes of the electrolyte balance in the form of hypokalaemia and hypo-chloraemic alkalosis. In such cases supplementary potassium chloride is recommended. Asymptomatic hyperuricaemia has been observed in some patients. Occasionally, intensive therapy in patients with severe chronic renal failure has been associated with muscular cramps or pain, which have subsided on withdrawal of therapy. Skin rashes, agranulocytosis or thrombocytopenia, and abdominal discomfort has been recorded in a few cases. The ototoxic potential is very low.

OVERDOSAGE:
General measures should be taken to restore blood volume, maintain blood pressure and correct electrolyte disturbance.

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