

SOTAL Tablets



Composition:

- Each **Sotal 80** tablet contains 80mg Sotalol Hydrochloride.
- Each **Sotal 120** tablet contains 120mg Sotalol Hydrochloride.

Properties:

Sotal is a non-cardioselective beta-blocker. It is reported to lack both intrinsic sympathomimetic and membrane-stabilising properties so it's anti-arrhythmic drug which has the properties of both class II (Adrenoceptor B blocker) and class III (lengthens the duration of the cardio action potency).

Pharmacokinetics:

- Sotalol Hydrochloride is completely absorbed from the gastro-intestinal tract. Peak plasma concentrations are obtained about 2 to 4 hours after a dose. It has low lipid solubility, very little is metabolised and it is excreted unchanged in urine.
- Sotalol Hydrochloride binds to plasma proteins in small percentages, passing the then dispersing into mother's milk.

Indications:

- **Sotal** is used in the management of ventricular and supraventricular arrhythmias (ventricular tachyarrhythmias, non-sustained ventricular tachyarrhythmias).
- Prophylaxis of paroxysmal atrial tachycardia, fibrillation, paroxysmal supraventricular tachycardia after cardiac surgery, and maintenance of sinus rhythm following cardioversion.
- In treatment of hypertension and angina pectoris and in thyrocele after your doctor consultation.

Contra-Indications:

- Patients with bronchospasm or asthma.
- Sinus bradycardia.
- Atrioventricular block (second or third degree).
- Patients with renal failure or Patients with congestive heart failure can't be controlled.
- Patients with asymptomatic ventricular arrhythmias.
- Congenital or acquired long QT syndrome (torsades de pointes).
- Pregnancy.
- Sensitivity to Sotalol Hydrochloride.

Side effects:

Bradycardia, bronchospasm, fatigue, coldness of the extremities, myasthenia, Hypotension, dizziness, sleep disturbances, nausea, skin rash and pruritus, rarely agranulocytosis, and it has arrhythmogenic effect.

Precautions:

- The dose may need to be reduced in patients with renal dysfunction.
- Patients on long-term treatment with **Sotal** should have their medication discontinued gradually over a period of 1-2 weeks.
- Serum electrolyte concentrations should be monitored before and during treatment with **Sotal**.
- The QT interval should be monitored and extreme caution is required if the QT interval exceeds 0.5 second, and **Sotal** should be discontinued or the dose reduced if the QT interval exceeds 0.55 second.
- It must be taken with caution by patients with: il sinus node syndrome, new cardiac infarction, thyroid gland disturbances, and diabetes.
- It's not recommended for nursing-mothers for it has been reported to be present in human milk.

Drug Interactions:

- **Sotal** should not be given concurrently with other drugs that prolong the QT interval due to the increased risk of precipitating ventricular arrhythmias.
- **Sotal** should not be given with amiodarone, disopyramide, procainamide, quinidine, phenothiazine, astemizole, and erythromycin.
- **Sotal** may potentiate bradycardia due to digoxin.
- **Sotal** should not be given with drugs that cause electrolyte disturbances such as diuretics.

Dosage & Administration:

- Initiation of **Sotal** treatment should be in hospital with suitable monitoring facilities.
- The QT interval is monitored before the treatment and whenever the dosage is adjusted.
- Dosage to be determined according to patient's response.
- Dosage is increased gradually allowing two or three days between dosing increments.
- Suggested initial dose is 80 mg daily as a single dose or in two divided doses.
- Most patients respond to doses of 240 mg to 320 mg daily. (Usually given in two divided doses 120-160mg).
- Some patients may require doses as high as 460 mg.
- Dose of 80-120 mg daily in treatment of hypertension.

STORAGE CONDITIONS:

- Store at room temperature, between (15 - 30) °C.
- Keep away from light and moisture
- Keep out of reach of children.

Presentation:

- 2 blisters, each one contains 10 **white** tablets **Sotal 80** / carton box.
- 2 blisters, each one contains 10 **pink** tablets **Sotal 120** / carton box.

* THIS IS A MEDICAMENT *

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

(Council of Arab Ministers)

(Union of Arab Pharmacists)

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