

Dotfix™

Dotinurad INN

Composition

Dotfix™ 1 Tablet: Each tablet contains Dotinurad INN 1 mg.

Dotfix™ 2 Tablet: Each tablet contains Dotinurad INN 2 mg.

Description

Dotinurad is a selective urate reabsorption inhibitor (SURI) which potently inhibits urate transporter-1 in the apical surface of renal proximal tubular cells. It has been approved for the treatment of gout and hyperuricemia.

Mode of action

Dotinurad, a novel selective urate reabsorption inhibitor (SURI), reduces serum uric acid levels by selectively inhibiting urate transporter 1 (URAT1), which is expressed on the proximal renal tubules and is responsible for the reabsorption of uric acid.

Indications

Gout and hyperuricemia.

Dosage & Administration

In general, for adults, start with 0.5 mg of the active ingredient at a time once a day. The dosage may be gradually increased according to blood uric acid level as needed. It may be increased to 1 mg at a time once a day after 2 weeks, and then 2 mg at a time once a day as a maintenance dose after 6 weeks. The dosage may be adjusted according to condition. However, it should not exceed 4 mg at a time once a day.

Contraindications

Hypersensitivity to any component of dotinurad.

Side Effects

Gouty arthritis, arthritis, and discomfort in limbs.

Precautions

Gouty arthritis: Dotinurad is a uric acid lowering drug. By lowering the blood uric acid level at the onset of gouty arthritis (gouty attack), it may exacerbate gouty arthritis. If gouty arthritis (gouty attack) is observed before administration of the drug, the administration should not be started until the symptoms subside. If gouty arthritis occurs during the administration of drug, the administration

should be continued without changing the dose of this drug. Colchicine, NSAID, corticosteroids, etc. may be administered depending on the symptoms.

Patients with Urolithiasis: Do not administer unless it is judged to be unavoidable for treatment. The pharmacological action of this drug may exacerbate the symptoms of urinary calculi due to increased urinary excretion.

Patients with renal impairment: As the drug acts in the renal proximal tubule, its efficacy may be reduced depending on the degree of renal dysfunction. In particular, administration of this drug should be avoided in patients with oliguria or anuria, as its efficacy cannot be expected.

Patients with hepatic impairment: Careful follow-up should be performed.

Use In Pregnancy & lactation

May need to be careful when using this medicine.

Drug-drug interaction

Pyrazinamide: The effect of this drug may be weakened as Pyrazinamide is known to suppress uric acid secretion in renal tubules and may antagonize the promotion of uric acid excretion by the drug.

Salicylic acid preparation (Aspirin): Salicylic acid preparations are known to suppress uric acid excretion and may antagonize the promotion of uric acid excretion by this drug.

Storage

Store below 30° C. Protect from light and moisture. Keep out of the reach of children.

Packaging

Dotfix™ 1 Tablet: Each box contains 3x10's tablets in blister pack.

Dotfix™ 2 Tablet: Each box contains 2x10's tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS PLC.
BANGLADESH