Also Avail:





Tyrael®-Ex

Each Tablet contains:

Glimepiride and Metformin Hydrochloride Extended Release Tablets

COMPOSITION:

Tyrael-Ex 501

Each tablet contains

Glimepiride......1 mg

Metformin Hydrochloride extended-release......500 mg

Tyrael-Ex 502

Each tablet contains

Glimepiride......2 mg

Metformin Hydrochloride extended-release500 mg

Tyrael-Ex FORTE 1

Each uncoated inlay tablet contains

Glimepiride......1 mg

Metformin Hydrochloride extended-release......1000 mg

Tyrael-Ex FORTE 2

Each uncoated inlay tablet contains

Glimepiride......2 mg

Metformin Hydrochloride extended-release......1000 mg

INDICATIONS:

Tyrael-Ex is indicated as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes who are already treated with a combination of glimepiride and metformin or whose diabetes is not adequately controlled with metformin alone, or for those patients who have initially responded to glimepiride alone and require additional glycaemic control.

DOSAGE AND ADMINISTRATION:

General

Dosage should be individualized on the basis of both effectiveness and tolerance. The combination should be given once daily with meals and should be started at a low dose. The initial recommended dose is one tablet once daily with breakfast or first main meal of the day.





Tyrael®-Ex

Starting dose for patients inadequately controlled on metformin monotherapy

Based on the usual starting dose of glimepiride (1-2 mg daily), Tyrael-Ex 501 or Tyrael-Ex 502 may be initiated once daily, and gradually titrated after assessing adequacy of therapeutic response.

Starting dose for patients who initially responded to glimepiride monotherapy and require additional glycaemic control

Based on the usual starting doses of metformin extended release (500 mg once daily), Tyrael-Ex 501 or Tyrael-Ex 502 may be initiated once daily, and gradually titrated after assessing adequacy of therapeutic response.

Starting dose for patients switching from combination therapy of glimepiride plus metformin as separate tablets

Tyrael-Ex 501 or Tyrael-Ex 502 may be initiated based on the dose of glimepirde and metformin already being taken.

In case of inadequate glycaemic control with above mentioned regimes, consider one tablet of Tyrael-Ex FORTE 1 or 2 .

Maximum Recommended Dose

The maximum recommended dose for glimiperide is 8 mg daily. The maximum recommended daily dose for metformin extended release is 2000 mg in adults.

CONTRAINDICATIONS:

- 1. Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ³ 1.5 mg/dL [males], ³ 1.4 mg/dL [females] or abnormal creatinine clearance), which may also result from conditions such as cardiovascular collapse (shock), acute
- myocardial infarction, and septicaemia.
- 2. Congestive heart failure requiring pharmacologic treatment.
- 3. Known hypersensitivity to this product or any of its components.
- 4. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.
- 5. Patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function.





Tyrael®-Ex

PACKAGING INFORMATION:

| Tyrael-Ex 501 | Strip of 10 tablets |
|-------------------|---------------------|
| Tyrael-Ex 502 | Strip of 10 tablets |
| Tyrael-Ex FORTE 1 | Strip of 10 tablets |
| Tyrael-Ex FORTE 2 | Strip of 10 tablets |