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گولیاں

پائیوفِٹ®

پائیوگلیٹازون ہائیڈروکلورائیڈ — ۱۵ ملی گرام، ۳۰ ملی گرام اور ۴۵ ملی گرام

شوگر کے علاج کے لیے

خوراک:

پائیوفِٹ کی ابتدائی تجویز کردہ خوراک ۱۵ ملی گرام سے ۳۰ ملی گرام روزانہ ایک مرتبہ ہے۔ جن مریضوں میں پائیوفِٹ کی ابتدائی خوراک سے واضح افاقہ محسوس نہ ہو ان میں خوراک ۴۵ ملی گرام تک بڑھائی جا سکتی ہے۔

ہدایات:

* دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* دوا کو ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیکنگ:

پائیوفِٹ ۱۵ ملی گرام گولیاں (۲×۱۰) ایلو-ایلو بلسٹر پیک میں دستیاب ہیں۔
پائیوفِٹ ۳۰ ملی گرام گولیاں (۲×۱۰) ایلو-ایلو بلسٹر پیک میں دستیاب ہیں۔
پائیوفِٹ ۴۵ ملی گرام گولیاں (۲×۱۰) ایلو-ایلو بلسٹر پیک میں دستیاب ہیں۔

Manufactured by
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

PioFit®

Tablets

Pioglitazone Hydrochloride 15mg, 30mg & 45mg

Anti-Diabetic

COMPOSITION:
Each tablet contains:
Pioglitazone (as hydrochloride) Sch. Specs. .... 15 mg.
Pioglitazone (as hydrochloride) Sch. Specs. .... 30 mg.
Pioglitazone (as hydrochloride) Sch. Specs. .... 45 mg.

CLINICAL PHARMACOLOGY:
MECHANISM OF ACTION:
Pioglitazone hydrochloride is an oral antidiabetic agent that acts primarily by decreasing insulin resistance. It is used in the management of type 2 diabetes mellitus (also known as non-insulin-dependent diabetes mellitus or adult-onset diabetes).
Pioglitazone is a thiazolidinedione antidiabetic agent that depends on the presence of insulin for its mechanism of action. Pioglitazone decreases insulin resistance in the periphery and in the liver resulting in increased insulin-dependent glucose disposal and decreased hepatic glucose output. Unlike sulfonylureas, pioglitazone is not an insulin secretagogue. Pioglitazone is a highly selective and potent agonist for the peroxisome proliferator-activated receptor gamma (PPARg). PPAR receptors are found in tissues important for insulin action such as adipose tissue, skeletal muscle, and liver. Activation of PPARg nuclear receptors modulates the transcription of a number of insulin responsive genes involved in the control of glucose and lipid metabolism.

PHARMACOKINETICS:
Absorption: Following oral administration, in the fasting state, pioglitazone is first measurable in serum within 30 minutes, with peak concentrations observed within 2 hours. Food slightly delays the time to peak serum concentration to 3 to 4 hours, but does not alter the extent of absorption.
Distribution: The mean apparent volume of distribution (Vd/F) of pioglitazone following single dose administration is 0.63 ± 0.41 (mean ± SD) L/kg of body weight. Pioglitazone is extensively protein bound (>99%) in human serum, principally to serum albumin. Pioglitazone also binds to other serum proteins, but with lower affinity. Metabolites M-III and M-IV also are extensively bound (>98%) to serum albumin.
Metabolism: Pioglitazone is extensively metabolized by hydroxylation and oxidation; the metabolites also partly convert to glucuronide or sulphate conjugates. Metabolites, M-III (keto derivative of pioglitazone) and M-IV (hydroxy derivatives of pioglitazone) are the principal drug-related species found in human serum following multiple dosing. At steady-state, in both healthy volunteers and in patients with type 2 diabetes, pioglitazone comprises approximately 30% to 50% of the total peak serum concentrations and 20% to 25% of the total AUC.
Excretion and Elimination: Following oral administration, approximately 15% to 30% of the pioglitazone dose is recovered in the urine. Renal elimination of pioglitazone is negligible, and the drug is excreted primarily as metabolites ...

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INDICATIONS:
Piofit is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes (non-insulin-dependent diabetes mellitus, NIDDM). **Piofit** is indicated for monotherapy and is also indicated for use in combination with a sulfonylurea, metformin or insulin when diet and exercise plus the single agent does not result in adequate glycemic control. Management of type 2 diabetes should also include nutritional counseling, weight reduction as needed and exercise. These efforts are important not only in the primary treatment of type 2 diabetes, but also to maintain the efficacy of drug therapy.

DOSAGE & ADMINISTRATION:
Piofit tablets are taken once daily with or without meals and should be taken about the same time everyday. However, skipping meals while taking this medicine is not advised. This can cause hypoglycemia.

Monotherapy: Piofit monotherapy in patients not adequately controlled with diet and exercise may be initiated at 15mg or 30mg once daily. For patients who respond inadequately to the initial dose of **Piofit**, the dose can be increased in increments up to 45mg once daily. For patients not responding adequately to monotherapy, combination therapy should be considered.

Combination therapy:
Sulfonylurea: Piofit in combination with a sulfonylurea may be initiated at 15mg or 30mg once daily. The current sulfonylurea dose can be continued upon initiation of piofit therapy. If patients report hypoglycemia, the dose of sulfonylurea should be decreased.

Metformin: Piofit in combination with metformin may be initiated at 15mg or 30mg once daily. The current metformin dose can be continued upon initiation of piofit therapy. It is unlikely that the dose of metformin will require adjustment due to hypoglycemia during combination therapy with **Piofit**.

Insulin: Piofit in combination with insulin may be initiated at 15mg or 30mg once daily. The current insulin dose can be continued upon initiation of **Piofit** therapy. In patients receiving **Piofit** and insulin, the insulin dose can be decreased by 10% to 25% if the patient reports hypoglycemia or if plasma glucose concentrations decrease to less than 100 mg/dL. Further adjustments should be individualized based on glucose-lowering response.

Maximum recommended dose: The dose of **Piofit** should not exceed 45mg once daily in monotherapy or in combination with sulfonylurea, metformin or insulin.

Hepatic Impaired Patients:
The intrinsic clearance of pioglitazone may be reduced in patients with hepatic disease. Dosage should start at 15mg and be increased cautiously.

- **Ovulation:** Therapy with pioglitazone, like other thiazolidinediones, may result in ovulation in some premenopausal anovulatory women. As a result, these patients may be at an increased risk for pregnancy while taking pioglitazone. Thus, adequate contraception in premenopausal women should be recommended.
- **Hepatic effects:** Therapy with pioglitazone should not be initiated if the patient exhibits clinical evidence of active liver disease or increased serum transaminases levels (ALT, alanine aminotransferase greater than 2.5 times the upper limit of normal) at start of therapy. Liver enzyme monitoring is recommended in all patients prior to initiation of therapy with pioglitazone and periodically thereafter.

- PREGNANCY:
Pioglitazone should be used in pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

- NURSING MOTHERS:
Pioglitazone should not be administered to a nursing woman.

- PEDIATRIC USE:
Safety and effectiveness in pediatric patients have not been established.

DRUG INTERACTIONS:
Ketoconazole: Ketoconazole inhibited up to 85% of hepatic pioglitazone metabolism in vitro at a concentration equal molar to pioglitazone. Pending the availability of additional data, patients receiving ketoconazole concomitantly with pioglitazone should be evaluated more frequently with respect to glycemic control.
Oral contraceptives: Administration of thiazolidinedione with an oral contraceptive containing ethinyl estradiol and norethindrone reduced the plasma concentrations of both hormones by approximately 30%, which could result in loss of contraception. Therefore, additional caution regarding contraception should be exercised in patients receiving pioglitazone and an oral contraceptive.
Glipizide: Co-administration of pioglitazone and 5mg glipizide administered orally once daily for 7 days did not alter the steady state pharmacokinetics of glipizide.
Warfarin: Co-administration of pioglitazone for 7 days with warfarin did not alter the steady state pharmacokinetics of warfarin. Pioglitazone has no clinically significant effect on prothrombin time when administered to patients receiving chronic warfarin therapy.
Digoxin: Co-administration of pioglitazone and 0.25mg digoxin administered orally once daily for 7 days did not alter the steady state pharmacokinetics of digoxin.
Metformin: Co-administration of a single dose of metformin (1000mg) and pioglitazone after 7 days of pioglitazone did not alter the pharmacokinetics of the single dose of metformin.

SIDE EFFECTS:
The adverse effects reported included upper respiratory tract infection, headache, sinusitis, myalgia, tooth disorder, diabetes mellitus aggravated and pharyngitis. There was a tendency to a modest weight gain. Some people may also experience anaemia and fluid retention. These side effects do not happen in all people.

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