

PRODUCT NAME	Pioglitazone and Metformin Hydrochloride Tablets	COUNTRY : US	LOCATION : Indrad
ITEM / PACK	Outsert	NO. OF COLORS: 1	REMARK :
DESIGN STYLE	Front Side	PANTONE SHADE NOS.:	SUBSTRATE : 40 gm/2 Buble Paper
CODE	8099813	Black	Activities Department Name Signature
DIMENSIONS (MM)	640 x 510		Prepared By Pkg. Dev.
ART WORK STYLE	S/S		Reviewed By Pkg. Dev.
DATE	07-03-2025	Font size 6 pt_Med 10 pt	Approved By Quality

Supersedes AW No.:

V. No. : 01

Note: Pharma code/ Bar code and adjacent text must be visible on folded leaflet. These details can be moved by printed to arrange pharma code/ Bar code and adjacent text visible on folded leaflet.

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#### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PIOGLITAZONE AND METFORMIN HYDROCHLORIDE TABLETS safely and effectively. See full prescribing information for PIOGLITAZONE AND METFORMIN HYDROCHLORIDE TABLETS.

#### PIOGLITAZONE AND METFORMIN HYDROCHLORIDE TABLETS, for oral use

U.S. Approval: 2005

#### WARNING: CONGESTIVE HEART FAILURE AND LACTIC ACIDOSIS

See full prescribing information for complete boxed warning.

- Congestive Heart Failure:**
  - Thiazolidinediones, including pioglitazone, which is a component of pioglitazone and metformin hydrochloride tablets, cause or exacerbate congestive heart failure in some patients. (5.1)
  - After initiation of pioglitazone and metformin hydrochloride tablets, and after dose increases, monitor patients carefully for signs and symptoms of heart failure (e.g., excessive, rapid weight gain, dyspnea, and/or edema). If congestive heart failure develops while taking pioglitazone and metformin hydrochloride tablets, consider discontinuation of pioglitazone and metformin hydrochloride tablets. (4)
  - Pioglitazone and metformin hydrochloride tablets are not recommended in patients with symptomatic heart failure. (5.1)
- Initiation of pioglitazone and metformin hydrochloride tablets in patients with established New York Heart Association (NYHA) Class III or IV heart failure is contraindicated. (4.5, 4.1)

#### Lactic Acidosis

- Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradycardia. Symptoms included elevated lactate, hypothermia, cyanosis, and anion gap metabolic acidosis. Laboratory abnormalities included elevated blood urea nitrogen, lactic acidosis, increased lactate/pyruvate ratio, and metformin plasma levels generally greater than 5 mg/mL. (5.2)
- Risk factors for metformin-related lactic acidosis include renal impairment, concomitant use of certain drugs, age 65 years or older, radiological studies with contrast, surgery and other procedures, hepatic dysfunction, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. (5.2)
- If lactic acidosis is suspected, discontinue pioglitazone and metformin hydrochloride tablets and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. (5.2)

- Monitor patients for adverse events related to fluid retention after initiation and dose increases. (2.4)
- Pioglitazone and metformin hydrochloride tablets may need to be discontinued at one end, or prior to, indicated contrast imaging procedures. (2.6)

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#### ADVERSE REACTIONS

- Most common adverse reactions (≥5%) are upper respiratory tract infection, edema, diarrhea, headache and weight gain. (6.1)**
- Other adverse reactions (≥1%) include:**
  - Headache
  - Diarrhea
  - Upper respiratory tract infection
  - Edema
  - Weight gain
  - Flatulence
  - Constipation
  - Abdominal pain
  - Back pain
  - Indigestion
  - Nausea/vomiting
  - Fatigue
  - Dizziness
  - Headache
  - Diarrhea
  - Upper respiratory tract infection
  - Edema
  - Weight gain
  - Flatulence
  - Constipation
  - Abdominal pain
  - Back pain
  - Indigestion
  - Nausea/vomiting
  - Fatigue
  - Dizziness

#### INDICATIONS AND USAGE

- Pioglitazone and metformin hydrochloride tablets are a combination of pioglitazone, a thiazolidinedione agonist of peroxisome proliferator receptor gamma, and metformin hydrochloride (HCl), a biguanide. Pioglitazone and metformin hydrochloride tablets improve glycemic control in adults with type 2 diabetes mellitus. (1)
- Limitations of Use:
  - Not recommended for treatment of type 1 diabetes or diabetic ketoacidosis. (1)
- Contraindications:**
  - Obtain liver tests before initiation. If abnormal, use caution when treating with pioglitazone and metformin hydrochloride tablets, investigate the probable cause, treat if appropriate, and follow accordingly. (2.1)
  - Take orally with meals to reduce gastrointestinal adverse effects. (2.2)
  - Individualize the starting dose based on the patient's current regimen and titrate the dosage gradually, as needed after additional recommendations for use in patients with renal impairment. (2.3)
  - Coadministration with Strong CYP2C8 Inhibitors (2.4)
  - Coadministration with Strong CYP2C8 Inducers (2.5)
- Warnings and Precautions:**
  - Congestive Heart Failure (5.1)
  - Lactic Acidosis (5.2)
  - Weight Gain (5.3)
  - Diarrhea (5.4)
  - Upper Respiratory Tract Infection (5.5)
  - Edema (5.6)
  - Weight Gain (5.7)
  - Flatulence (5.8)
  - Constipation (5.9)
  - Abdominal Pain (5.10)
  - Back Pain (5.11)
  - Indigestion (5.12)
  - Nausea/Vomiting (5.13)
  - Fatigue (5.14)
  - Dizziness (5.15)
  - Headache (5.16)
  - Diarrhea (5.17)
  - Upper Respiratory Tract Infection (5.18)
  - Edema (5.19)
  - Weight Gain (5.20)
  - Flatulence (5.21)
  - Constipation (5.22)
  - Abdominal Pain (5.23)
  - Back Pain (5.24)
  - Indigestion (5.25)
  - Nausea/Vomiting (5.26)
  - Fatigue (5.27)
  - Dizziness (5.28)
  - Headache (5.29)
  - Diarrhea (5.30)
  - Upper Respiratory Tract Infection (5.31)
  - Edema (5.32)
  - Weight Gain (5.33)
  - Flatulence (5.34)
  - Constipation (5.35)
  - Abdominal Pain (5.36)
  - Back Pain (5.37)
  - Indigestion (5.38)
  - Nausea/Vomiting (5.39)
  - Fatigue (5.40)
  - Dizziness (5.41)
  - Headache (5.42)
  - Diarrhea (5.43)
  - Upper Respiratory Tract Infection (5.44)
  - Edema (5.45)
  - Weight Gain (5.46)
  - Flatulence (5.47)
  - Constipation (5.48)
  - Abdominal Pain (5.49)
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  - Indigestion (5.51)
  - Nausea/Vomiting (5.52)
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  - Dizziness (5.67)
  - Headache (5.68)
  - Diarrhea (5.69)
  - Upper Respiratory Tract Infection (5.70)
  - Edema (5.71)
  - Weight Gain (5.72)
  - Flatulence (5.73)
  - Constipation (5.74)
  - Abdominal Pain (5.75)
  - Back Pain (5.76)
  - Indigestion (5.77)
  - Nausea/Vomiting (5.78)
  - Fatigue (5.79)
  - Dizziness (5.80)
  - Headache (5.81)
  - Diarrhea (5.82)
  - Upper Respiratory Tract Infection (5.83)
  - Edema (5.84)
  - Weight Gain (5.85)
  - Flatulence (5.86)
  - Constipation (5.87)
  - Abdominal Pain (5.88)
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  - Weight Gain (5.98)
  - Flatulence (5.99)
  - Constipation (6.00)
  - Abdominal Pain (6.01)
  - Back Pain (6.02)
  - Indigestion (6.03)
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  - Fatigue (6.05)
  - Dizziness (6.06)
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  - Indigestion (10.19)
  - Nausea/Vomiting (10.20)
  - Fatigue (10.21)
  - Dizziness (10.22)
  - Headache (10.23)
  - Diarrhea (10.24)
  - Upper Respiratory Tract Infection (10.25)
  - Edema (10.26)
  - Weight Gain (10.27)
  - Flatulence (10.28)
  - Constipation (10.29)
  - Abdominal Pain (10.30)
  - Back Pain (10.31)
  - Indigestion (10.32)
  - Nausea/Vomiting (10.33)
  - Fatigue (10.34)
  - Dizziness (10.35)
  - Headache (10.36)
  - Diarrhea (10.37)
  - Upper Respiratory Tract Infection (10.38)
  - Edema (10.39)
  - Weight Gain (10.40)
  - Flatulence (10.41)
  - Constipation (10.42)
  - Abdominal Pain (10.43)
  - Back Pain (10.44)
  - Indigestion (10.45)
  - Nausea/Vomiting (10.46)
  - Fatigue (10.47)
  - Dizziness (10.48)
  - Headache (10.49)
  - Diarrhea (10.50)
  - Upper Respiratory Tract Infection (10.51)
  - Edema (10.52)
  - Weight Gain (10.53)
  - Flatulence (10.54)
  - Constipation (10.55)
  - Abdominal Pain (10.56)
  - Back Pain (10.57)
  - Indigestion (10.58)
  - Nausea/Vomiting (10.59)
  - Fatigue (10.60)
  - Dizziness (10.61)
  - Headache (10.62)
  - Diarrhea (10.63)
  - Upper Respiratory Tract Infection (10.64)
  - Edema (10.65)
  - Weight Gain (10.66)
  - Flatulence (10.67)
  - Constipation (10.68)
  - Abdominal Pain (10.69)
  - Back Pain (10.70)
  - Indigestion (10.71)
  - Nausea/Vomiting (10.72)
  - Fatigue (10.73)
  - Dizziness (10.74)
  - Headache (10.75)
  - Diarrhea (10.76)
  - Upper Respiratory Tract Infection (10.77)
  - Edema (10.78)
  - Weight Gain (10.79)
  - Flatulence (10.80)
  - Constipation (10.81)
  - Abdominal Pain (10.82)
  - Back Pain (10.83)
  - Indigestion (10.84)
  - Nausea/Vomiting (10.85)
  - Fatigue (10.86)
  - Dizziness (10.87)
  - Headache (10.88)
  - Diarrhea (10.89)
  - Upper Respiratory Tract Infection (10.90)
  - Edema (10.91)
  - Weight Gain (10.92)
  - Flatulence (10.93)
  - Constipation (10.94)
  - Abdominal Pain (10.95)
  - Back Pain (10.96)
  - Indigestion (10.97)
  - Nausea/Vomiting (10.98)
  - Fatigue (10.99)
  - Dizziness (11.00)
  - Headache (11.01)
  - Diarrhea (11.02)
  - Upper Respiratory Tract Infection (11.03)
  - Edema (11.04)
  - Weight Gain (11.05)
  - Flatulence (11.06)
  - Constipation (11.07)
  - Abdominal Pain (11.08)
  - Back Pain (11.09)
  - Indigestion (11.10)
  - Nausea/Vomiting (11.11)
  - Fatigue (11.12)
  - Dizziness (11.13)
  - Headache (11.14)
  - Diarrhea (11.15)
  - Upper Respiratory Tract Infection (11.16)
  - Edema (11.17)
  - Weight Gain (11.18)
  - Flatulence (11.19)
  - Constipation (11.20)
  - Abdominal Pain (11.21)
  - Back Pain (11.22)
  - Indigestion (11.23)
  - Nausea/Vomiting (11.24)
  - Fatigue (11.25)
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  - Dizziness (11.52)
  - Headache (11.53)
  - Diarrhea (11.54)
  - Upper Respiratory Tract Infection (11.55)
  - Edema (11.56)
  - Weight Gain (11.57

