

NEXTFOR™

(USP Specification)

Metformin HCl

(USP Specification)

250mg & 500mg Film Coated Tablets

COMPOSITION

NEXTFOR 250mg Tablets: Each film coated tablet contains:

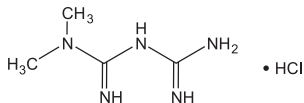
Metformin HCl 250mg
(USP Specification)

NEXTFOR 500mg Tablets: Each film coated tablet contains:

Metformin HCl 500mg
(USP Specification)

DESCRIPTION

NEXTFOR (Metformin HCl) is the first-line medication for the treatment of type 2 diabetes, particularly in people who are overweight. It is also used in the treatment of polycystic ovary syndrome. It is not associated with weight gain and is taken by mouth. Molecular Formula is $C_4H_{11}N_5$ and has structural formula:



Metformin Hydrochloride

CLINICAL PARTICULARS

Mechanism of Action:

NEXTFOR (Metformin HCl) acts as a metabolic inhibitor and alters both whole-body and cellular energy metabolism. It is primarily used in patients with type 2 diabetes mellitus, and its main mechanism of action in this disease setting is inhibition of hepatic gluconeogenesis.

Pharmacokinetics:

Absorption:

NEXTFOR (Metformin HCl) has an absolute oral bioavailability of 40 to 60%, and gastrointestinal absorption is apparently complete within 6 hours of ingestion.

Distribution:

The drug is widely distributed into body tissues including the intestine, liver, and kidney by organic cation transporters. There is a large interindividual variability in **NEXTFOR** (Metformin HCl) pharmacokinetics as measured by differences in trough steady-state **NEXTFOR** (Metformin HCl) plasma concentration ranging from 54 to 4133 ng/ml.

Metabolism:

NEXTFOR (Metformin HCl) is not metabolized.

Excretion:

Excreted unchanged in the urine, with a half-life of ~5 h. The population mean for renal clearance (Cl_r) is 510±120 ml/min. Active tubular secretion in the kidney is the principal route of **NEXTFOR** (Metformin HCl) elimination.

Special Population:

Elderly Patients:

NEXTFOR (Metformin HCl) is an attractive agent to use in older adults due

to a low risk of hypoglycemia. Healthy older adults may be treated similarly as younger adults with initiation of **NEXTFOR** (Metformin HCl) at the time of diabetes diagnosis, even if the presenting A1C is below the individualized medication-treated target.

Hepatic Impairment:

NEXTFOR (Metformin HCl) is not considered intrinsically hepatotoxic. In fact, **NEXTFOR** (Metformin HCl) may be beneficial in patients with nonalcoholic fatty liver disease and chronic hepatitis C. **NEXTFOR** (Metformin HCl) is only contraindicated in patients with advanced cirrhosis because it heightens the risk of developing lactic acidosis

Renal Impairment:

NEXTFOR (Metformin HCl) has traditionally been regarded as contraindicated in chronic kidney disease (CKD), though guidelines in recent years have been relaxed to permit therapy if the glomerular filtration rate (GFR) is > 30 mL/min. The main problem is the perceived risk of lactic acidosis (LA).

THERAPEUTIC INDICATIONS

NEXTFOR (Metformin HCl) is used with a proper diet and exercise program and possibly with other medications to control high blood sugar. It is used in patients with type 2 diabetes. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems.

DOSAGE AND ADMINISTRATION

Metformin HCl decreases the rate of conversion from prediabetes to diabetes. This is true at higher dosage (850 mg twice daily) and lower dosage (250 mg twice or thrice daily).

Adults Dosage Considerations:

Type 2 Diabetes Mellitus

Monotherapy or with sulfonylurea:

Initial dose:

500 mg orally every 12 hours with meals increase every two weeks.

Maintenance dose:

1500-2550 mg/day taken orally divided once every 8-12hr with meal.

Not to exceed 2550 mg/day.

Pediatric Dosage Considerations:

Type 2 Diabetes Mellitus

For 10-16 years:

Initial dose:

500 mg orally every 12 hours with meals.

Maintenance dose:

Titrate once/week by 500 mg; no more than 2000 mg/day in divided doses.

For 17 years of age and older:

Initial dose:

500 mg orally every 12 hours with meals; increase every two weeks.

Maintenance dose:

1500-2550 mg/day orally divided once every 8-12hr with meal.

No more than 2550 mg/day.

SIDE EFFECTS OF METFORMIN

- Physical weakness (asthenia)
- Diarrhea
- Gas (flatulence)
- Symptoms of weakness, muscle pain (myalgia)
- Upper respiratory tract infection
- Low blood sugar (hypoglycemia)
- Abdominal pain (GI complaints), lactic acidosis (rare)
- Low blood levels of vitamin B-12

TOXICITY

NEXTFOR (Metformin HCl) is a biguanide oral hypoglycemic agent used for non-insulin dependent diabetes mellitus (NIDDM). **NEXTFOR** (Metformin HCl) poisoning can cause fatal complications like severe lactic acidosis, hemolytic anemia and pancreatitis. Early diagnosis can result in successful outcome

CONTRAINDICATIONS

- Renal dysfunction
- Congestive cardiac failure needing drug treatment
- Hypersensitivity to **NEXTFOR** (Metformin HCl)
- Acute or chronic metabolic acidosis
- Impaired hepatic function

PREGNANCY

Category A, **NEXTFOR** (Metformin HCl) has a very low risk of birth defects and complications for your baby, making this drug safe to take before and during pregnancy. **NEXTFOR** (Metformin HCl) is also safe to take while breastfeeding your child.

PRECAUTIONS

The very limited amounts of **NEXTFOR** (Metformin HCl) observed in breast milk are highly unlikely to lead to substantial exposure in the breastfed baby. **NEXTFOR** (Metformin HCl) can be considered a safe medication for the treatment of type 2 diabetes in a breastfeeding mother.

DRUG INTERACTIONS

- Acenocoumarin; Paracetamol increases the anticoagulant effect of acenocoumarin.
- Alcohol; Both paracetamol and alcohol can increase the risk of hepatotoxicity.

DISEASE INTERACTION

- Diuretics, such as acetazolamide
- Corticosteroids, such as prednisone
- Blood pressure medication, such as amlodipine (Norvasc)
- Anticonvulsants, such as topiramate (Topamax) and zonisamide (Zonegran)
- Oral contraceptives
- Antipsychotic drugs, such as chlorpromazine

OVERDOSES OF METFORMIN

NEXTFOR (Metformin HCl) overdose associated with lactic acidosis presents with nonspecific symptoms and includes severe nausea, vomiting, diarrhea, epigastric pain, thirstiness, lost appetite, lethargy and hyperpnea. Hypotension, hypothermia, acute renal failure, coma and cardiac arrest also represent significant clinical features.

TREATMENTS OF OVERDOSE

Treatment of **NEXTFOR** (Metformin HCl) poisoning is symptomatic and supportive and there is no antidote available. Typical treatment strategies consist of correcting acidosis with intravenous sodium bicarbonate and decreasing the blood levels of **NEXTFOR** (Metformin HCl).

STORAGE:

Store at 20-25°C. Protect from light and moisture.
(excursions permitted to 15°C to 30°C)

HOW SUPPLIED

NEXTFOR 250mg Tablets: Pack of 100 film coated tablets.

NEXTFOR 500mg Tablets: Pack of 50 film coated tablets.

TO BE SOLD ON THE PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Lactose & Gluten Free

نیکسٹ فور

(میٹ فورمن)

250 ملی گرام اور 500 ملی گرام

فلم کوٹڈ گولیاں

خوراک و ہدایات

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخے کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 25°C-20°C درجہ حرارت پر رکھیں اور روشنی سے محفوظ رکھیں۔

(درجہ حرارت کی حد 15°C سے 30°C ہے)

NEXT
PHARMACEUTICAL

Manufactured by:
NEXT Pharmaceutical Products (Pvt.) Ltd.
Plot no. 44-A&B, Sunder Industrial Estate Lahore-Pakistan