

# Toradolín® Tablet

Ketorolac Tromethamine USP



Non-steroidal anti-inflammatory agent.

## COMPOSITION:

Each film coated tablet contains Ketorolac Tromethamine USP 10 mg.

## CLINICAL PHARMACOLOGY:

TORADOLIN (ketorolac tromethamine) is a non-steroidal anti-inflammatory drug (NSAID) that exhibits analgesic activity mediated by peripheral effects. The mechanism of action of ketorolac, like that of other NSAIDs, is not completely understood, but is believed to be related to prostaglandin synthetase inhibition.

## Pharmacokinetics:

The pharmacokinetics are linear following single and multiple dosing. Steady state plasma levels are attained after one day of Q.I.D. dosing.

Following oral administration, peak plasma concentrations of 0.7 to 1.1 g/mL occur at an average of 44 minutes after a single 10 mg dose. The terminal plasma elimination half-life ranges between 2.4 and 9.0 hours in healthy adults, and between 4.3 and 7.6 hours in elderly subjects (mean age 72 years). A high fat meal decreases the rate, but not the extent, of absorption of oral ketorolac tromethamine. The use of an antacid has not been demonstrated to affect the pharmacokinetics of ketorolac.

In renally impaired patients there is a reduction in clearance and an increase in the terminal half life of ketorolac tromethamine (see table 5 below).

A series of studies were carried out in mice, rats, rabbits, monkeys and humans to characterize the pharmacokinetic profile of the free acid of ketorolac and ketorolac tromethamine. The salt form of the compound was later selected for development due to its more rapid and complete absorption.

## INDICATIONS:

Orally administered TORADOLIN (ketorolac tromethamine) is indicated for the short-term management (not to exceed 5 days for post-surgical patients or 7 days for patients with musculoskeletal pain) of moderate to moderately severe acute pain, including post-surgical pain (such as general, orthopaedic and dental surgery), acute musculoskeletal trauma pain and post-partum uterine cramping pain. The total duration of combined intramuscular and oral treatment should not exceed 5 days.

For patients with an increased risk of developing CV and/or GI adverse events, other management strategies that do not include the use of NSAIDs should be considered first

Use of TORADOLIN should be limited to the lowest effective dose for the shortest possible duration of treatment in order to minimize the potential risk for cardiovascular or gastrointestinal adverse events. TORADOLIN, as a NSAID, does not treat clinical disease or prevent its progression.

TORADOLIN, as a NSAID, only relieves symptoms and decreases inflammation for as long as the patient continues to take it.

Geriatrics (> 65 years of age): Evidence from clinical studies and post-market experience suggests that use in the geriatric population is associated with differences in safety.

Pediatrics (< 18 years of age): Safety and efficacy have not been established in the pediatric population.

## DOSE AND ADMINISTRATION:

Dosing Considerations: Use of TORADOLIN should be limited to the lowest effective dose for the shortest possible duration of treatment. In no case is the duration of TORADOLIN treatment to exceed 7 days.

## Recommended Dose and Dosage Adjustment

Adults (>18 years of age): Dosage should be adjusted according to the severity of the pain and the response of the patient.

Oral: The usual oral dose of TORADOLIN (ketorolac tromethamine) is 10 mg every 4 to 6 hours for pain as required. Doses exceeding 40 mg per day are not recommended. The maximum duration of treatment with the oral formulation is 5 days for post-surgical patients and 7 days for patients with musculoskeletal pain. TORADOLIN is not indicated for chronic use.

Conversion from Parenteral to Oral Therapy: When TORADOLIN tablets are used as a follow-on therapy to parenteral ketorolac, the total combined daily dose of ketorolac (oral + parenteral) should not exceed 120 mg in younger adult patients or 60 mg in elderly patients on the day the change of formulation is made. On subsequent days, oral dosing should not exceed the recommended daily maximum of 40 mg. Ketorolac IM should be replaced by an oral analgesic as soon as feasible. The total duration of combined intramuscular and oral treatment should not exceed 5 days.

Renal Impairment: TORADOLIN is contraindicated in patients with moderate to severe renal impairment (serum creatinine >442 µmol/L). TORADOLIN should be used with caution in patients with lesser renal impairment (serum creatinine 170 - 442 µmol/L). Such patients should receive a reduced dose of TORADOLIN, and their renal status should be closely monitored. It is recommended that the daily dose be reduced by half; a total daily dose of 60 mg should not be exceeded. Dialysis does not significantly clear ketorolac from bloodstream.

Hepatic Impairment: TORADOLIN is contraindicated in patients with severe liver impairment or active liver disease. Caution should be observed in giving TORADOLIN to patient with mild to moderate hepatic insufficiency.

Elderly, Frail or Debilitated Patients: These patients are at increased risk of the serious consequences of adverse reactions.

Oral: The lowest effective dose is recommended.

## Missed Dose

The missed dose should be taken as soon as remembered, and then the regular dosing schedule should be continued. Two doses of TORADOLIN should not be taken at the same time.

## Route of administration: Oral

## CONTRAINDICATIONS:

TORADOLIN is contraindicated in:

- the peri-operative setting of coronary artery bypass graft surgery (CABG). Although TORADOLIN has Not been studied in this patient population, a selective COX-2 inhibitor NSAID studied in such a setting has led to an increased incidence of cardiovascular/thromboembolic events, deep surgical infections and sternal wound complications
- the third trimester of pregnancy, because of risk of premature closure of the ductus arteriosus and prolonged parturition
- labour and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect fetal circulation and inhibit uterine musculature, thus increasing the risk of uterine haemorrhage
- women who are breastfeeding, because of the potential for serious adverse reactions in nursing infants
- severe uncontrolled heart failure
- known hypersensitivity to TORADOLIN or to other NSAIDs, including any of the components/excipients
- history of asthma, urticaria, or allergic-type reactions after taking ASA or other NSAIDs (i.e. complete or partial syndrome of ASA-intolerance - rhinosinusitis, urticaria/angioedema, nasal polyps, asthma). Fatal anaphylactoid reactions have occurred in such individuals. Individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction. The potential for cross-reactivity between different NSAIDs must be kept in mind.
- active gastric / duodenal / peptic ulcer, active GI bleeding
- inflammatory bowel disease
- cerebrovascular bleeding or other bleeding disorders
- coagulation disorders, post-operative patients with high haemorrhagic risk or incomplete haemostasis in patients with suspected or confirmed cerebrovascular bleeding.
- immediately before any major surgery and intraoperatively when haemostasis is critical because of the increased risk of bleeding
- severe liver impairment or active liver disease
- moderate to severe renal impairment (serum creatinine >442 µmol/L and/or creatinine clearance <30 mL/min or 0.5 mL/sec) or deteriorating renal disease (individuals

with lesser degrees of renal impairment are at risk of deterioration of their renal function when prescribed NSAIDs and must be monitored)

- known hyperkalemia.
- concurrent use with other NSAIDs due to the absence of any evidence demonstrating synergistic benefits and potential for additive side effects
- concomitant use with probenecid.
- concomitant use with oxpentifylline.
- children and adolescents aged less than 18 years

## Special Populations:

**Pregnant Women:** TORADOLIN is contraindicated for use during the third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and the potential to prolong parturition (see contraindications).

Caution should be exercised in prescribing TORADOLIN during the first and second trimesters of pregnancy.

Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or the embryo-foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy.

In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

TORADOLIN is not recommended in labour and delivery because, through their prostaglandin synthesis inhibitory effect, they may adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage

Geriatrics: Patients older than 65 years (referred to in this document as older or elderly) and frail or debilitated patients are more susceptible to a variety of adverse reactions from NSAIDs. The incidence of these adverse reactions increases with dose and duration of treatment. In addition, these patients are less tolerant to ulceration and bleeding. Most reports of fatal GI events are in this population. Older patients are also at risk of lower esophageal injury including ulceration and bleeding. For such patients, consideration should be given to a starting dose lower than the one usually recommended, with individual adjustment when necessary and under close supervision.

## WARNINGS AND PRECAUTIONS:

Risk of Cardiovascular (CV) Adverse Events: Ischemic Heart Disease, Cerebrovascular Disease, Congestive Heart Failure (NYHA II-IV).

TORADOLIN is a non-steroidal anti-inflammatory drug (NSAID). Use of some NSAIDs is associated with an increased incidence of cardiovascular adverse events (such as myocardial infarction, stroke or thrombotic events) which can be fatal. The risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Caution should be exercised in prescribing TORADOLIN to any patient with ischemic heart disease (including but not limited to acute myocardial infarction, history of myocardial infarction and/or angina), cerebrovascular disease (including but not limited to stroke, cerebrovascular accident, transient ischemic attacks and/or amaurosis fugax) and/or congestive heart failure (NYHA II-IV).

Use of NSAIDs, such as TORADOLIN, can promote sodium retention in a dose-dependent manner, through a renal mechanism, which can result in increased blood pressure and/or exacerbation of congestive heart failure.

Randomized clinical trials with TORADOLIN have not been designed to detect differences in cardiovascular events in a chronic setting. Therefore, caution should be exercised when prescribing TORADOLIN. Risk of Gastrointestinal (GI) Adverse Events

Use of NSAIDs, such as TORADOLIN, is associated with an increased incidence of gastrointestinal adverse events (such as peptic/duodenal ulceration, perforation, obstruction and gastrointestinal bleeding).

## SIDE EFFECTS:

### Adverse Drug Reaction Overview

The most common adverse reactions encountered with non-steroidal anti-inflammatory drugs are gastrointestinal, of which peptic ulcer, with or without bleeding is the most severe. Fatalities have occurred, particularly in the elderly.

### Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

## TORADOLIN TABLETS

### SHORT-TERM PATIENT STUDIES

The incidence of adverse reactions in 371 patients receiving multiple 10 mg doses of TORADOLIN (ketorolac tromethamine) for pain resulting from surgery or dental extraction during the postoperative period (less than 2 weeks) is listed below. These reactions may or may not be drug related.

Table 1: Most Common Clinical Trial Adverse Drug Reactions (4-9% and 2-3%)

Body System	Incidence	Adverse Reaction
Nervous System	4-9%	Somnolence, insomnia
	2-3%	Nervousness, headache, dizziness
Digestive System	4-9%	Nausea
	2-3%	Diarrhea, dyspepsia, gastrointestinal pain, constipation
Body as a whole	2-3%	Fever

Table 2: Less Common Clinical Trial Adverse Drug Reactions (≤ 1%)

**Nervous System:** abnormal dreams, anxiety, dry mouth, hyperkinesia, paresthesia, increased sweating, euphoria, hallucinations

**Digestive System:** anorexia, flatulence, vomiting, stomatitis, gastritis, gastrointestinal disorder, sore throat

**Body as a Whole:** asthenia, pain, back pain

**Cardiovascular System:** increased cough, rhinitis, dry nose

**Musculoskeletal System:** myalgia, arthralgia

**Skin and Appendages:** rash, urticaria

**Special Senses:** vision, ear pain

**Urogenital System:** dysuria

## LONG-TERM PATIENT STUDY

The adverse reactions listed below were reported to be probably related to study drug in 553 patients receiving long-term oral therapy (approximately 1 year) with TORADOLIN.

Table 3: Most Common Clinical Trial Adverse Drug Reactions (10-12%, 4-9% and 2-3%)

Body System	Incidence	Adverse Reaction
Digestive System	10-12%	Dyspepsia, gastrointestinal pain
	4-9%	Nausea, constipation
	2-3%	Diarrhea, flatulence, gastrointestinal fullness, peptic ulcers
Nervous System	4-9%	Headache
Metabolic/ Nutritional Disorder	2-3%	Dizziness, somnolence
	2-3%	Edema

Table 4: Less Common Clinical Trial Adverse Drug Reactions (≤ 1%)

**Digestive System:** Eructation, stomatitis, vomiting, anorexia,

duodenal ulcer, gastritis, gastrointestinal haemorrhage, increased appetite, melena, mouth ulceration, rectal bleeding, sore mouth  
**Nervous System:** Abnormal dreams, anxiety, depression, dry mouth, insomnia, nervousness, paresthesia

**Special Senses:** Tinnitus, taste perversion, abnormal vision, blurred vision, deafness, lacrimation disorder

**Metabolic/Nutritional Disorder:** Weight gain, alkaline phosphatase increase, BUN increased, excessive thirst, generalized edema, hyperuricemia

**Skin & Appendages:** Pruritus, rash, burning sensation skin

**Body as a Whole:** Asthenia, pain, back pain, face edema, hernia

**Musculo-skeletal System:** Arthralgia, myalgia, joint disorder

**Cardiovascular System:** Chest pain, chest pain substernal, migraine

**Respiratory System:** Dyspnea, asthma, epistaxis

**Urogenital System:** Haematuria, increased urinary frequency, oliguria, polyuria

**Haemetic & Lymphatic:** Anemia, purpura

**Abnormal Haematologic and Clinical Chemistry Findings**  
Elevations of blood urea nitrogen (BUN) and creatinine have been reported in clinical trials with ketorolac.

#### USE IN PREGNANCY & LACTATION:

There are no adequate and well-controlled studies of TORADOLIN in pregnant women. TORADOLIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### Nursing Mothers

Exercise caution when ketorolac is administered to a nursing woman. Available information has not shown any specific adverse events in nursing infants; however, instruct patients to contact their infant's health care provider if they note any adverse events.

#### USE IN CHILDREN & ADOLESCENTS:

TORADOLIN is not indicated for use in pediatric patients. The safety and effectiveness of TORADOLIN in pediatric patients below the age of 18 have not been established.

#### DRUG INTERACTIONS:

##### Drug-Drug Interactions

**Acetylsalicylic acid (ASA) or other NSAIDs:** The use of TORADOLIN in addition to most NSAIDs, including over-the-counter ones (such as ibuprofen) for analgesic and/or anti-inflammatory effects is usually contraindicated because of the absence of any evidence demonstrating synergistic benefits and the potential for additive adverse reactions.

The exception is the use of low dose ASA for cardiovascular protection, when another NSAID is being used for its analgesic/anti-inflammatory effect, keeping in mind that combination NSAID therapy is associated with additive adverse reactions.

Some NSAIDs (e.g. ibuprofen) may interfere with the anti-platelet effects of low dose ASA, possibly by competing with ASA for access to the active site of cyclooxygenase-1. In vitro studies indicated that, at therapeutic concentrations of salicylates (300 µg/mL), the binding of ketorolac tromethamine was reduced from approximately 99.2% to 97.5% representing a potential two-fold increase in unbound TORADOLIN plasma levels.

**Antacids:** There is no definitive evidence that the concomitant administration of histamine H<sub>2</sub> receptor antagonists and/or antacids will either prevent the occurrence of gastrointestinal side effects or allow the continuation of TORADOLIN therapy when and if these adverse reactions appear.

**Anti-hypertensives:** NSAIDs may diminish the anti-hypertensive effects of angiotensin converting enzyme (ACE) inhibitors. Combinations of ACE inhibitors, angiotensin-II antagonists, or diuretics with NSAIDs might have an increased risk for acute renal failure and hyperkalemia. Blood pressure and renal function (including electrolytes) should be monitored more closely in this situation, as occasionally there can be a substantial increase in blood pressure.

**Anti-platelet Agents (including ASA):** There is an increased risk of bleeding, via inhibition of platelet function, when anti-platelet agents are combined with NSAIDs, such as TORADOLIN.

**Digoxin:** Concomitant administration of an NSAID with digoxin can result in an increase in digoxin concentrations which may result in digitalis toxicity. Increased monitoring and dosage adjustments of digitalis glycosides may be necessary during and following concurrent NSAID therapy. Ketorolac tromethamine does not alter digoxin protein binding.

**Diuretics:** Clinical studies as well as post-marketing observations have shown that NSAIDs can reduce the effect of diuretics. Ketorolac tromethamine reduces the diuretic response to furosemide by approximately 20% in normovolemic subjects, so particular care should be taken in patients with cardiac decompensation.

**Glucocorticoids:** Some studies have shown that the concomitant use of NSAIDs and oral glucocorticoids increases

the risk of GI adverse events such as ulceration and bleeding. This is especially the case in older (> 65 years of age) individuals.

**Lithium:** Monitoring of plasma lithium concentrations is advised when stopping or starting a NSAID, as increased lithium concentrations can occur. Some NSAIDs have been reported to inhibit renal lithium clearance, leading to an increase in plasma lithium concentrations and potential lithium toxicity. The effect of ketorolac tromethamine on lithium plasma levels has not been studied. Cases of increased lithium plasma concentrations during therapy with TORADOLIN have been reported.

**Methotrexate:** Caution is advised in the concomitant administration of methotrexate and NSAIDs, as this has been reported to reduce the clearance of methotrexate, thus enhancing its toxicity. In case combination treatment with methotrexate and NSAIDs is necessary, blood cell count and the renal function should be monitored. Concomitant administration of NSAIDs with a potentially myelotoxic drug, such as methotrexate, appears to be a predisposing factor to the onset of a cytopenia.

**Oxpentifylline:** When TORADOLIN is administered concurrently with oxpentifylline, there is an increased tendency to bleeding. The concomitant use of TORADOLIN and oxpentifylline is contraindicated.

**Probenecid:** Concomitant administration of ketorolac tromethamine and probenecid results in the decreased clearance and volume of distribution of ketorolac and a significant increase in ketorolac plasma levels (approximately three-fold increase) and terminal half-life (approximately two-fold increase). The concomitant use of TORADOLIN and probenecid is contraindicated.

**Selective Serotonin Reuptake Inhibitors (SSRIs):** Concomitant administration of NSAIDs and SSRIs may increase the risk of gastrointestinal ulceration and bleeding.

#### OVERDOSE:

**Signs and Symptoms:** Overdoses of TORADOLIN have been variously associated with abdominal pain, nausea, vomiting, hyperventilation, peptic ulcers and/or erosive gastritis, gastrointestinal bleeding, and renal dysfunction which have generally resolved after discontinuation of dosing. Metabolic acidosis has been reported following intentional overdosage. Although rare, hypertension, acute renal failure, respiratory depression, coma and death have been reported after significant overdose of NSAIDs. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs and may occur following an overdose. In a gastroscopic study of healthy subjects, daily doses of 360 mg given over an 8-hour interval for each of five consecutive days (3 times the highest recommended dose) caused pain and peptic ulcers which resolved after discontinuation of dosing.

#### Treatment:

Patients should be managed by symptomatic and supportive care following overdose. There are no specific antidotes. Dialysis does not significantly clear ketorolac from the bloodstream. For management of a suspected drug overdose contact your regional Poison Control Centre.

#### Pharmaceutical Precaution:

This medicine must not be used after the expiry date (EXP) shown on the pack.

#### STORAGE:

Do not store above 30°C, protect from light & moisture.

Medicine: Keep out of reach of children.

#### PACKING:

Each box contains 2 x 10 tablets in Alu-Alu blister pack.

® Registered Trade Mark

**RADIANT**  
PHARMACEUTICALS

Manufactured by  
**Radiant Pharmaceuticals Limited**  
B-34 & B-46, BSCIC Industrial Estate  
Tongi, Gazipur-1710, Bangladesh

## টোরাডলিন® ট্যাবলেট

কিটোরোলাক ট্রোমেথামিন ইউএসপি

#### উপস্থাপনঃ

প্রতিটি ফিল্ম কোটেড ট্যাবলেটে আছে কিটোরোলাক ট্রোমেথামিন ইউএসপি ১০ মিগ্রা।

টোরাডলিন একটি শক্তিশালী বেদনানাশক যা নন স্টেরয়ডাল এন্টিইনফ্ল্যামেটরী শ্রেণীভুক্ত। ইহা সাইক্লো অক্সিজেনেজ এনজাইম সিষ্টেমকে বাধা দিয়ে প্রোস্টাগ্ল্যান্ডিন সংশ্লেষণ বাধাগ্রস্ত করে।

#### কার্যপ্রণালীঃ

টোরাডলিন একটি নন-স্টেরয়ডাল এন্টি-ইনফ্ল্যামেটরি ওষুধ যা প্রান্তিক/পেরিফেরাল প্রভাব এর মাধ্যমে ব্যথানাশক ক্রিয়া প্রদর্শন করে। কিটোরোলাক এর কার্যপ্রণালী অন্যান্য NSAID এর মতই পুরোপুরি উপলব্ধি করা যায় না। তবে ধারণা করা হয় এটি প্রোস্টাগ্ল্যান্ডিন সিনথেসিস সংশ্লেষণ বাধাগ্রস্ত করার সাথে সম্পর্কিত।

#### শোষণঃ

মুখে গ্রহণের পর কিটোরোলাক ট্রোমেথামিন খুব দ্রুত এবং সম্পূর্ণ পরিশোষিত হয় এবং সর্বোচ্চ ঘনমাত্রায় পৌঁছানোর সময় ০.২৫ থেকে ১.৫ ঘন্টা।

#### নির্দেশনাঃ

টোরাডলিন স্বল্পকালীন মাঝারী থেকে তীব্র ব্যথায় নির্দেশিত।

#### মাত্রা ও প্রয়োগঃ

পূর্ণ বয়স্ক রোগীর ক্ষেত্রে (>১৮ বছর): ব্যথার তীব্রতা অনুযায়ী টোরাডলিন ১০ মিগ্রা ট্যাবলেট প্রতি ৪-৬ ঘন্টা অন্তর নির্দেশিত।

মাত্রা নির্দেশ সুবিন্যস্ত করতে হবে ব্যথার তীব্রতা এবং রোগীর প্রতিক্রিয়া অনুসারে।

টোরাডলিন ট্যাবলেট শুধুমাত্র স্বল্পকালীন ব্যবহারের জন্য পরামর্শ দেওয়া হয় (সাত দিন পর্যন্ত) এবং ইহা দীর্ঘস্থায়ী ব্যবহারের জন্য পরামর্শ দেওয়া হয় না।

#### বিরূপ ব্যবহারঃ

- রোগীর পাকস্থলীর ক্ষত ও পাকতাত্ত্বিক রক্তক্ষরণের পূর্ব বৃত্তান্ত যদি থাকে।
- সন্দেহজনক বা নিশ্চিত মস্তিষ্ক ও সংবহন নালিকার রক্তক্ষরণ।
- রক্ত জমাট বাঁধন বিশৃঙ্খলা সহ রক্তক্ষরণজনিত রোগ প্রবণতা।
- কিটোরোলাক বা অন্যান্য NSAID এর প্রতি অতি সংবেদনশীলতা।
- ন্যাসাল পলিপস, এনজিও ইডিমা অথবা ব্রোঙ্কোস্পাজমের সম্পূর্ণ বা আংশিক লক্ষণযুক্ত রোগী।
- অন্যান্য NSAID, অক্সিপেনটিফাইলাইন, প্রোবেনিসিড অথবা লিথিয়াম সল্ট এর সাথে সহ চিকিৎসায়।
- যে কোন কারণে ডিহাইড্রেশন বা হাইপোভোলেমিয়া।
- লঘু বা তীব্র বৃক্ক সঙ্কীর্ণ দুর্বলতা (সিরাম ক্রিয়েটিনিন >১৬০ মাইক্রোমোল/ লিটারের নিচে)।

- হাঁপানি রোগের পূর্ববৃত্তান্ত যদি থাকে।
- যাদের অস্ত্রোপচার জনিত রক্তক্ষরণের তীব্র আশংকা আছে।
- রক্ত জমাট বাঁধন রোধী স্বল্পমাত্রার হেপারিন চিকিৎসায় রয়েছে এমন রোগী (১২ ঘন্টায় ২৫০০-৫০০০ ইউনিট)
- গর্ভকালীন সময়ে, প্রসবাবস্থায় এবং প্রসব কালীন সময়ে।
- ১৮ বছরের নিচে শিশুদের ক্ষেত্রে।

#### সংরক্ষণঃ

আলো থেকে দূরে, ঠাণ্ডা ও শুষ্ক স্থানে ৩০° সেঃ তাপমাত্রার নীচে সংরক্ষণ করুন।

প্যাকেট এর উপর লেখা মেয়াদ উত্তীর্ণের তারিখ অতিক্রম করলে ওষুধ ব্যবহার করা উচিত নয়।

#### সরবরাহঃ

প্রতি বাক্সে আছে ২ X ১০ টি ট্যাবলেট অ্যালু-অ্যালু ব্লিষ্টার প্যাকিং এ।

ওষুধ শিশুদের নাগালের বাইরে রাখুন।

বিস্তারিত তথ্যের জন্য ইংরেজী অংশ দেখুন।

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