Safety Data Sheet
Etodolac Extended-release Tablets, USP

Strength: 400/500/600 mg. **Pack Size:** 60/100/500/1000 Tablets per bottle

Blister cartons of 100 (10 x 10) unit dose tablets **Revision No.:** 02

EMERGENCY OVERVIEW

Each Etodolac extended-release tablet contain etodolac and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

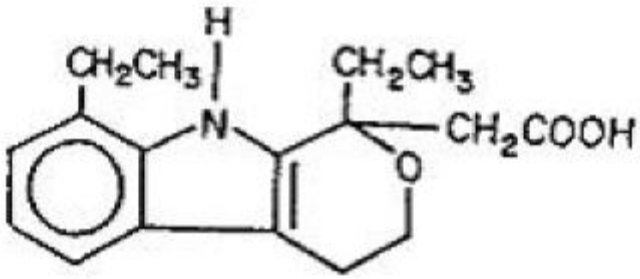
Section 1. Identification

Identification of the product

Product name: Etodolac extended-release tablets,USP

Formula: $C_{17}H_{21}NO_3$

Chemical Name: (±) 1,8-diethyl-1,3,4,9-tetrahydropyrano-[3,4-b]indole-1-acetic acid.



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India

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Recommended use / Therapeutic Category Non-steroidal anti-inflammatory drugs

Restriction on Use / Contraindications: Etodolac extended-release tablets are contraindicated in patients with known hypersensitivity to etodolac.
Etodolac extended-release tablets should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe,

rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients Etodolac extended-release tablets are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery

Section 2. Hazard(s) Identification

Dose and Administration

Juvenile Rheumatoid Arthritis
For the relief of the signs and symptoms of juvenile rheumatoid arthritis in patients 6 to 16 years of age, the recommended dose given orally once per day should be based on body weight, according to the following table:

Body Weight Range (kg)	Dose
20 to 30	400 mg Tablet x 1
31 to 45	600 mg Tablet x 1
46 to 60	400 mg Tablet x 2
> 60	500 mg Tablet x 2

Rheumatoid Arthritis and Osteoarthritis
For the relief of the signs and symptoms of osteoarthritis or rheumatoid arthritis, the recommended starting dose of etodolac extended-release tablets is 400 to 1000 mg given orally once per day.

As with other NSAIDs, the lowest effective dose should be sought for each patient. In chronic conditions, a therapeutic response to therapy with etodolac extended-release tablets is sometimes seen within one week of therapy, but most often is observed by two weeks.

Adverse Effects

Gastrointestinal experiences including : Abdominal, pain, dyspepsia, gross bleeding/perforation, constipation, flatulence, nausea, Diarrhea, GI ulcers (gastric/duodenal)' Vomiting
Other events including::abnormal renal function, dizziness, headaches infection, rashes anemia, edema' hypertension, pharyngitis, rhinitis, asthenia elevated liver enzymes' increased bleeding time, pruritus, tinnitus

Over Dose Effect

Overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have

	been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
Medical Conditions	Tell your healthcare provider about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. Keep a list of your medicines to show to your healthcare provider and pharmacist. If you are pregnant. NSAID medicines should not be used by pregnant women late in their pregnancy. If you are breastfeeding. Talk to your doctor.
Contraindications	Etodolac extended-release tablets are contraindicated in patients with known hypersensitivity to etodolac. Etodolac extended-release tablets should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients Etodolac extended-release tablets are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery
Pregnancy Comment	In late pregnancy, as with other NSAIDs, etodolac extended-release tablets should be avoided because it may cause premature closure of the ductus arteriosus
Pregnancy Category	C

Section 3. Composition / information on ingredients

Component	**Exposure Limit**	**CAS No.**
Principle Component:		
Etodolac	Not Found	41340-25-4
Inactive ingredients :		
Disodium hydrogen phosphate	Not Found	7558-79-4
Hypromellose	Not Found	9004-65-3

Magnesium stearate	Not Found	577-04-0
Ethylcellulose	Not Found	9004-57-3
Polyethylene glycol	Not Found	25322-68-3
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7
Lactose monohydrate	Not Found	5989-81-1
Triacetin	Not Found	102-76-1
For 400 mg		
D&C yellow # 10 aluminum lake	Not Found	NA
FD&C Red # 40 aluminum lake and	Not Found	NA
FD&C Yellow # 6 aluminum lake	Not Found	NA
For 500 mg		
FD&C Blue # 2 aluminum lake	Not Found	NA
Iron oxide black	Not Found	NA
Iron oxide yellow	Not Found	NA
For 600 mg		
FD&C blue # 2 aluminum lake	Not Found	NA
Iron oxide red	Not Found	NA
Iron oxide yellow.	Not Found	NA

Section 4. First -aid measures

General	Inhalation:Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention. Contact with skin:Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention. Contact with eyes:Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice Ingestion:If swallowed, wash out mouth with water, provided person is concious. Seek medical advice Remove and wash/dispose of contaminated clothing promptly.
Overdose Treatment	Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of the urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

Section 5. Fire -fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage	Store at 20° to 25° C (68° to 77° F). Protect from excessive heat and humidity.
Incompatibility	No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 9. Physical and chemical properties

Appearance	Etodolac Extended-release Tablets USP, 400 mg are orange-colored, oval-shaped, beveled edged, film-coated tablets, debossed with "271" on one side and plain on other side Etodolac Extended-release Tablets USP, 500 mg are grey-colored, oval-shaped, beveled edged, film-coated tablets, debossed with "272" on one side and plain on other side Etodolac Extended-release Tablets USP, 600 mg are blue-colored, oval-shaped, beveled edged, film-coated tablets, debossed with "273" on one side and plain on other side

Solubility in water	Insoluble in water but soluble in alcohols, chloroform, dimethyl sulfoxide, and aqueous polyethylene glycol.	**Odour**	No Data Available
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available	**Other information**	Not Applicable

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities	No data available.		

Section 11. Toxicological information

General Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Other Not Applicable

Section 12. Ecological information

No data available on Ecotoxicity. Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground(DOT), or sea(IMDG). May be shipped normally as a non hazardous material.

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 091134

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.