

Firocoxib Chewable Tablets

Safety Data Sheet



Date of issue: 26 Jul 2023

Version: 00

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Firocoxib Chewable Tablets 57 mg and 227mg

1.2. Intended Use of the Product

Use of the substance/mixture: Firocoxib Chewable Tablets are indicated for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs

1.3. Name, Address of the Responsible Party

Felix Pharmaceuticals Private Limited
25-28, North Wall Quay Dublin 1,
Republic of Ireland

1.4. Emergency Telephone Number

Emergency Number: contact Felix Pharmaceuticals Private Limited at 1-833-571-1525.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

2.2. Label Elements

No labeling applicable

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Ingredient Name

Firocoxib

3.2. Chemical Formula: 3-(cyclopropylmethoxy)-4-(4-(methylsulfonyl)phenyl)-5,5-dimethylfuranone

3.3. Mixture

Component	Approximate Quantity	CAS number
Firocoxib	57/227 mg	189954-96-9
Non-hazardous Ingredients	q.s	Not Applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: If you feel unwell, seek medical advice.

First-aid Measures After Inhalation: Not an expected route of exposure. In case of over exposure, move exposed person to fresh air. Refer to a physician if subject experiences difficulty breathing.

First-aid Measures After Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service.

Do not home launder. If irritation occurs or persists, get medical attention.

First-aid Measures After Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

First-aid Measures After Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries After Inhalation: Due to the product's final form, inhalation is an unlikely route of exposure.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Chronic Symptoms: None expected under normal conditions of use

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

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None

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Select extinguishing media suitable for surrounding area.

Unsuitable Extinguishing Media: There is no restriction on the type of extinguisher which may be used.

5.2. Special Hazards Arising from the Substance or Mixture

Fire Hazard: Not considered flammable.

Explosion Hazard: Product itself is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Special Fire Fighting Procedure: Use water delivered as a fine spray to control fire and cool adjacent area.

Do not approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location.

If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

6.2. Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Avoid Keep away from heat. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust. Keep away from heat, sparks, and flame.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F). [See USP controlled room temperature].

Incompatible Products: No known incompatibilities.

7.3. Specific End Use(s)

Not available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

8.2. Exposure Controls

Appropriate Engineering Controls : Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment : Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hand Protection : Wear impervious gloves if skin contact is possible.

Eye Protection : Safety glasses or goggles.

Skin and Body Protection : Wear suitable protective clothing if skin contact with drug product is possible.

Respiratory Protection : If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Chewable tablets
Appearance	: Brownish yellow to pale brown colored round shaped tablet
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** No data available.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions.
- 10.3. **Possibility of Hazardous Reactions:** The product is not considered to be stable under standard storage condition and hence hazardous reaction is not expected.
- 10.4. **Conditions to Avoid:** None.
- 10.5. **Incompatible Materials:** None Known.
- 10.6. **Hazardous Decomposition Products:** No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

Local Effects:	Not Classified.
Reproductive Effects:	Not Classified
Mutagenicity:	Not Classified

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. **Toxicity** No data available
- 12.2. **Persistence and Degradability** No data available
- 12.3. **Bio accumulative Potential** No data available
- 12.4. **Mobility in Soil** No data available
- 12.5. **Other Adverse Effects** No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

Transport according to all local, state and federal regulation

SECTION 15: REGULATORY INFORMATION

No additional information available

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SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : Not Applicable

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

To the best of Felix's knowledge, the information contained here is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All material may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.