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SECTION 1 - IDENTIFICATION

Product Identification:

Flurbiprofen Tablets USP, 100 mg, 100 Ct Bottles	NDC 64950-218-10
Flurbiprofen Tablets USP, 100 mg, 30 Ct Bottles	NDC 64950-218-03

Product Name: Flurbiprofen Tablets USP

Recommended use: Flurbiprofen Tablets USP are a nonsteroidal anti-inflammatory drug (NSAIDs) indicated for relief of the signs and symptoms of rheumatoid arthritis and the relief of the signs and symptoms of osteoarthritis.

Restrictions: Patients with history of asthma, urticaria, or other allergic type reactions after taking aspirin or other NSAID, or patients with coronary artery bypass surgery should not take Flurbiprofen Tablets.

Manufacturer Name:
Manufacturer Address:
Piramal Pharma Limited
Plot 67-70, Sector II,
Pithampur, Indore 454775,
Madhya Pradesh, India

Telephone number: 91-729-242-8401

Distributor Name:
Distributor Address:
Genus Lifesciences Inc.
514 N. 12th Street
Allentown, PA 18102

Telephone number: (610) 782-9780
Fax number: (610) 782-9781

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product Flurbiprofen Tablets USP is a non-hazardous pharmaceutical mixture and does not meet OSHA's Hazard Communication Standard (HCS) 2012, 29CFR 1910.1200 and OSHA's Globally Harmonized System (GHS) hazard criteria. As per OSHA section 1910.1200(b)(6)(vii), "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient; drugs which are packaged by the chemical manufacturer for sale to consumers in a

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retail establishment" are exempt. The GHS hazards listed below are for the active product ingredient (API), Flurbiprofen, and **NOT** for the Tablet product itself.

Physical hazards:	Not classified
Health hazards:	Oral Acute Toxicity Category 3 Skin Irritant Category 2 Eye Irritant Category 2 Reproductive Toxicity Category 2
Environmental hazards:	None Available

Signal Word: Warning

Hazard Statement: Active ingredient Flurbiprofen causes skin irritation and serious eye irritation. It is suspected of damaging fertility or the unborn child.

Pictogram:

Precautionary Statement: Generally safe at recommended doses. NSAIDs are associated with reversible infertility. Have a risk of serious cardiovascular and gastrointestinal events.

Hazards Not Otherwise Classified: None known.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Croscarmellose Sodium	Modified cellulose gum	74811-65-7
FD&C Blue No 1 Aluminum Lake	Brilliant blue	15792-67-3
Flurbiprofen	N/A	5104-49-4
Hypromellose 2910	(Hydroxypropyl) methyl cellulose	9004-65-3
Lactose Monohydrate	Pharmatose DCL 14, Lactose hydrate	64044-51-5
Magnesium Stearate	Calcium stearate	557-04-0
Microcrystalline Cellulose	Avicel PH	9004-34-6
Polyethylene Glycol	Ethylene oxide	25322-68-3
Polysorbate 80	Monitan	9005-65-6
Silicon Dioxide	Silica, Aerosil	7631-86-9
Titanium Dioxide	Anatase	13463-67-7

* Chemical exact percentage (concentration) of composition has been withheld as a trade secret.

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SECTION 4 – FIRST AID MEASURES

Eye Contact: As a finished product is not an expected route of exposure. If contact suspected, flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.

Skin Contact: Wash with soap and large amount of water. Contact medical personnel if irritation persists.

Ingestion: This product is intended for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician immediately.

Inhalation: As a finished product is not an expected route of exposure. If breathing is difficult, move to fresh air and seek medical attention.

Symptoms or effects: NSAID's might cause stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness. Stop taking your NSAID and call your healthcare provider right away if you get any of the following symptoms: nausea, vomit blood, more tired or weaker than usual, diarrhea, itching, there is blood in your bowel movement or it is black and sticky like tar, unusual weight gain, your skin or eyes look yellow, skin rash or blisters with fever, indigestion or stomach pain, swelling of the arms, legs, hands and feet, or have flu-like symptoms.

Recommendations: Immediate medical attention is required if an overdose is suspected. Symptoms following acute NSAID overdoses have been typically limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Call a Poison Control Center (1-800-222-1222) or 911 if you feel unwell. No action shall be taken involving any personal risk or without suitable training. If needed and if possible, give artificial respiration and/or CPR. Administer activated charcoal as slurry.

Note to Physician: Advise patients to be alert for the symptoms of cardiovascular thrombotic events, including chest pain, shortness of breath, weakness, or slurring of speech; be alert for the symptoms of congestive heart failure including shortness of breath, unexplained weight gain, or edema and to report any of these symptoms to their health care provider immediately. Patients should report symptoms of ulcerations and bleeding, including epigastric pain, dyspepsia, melena, and hematemesis to their health care provider. In the setting of concomitant use of low-dose aspirin for cardiac prophylaxis, inform patients of the increased risk for and the signs and symptoms of GI bleeding.

Inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, diarrhea, jaundice, right upper quadrant tenderness, and "flu-like" symptoms) and signs of an anaphylactic reaction (e.g., difficulty breathing, swelling of the face or throat), or if they develop any type of rash or fever. If these occur, instruct patients to stop Flurbiprofen Tablets and seek immediate medical therapy.

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Advice females of reproductive potential who desire pregnancy that NSAIDs may be associated with reversible delay in ovulation. Inform pregnant women to avoid use of NSAIDs starting at 30 weeks gestation due to the risk of the premature closing of the fetal ductus arteriosus. If treatment with Flurbiprofen is needed for a pregnant woman between about 20 to 30 weeks gestation, she may need to be monitored for oligohydramnios, if treatment continues for longer than 48 hours.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media — Use Water spray, Dry chemical, CO_2, or any material appropriate for fire in the surrounding area. Use water spray to cool unopened containers.

Specific hazards arising from the mixture: — None known for the finished product. (Refer to section 10)

Advice to the firefighters: — Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: — No action shall be taken involving any personal risk or without suitable training. Clean the spill if is safe to do so. Minimize exposure. Keep unnecessary personnel away. Do not touch or walk through spilled material.

Protective Equipment: — Safety Glasses or goggles, gloves, protecting clothes. (Refer to section 8)

Emergency procedures: — Evacuate the area. Keep unnecessary personnel away. Prevent further spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Containment Precautions: — Isolate area around spill as specified by site procedures.

Clean Up Procedures: — Collect the material in a compatible container and dispose according to applicable regulations (Refer to section 13). Decontaminate the area with water.

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling: Observe safe industrial practices. No special handling requirements for normal use of this material. Dispense content with a child resistant closure and in a tight, light-resistant

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container as defined in the USP/NF.

Conditions for safe storage: Store in original container at 20°C to 25°C (68°F to 77°F). Protect from Moisture. Keep container tightly closed. Keep out of reach of children. Do not use if seal under cap is missing or broken. For more information follow directions in product packaging.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There are no exposure limits for the Clemastine Fumarate Tablet products. The exposure limits listed below are for the Active Product Ingredient (API) Clemastine Fumarate and not for the finished Tablet product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	Not Available
Acceptable Daily Exposure (ADE):	Not Available
5 Band System Exposure Classification:	Not Available
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	Not Available
Time Weight Average (TWA) – 8 Hours:	Not Available
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Good ventilation should be use and should be matched to conditions. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Clean work areas routinely to prevent accumulation of product as appropriate.

Personal Protective Measures:

Respiratory protection: Not required under normal conditions of use for finished product. If it found to be necessary, wear a mask or an appropriate NIOSH approved respirator.

Eye protection: Not required under normal conditions of use for finished product. If it found to be necessary, wear safety glasses or goggles as appropriate for the task.

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Protective gloves:	Not required under normal conditions of use for finished product. If it found to be necessary, wear chemical compatible gloves.
Skin and body protection:	Not required under normal conditions of use for finished product. During manufacture or other similar industrial operations, wear the necessary protection.
Hygiene measures:	Wash hands, wrist, forearms and face thoroughly after handling chemicals and products, before eating, and at the end of working period. Contaminated clothing should not be allowed out of the workplace. Wash clothing before reusing.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Round Tablet	Odor:	None
Density:	Not Available	Boiling Point:	Not available
Color:	Blue	Solubility:	Water, Alcohol
Viscosity:	Not Available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	Not Available	Flash Point:	Not Available
Reactivity:	Refer to section 10	Toxicity:	Refer to section 11

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid: Moisture and heat.

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Incompatible materials:	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products:	None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Ingestion

Delayed, immediate and chronic effects for short and long term exposure:

General effects:	Common side effects might include stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.
Sensitization:	No known significant effects.
Carcinogenicity:	Flurbiprofen was not carcinogenic in long-term studies in Fischer-344 and CD rats at doses up to 5 mg/kg/day and in CFLP mice at doses up to 12 mg/kg/day (0.16-times and 0.19-times respectively the human dose of 300 mg/day). Product not listed as a carcinogen by OSHA.
Mutagenic effects:	Flurbiprofen was not genotoxic in an in vivo micronucleus assay in rats.
Reproductive toxicity:	No effect on male or female fertility in rats was observed after oral administration of 3 mg/kg Flurbiprofen for 65 days prior to mating in males and 14 days prior to mating through Gestation Day 16 in females (equivalent to 0.1-times the human dose of 300 mg/day). This dose was not associated with significant toxicity.
Fetotoxic / Teratogenic Effects:	No data available of harm to the fetus.

Specific Target Organ Toxicity (STOT):

Single exposure:	Category 3
Repeated exposure:	No data available

Toxicity (LD50):

Toxicity studies have not been conducted with the Flurbiprofen Tablets product. The exposure limits listed below are for the active product ingredient (API) Flurbiprofen and not for the finished Tablet product itself.

Oral LD_{50} Rat:	117 mg/kg	Intraperitoneal LD_{50} Rat:	108 mg/kg
Subcutaneous LD_{50} Rat:	100 mg/kg	Oral LD_{50} Mouse:	640 mg/kg
Intraperitoneal LD_{50} Mouse:	890 mg/kg	Subcutaneous LD_{50} Mouse:	550 mg/kg

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Adverse Reactions: Flurbiprofen Tablets may cause Cardiovascular Thrombotic Events, GI Bleeding, Ulceration and Perforation, Hematologic Toxicity, Heart Failure and Edema, Hepatotoxicity, Hypertension, Serious Skin Reactions, Anaphylactic Reactions, Renal Toxicity and Hyperkalemia.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects): Ecotoxicity studies have not been conducted with the Flurbiprofen Tablets USP product.

Persistence and Degradability: Not Available

Bioaccumulation: Not Available

Leaching studies: Not Available

Other adverse effects: The pharmaceutical product is not classified as environmentally hazardous. No studies to aquatic organisms or environment were found, however; is highly recommended to avoid any environmental.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with the federal, state or local regulatory requirements.

Waste Disposal Methods: Dispose all the product waste in accordance with the federal, state or local regulatory requirements.

Special Precautions: Discard away from children's reach. Releases to the sewer should be avoided.

SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

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ICAO / IATA - International Civil Aviation Organization / International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO / IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known

SECTION 15 – REGULATORY INFORMATION

Drug Enforcement Administration (DEA): Not Listed as Controlled Substances.

Food and Drug Administration (FDA): Approved prescription medication.

Occupational Safety and Health Administration (OSHA):

GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Resource Conservation and Recovery Act (RCRA): No Code Applicable

SARA 302/304 Extreme Hazardous Substances (EHS): Not Listed

SARA 311/312 Hazard Categories:

Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

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SARA 313 Toxic Chemical Release Inventory (TRI): Not Regulated

Clean Water Act (CWA):

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following ingredients are included on the TSCA inventory 8(b):

Ingredient	CAS Number
FD&C Blue No 1 Aluminum Lake	15792-67-3
Hypromellose 2910	9004-65-3
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Polyethylene Glycol	25322-68-3
Polysorbate 80	9005-65-6
Silicon Dioxide	7631-86-9
Titanium Dioxide	13463-67-7

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Sep/10/24, New SDS

Revision Date: N/A

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

Genus Lifesciences Inc. believes that the information contained herein is based on the best available data at the date of preparation. However, no warranty is expressed or implied regarding the data's accuracy and completeness. Since the use of this information and the conditions of use of this material are not within the control of Genus Lifesciences Inc., it is the user's obligation to determine the conditions of safe use of this material.

Signature Manifest

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All dates and times are in Eastern Time.

SDS Flurbiprofen Tablets - 64950

Department Approval

Name/Signature	Title	Date	Meaning/Reason
July Ortiz (JORTIZ)		26 Sep 2024, 01:01:48 PM	Approved

Regulatory Affairs Approval

Name/Signature	Title	Date	Meaning/Reason
Demeitrius Sawickij (DSAWICKIJ)		27 Sep 2024, 09:12:27 AM	Approved

Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
Rama Chitirala (RCHITIRALA)	Vice President of Quality Assurance	27 Sep 2024, 11:08:49 AM	Approved