

# SAFETY DATA SHEET



Version 7.6	Revision Date: 2025/09/11	SDS Number: 100000014461	Date of last issue: 2025/09/10 Date of first issue: 2018/10/01
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## SECTION 1. IDENTIFICATION

Substance name : UPTRAVI 0,2 - 1,6 mg FC tablets  
selexipag

### Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.  
Address : 1125 Trenton-Harbourton Rd  
Titusville NJ 08560  
USA  
Telephone : +16097302000  
E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com  
Emergency telephone number : CHEMTREC US: 1-800-424-9300  
CHEMTREC International: +1 703-741-5970

### Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product  
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.  
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

## SECTION 2. HAZARDS IDENTIFICATION

### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Specific target organ toxicity : Category 2  
- repeated exposure

### GHS label elements

Hazard pictograms :

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Signal word : Warning

Hazard statements : H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

## Other hazards

Warning! May form combustible dust concentrations in air.

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## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

### Components

Chemical name	CAS-No.	Concentration (% w/w)
PROPYLENE GLYCOL	57-55-6	>= 10 - < 20
titandioxide	13463-67-7	>= 5 - < 10
SELEXIPAG	475086-01-2	>= 1 - < 5

Actual concentration is withheld as a trade secret

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## SECTION 4. FIRST AID MEASURES

If inhaled : Health injuries are not known or expected under normal use. Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately. Wash off with soap and water. If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.

Most important symptoms and effects, both acute and : Adverse effects from repeated ingestion may include Headache

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delayed	Diarrhoea nausea muscle pain Vomiting flushing jaw pain pain in extremity
Notes to physician	: Treat symptomatically.

## SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during firefighting	: No information available.
Further information	: No information available.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Evacuate personnel to safe areas.
Environmental precautions	: Should not be released into the environment.
Methods and materials for containment and cleaning up	: Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

## SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: No data available
Advice on safe handling	: Do not break, crush or spill this Finished Pharmaceutical Product. To avoid thermal decomposition, do not overheat. Use personal protective equipment as required.

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Avoid inhalation, ingestion and contact with skin and eyes.

Conditions for safe storage	: To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep away from heat and sources of ignition. Keep containers tightly closed in a dry, cool and well-ventilated place.
Recommended storage temperature	: 68 - 77 °F / 20 - 25 °C

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
PROPYLENE GLYCOL	57-55-6	TWA	10 mg/m3	US WEEL
titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
SELEXIPAG	475086-01-2	TWA	0.0028 mg/m3	J&J OEL/PBOEL HHC
		STV	0,028 mg/100cm <sup>2</sup>	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J OEL/PBOEL HHC
		Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3B., Notation SKIN: has the potential for absorption via the skin.		

Engineering measures	: All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary. If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
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### Personal protective equipment

Respiratory protection	: No personal respiratory protective equipment normally required.
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Hand protection Remarks	: Disposable gloves
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Eye protection	: No special precautions required.
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Skin and body protection	:	closed work clothing
Protective measures	:	The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Coated, tablet
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
<u>Water solubility</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available

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Decomposition temperature	:	No data available
Viscosity		
<u>Viscosity, dynamic</u>	:	No data available
<u>Viscosity, kinematic</u>	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

## SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

## SECTION 11. TOXICOLOGICAL INFORMATION

### Acute toxicity

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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#### Components:

#### **PROPYLENE GLYCOL:**

Acute oral toxicity	:	LD50 (Rat): > 10,400 mg/kg
Acute inhalation toxicity	:	LC50 (Rabbit): > 317,042 mg/l Exposure time: 2 h Test atmosphere: vapour
Acute dermal toxicity	:	LD50 (Rabbit): 20,800 mg/kg

#### **SELEXIPAG:**

Acute oral toxicity	:	mortality (Rat): >= 500 mg/kg Assessment: The component/mixture is moderately toxic after single ingestion.
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## Skin corrosion/irritation

### Components:

#### **SELEXIPAG:**

Method : in vitro skin corrosion test  
Result : negative

## Serious eye damage/eye irritation

### Components:

#### **SELEXIPAG:**

Species : Bovine cornea  
Result : Eye irritation  
Method : In vitro BCOP (Bovine Corneal Opacity and Permeability) assay

## Respiratory or skin sensitisation

### Components:

#### **SELEXIPAG:**

Test Type : In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)  
Result : negative

Test Type : KeratinoSens assay  
Result : positive

Test Type : Maximisation Test  
Exposure routes : Intradermal  
Species : Guinea pig  
Result : Not a skin sensitizer.  
Remarks : Not classified

## Germ cell mutagenicity

### Components:

#### **SELEXIPAG:**

Germ cell mutagenicity - Assessment : No evidence of mutagenicity based on weight of evidence.

## Carcinogenicity

### Components:

#### **SELEXIPAG:**

Species : Rat  
Exposure time : 2 y  
Dose : 100 mg/kg

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Result	: No evidence of carcinogenicity in animal studies.
Species	: Mouse
Exposure time	: 2 y
Dose	: 500 mg/kg
Result	: No evidence of carcinogenicity in animal studies.
Carcinogenicity - Assessment	: Animal testing did not show any carcinogenic effects.
<b>IARC</b>	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
<b>OSHA</b>	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
<b>NTP</b>	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

## Reproductive toxicity

### Components:

#### **SELEXIPAG:**

Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOEL: 60 mg/kg body weight
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Dose: 2, 6, 20 mg/kg/day Result: Not classified
	: Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Dose: 3, 10, 30 mg/kg Result: No adverse effects
Reproductive toxicity - Assessment	: Animal testing did not show any effects on fertility.
Teratogenicity - Assessment	: Did not show teratogenic effects in animal experiments.

## STOT - single exposure

No data available

## STOT - repeated exposure

### Components:

#### **SELEXIPAG:**

Assessment	: May cause damage to organs through prolonged or repeated
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exposure.

## Repeated dose toxicity

### Components:

#### **SELEXIPAG:**

Species	:	Rat
NOAEL	:	6 mg/kg
Application Route	:	Oral
Exposure time	:	26 weeks
Species	:	Dog
Application Route	:	Oral
Target Organs	:	Bone, Bone marrow, intestinal tract
Species	:	Dog
NOEL	:	2 mg/kg
Exposure time	:	39 weeks

## Aspiration toxicity

No data available

## Experience with human exposure

No data available

## Toxicology, Metabolism, Distribution

No data available

## Neurological effects

No data available

## Further information

No data available

## Other health hazards

No data available

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## SECTION 12. ECOLOGICAL INFORMATION

## Ecotoxicity

### Components:

#### **PROPYLENE GLYCOL:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 51,600 mg/l Exposure time: 96 h Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 43,500 mg/l Exposure time: 48 h
Toxicity to fish (Chronic toxicity)	:	NOEC: > 100 mg/l

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Toxicity to daphnia and other aquatic invertebrates : (Daphnia sp. (water flea)): 13,020 mg/l  
(Chronic toxicity) Exposure time: 7 d

## Persistence and degradability

### Components:

#### **PROPYLENE GLYCOL:**

Biodegradability : Biodegradation: 81 %  
Exposure time: 28 d

## Bioaccumulative potential

### Components:

#### **PROPYLENE GLYCOL:**

Bioaccumulation : Bioconcentration factor (BCF): < 100  
Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -0.92

### **titandioxide:**

Partition coefficient: n-octanol/water : Remarks: No data available

### **SELEXIPAG:**

Partition coefficient: n-octanol/water : Pow: 2.2

## Mobility in soil

### Components:

#### **PROPYLENE GLYCOL:**

Distribution among environmental compartments : Remarks: No data available

## Other adverse effects

### Components:

#### **PROPYLENE GLYCOL:**

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### 49 CFR

Not regulated as a dangerous good

## SECTION 15. REGULATORY INFORMATION

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Acute toxicity (any route of exposure)  
Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

#### Pennsylvania Right To Know

mannitol	87-78-5
PROPYLENE GLYCOL	57-55-6
titandioxide	13463-67-7

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## Maine Chemicals of High Concern

Product does not contain any listed chemicals

## Vermont Chemicals of High Concern

Product does not contain any listed chemicals

## Washington Chemicals of High Concern

Product does not contain any listed chemicals

## Other regulations

Restricted to professional users.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	: US. ACGIH Threshold Limit Values
J&J OEL/PBOEL HHC	: J&J OEL/PBOEL HHC
US WEEL	: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	: Time weighted average
J&J OEL/PBOEL HHC / STV	: STV: Surface Target Value
J&J OEL/PBOEL HHC / TWA	: Time weighted average
J&J OEL/PBOEL HHC /	: PBOEL-HHC
PBOEL-HHC	
US WEEL / TWA	: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals;

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OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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## Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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