

SAFETY DATA SHEET



Version 7.0	Revision Date: 2025/04/28	SDS Number: 100000015270	Date of last issue: 2024/04/27 Date of first issue: 2019/02/22
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SECTION 1. IDENTIFICATION

Substance name : Uptravi for injection, for intravenous use
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)

Skin irritation : Category 2
Eye irritation : Category 2A

GHS label elements

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Hazard pictograms :



Signal word :

Warning

Hazard statements :

H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements :

Prevention:

P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P362 Take off contaminated clothing and wash before reuse.

Other hazards

Warning! May form combustible dust concentrations in air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture :

Mixture

Chemical nature :

Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
phosphoric acid	7664-38-2	>= 1 - < 5
SELEXIPAG	475086-01-2	>= 0.1 - < 1
sodium hydroxide	1310-73-2	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled :

If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact :

Take off contaminated clothing and shoes immediately.
Wash off immediately with plenty of water.
If symptoms persist, call a physician.

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Wash contaminated clothing before reuse.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses.
Consult a physician.

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 delayed : Headache
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.
Avoid dust formation.
Avoid breathing dust.

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

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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.
Avoid inhalation, ingestion and contact with skin and eyes.
Keep away from heat and sources of ignition.

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.
Keep refrigerated.

Recommended storage temperature : 36 - 46 °F / 2 - 8 °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
phosphoric acid	7664-38-2	TWA	1 mg/m3	ACGIH
		STEL	3 mg/m3	ACGIH
		TWA	1 mg/m3	NIOSH REL
		ST	3 mg/m3	NIOSH REL
		TWA	1 mg/m3	OSHA Z-1
		TWA	1 mg/m3	OSHA P0
		STEL	3 mg/m3	OSHA P0
SELEXIPAG	475086-01-2	TWA	0.0028 mg/m3	J&J OEL/PBOEL HHC
		STV	0,028 mg/100cm ²	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J

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				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.			
sodium hydroxide	1310-73-2	C	2 mg/m3	ACGIH
		TWA	2 mg/m3	ACGIH
		C	2 mg/m3	NIOSH REL
		TWA	2 mg/m3	OSHA Z-1
		C	2 mg/m3	OSHA P0

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.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection Remarks : Disposable gloves

Eye protection : No special precautions required.

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 : powder, Vial

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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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
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 recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Exposure to light. Exposure to sunlight.

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Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Components:

phosphoric acid:

Acute oral toxicity : LD50 (Rat): 300 - 2,000 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

SELEXIPAG:

Acute oral toxicity : mortality (Rat): \geq 500 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

sodium hydroxide:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

Skin corrosion/irritation

Components:

phosphoric acid:

Result : Corrosive to skin

SELEXIPAG:

Method : in vitro skin corrosion test

Result : negative

sodium hydroxide:

Species : Rabbit

Result : Corrosive to skin

Remarks : Classification according to Regulation 1272/2008 Annex VI

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Serious eye damage/eye irritation

Components:

SELEXIPAG:

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

sodium hydroxide:

Species	:	Rabbit
Result	:	Corrosive

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

sodium hydroxide:

Species	:	human
Result	:	Does not cause skin sensitisation.

Germ cell mutagenicity

Components:

SELEXIPAG:

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

Genotoxicity in vivo	:	Result: negative Remarks: No significant adverse effects were reported
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Germ cell mutagenicity - Assessment	:	No evidence of mutagenicity based on in vitro and in vivo studies and expert judgment.
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Carcinogenicity

Components:

SELEXIPAG:

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

sodium hydroxide:

Carcinogenicity - Assessment : No information available.

IARC 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.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP 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

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Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Did not show teratogenic effects in animal experiments.

sodium hydroxide:

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

STOT - single exposure

No data available

STOT - repeated exposure

Components:

SELEXIPAG:

Assessment : May cause damage to organs through prolonged or repeated 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

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Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

sodium hydroxide:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 125 mg/l
Exposure time: 96 h

EC50 (Ceriodaphnia (water flea)): 40.4 mg/l
Exposure time: 48 h

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 22 mg/l
Exposure time: 15 min

Persistence and degradability

No data available

Bioaccumulative potential

Components:

phosphoric acid:

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

SELEXIPAG:

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

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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

: Skin corrosion or irritation
Serious eye damage or eye irritation

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

phosphoric acid	7664-38-2
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Pennsylvania Right To Know

Glycine	56-40-6
TWEEN 20	9005-64-5
phosphoric acid	7664-38-2
sodium hydroxide	1310-73-2

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

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Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

phosphoric acid	7664-38-2
sodium hydroxide	1310-73-2
No components listed on the New York City Hazardous Substances List	

New York City Hazardous Substances

phosphoric acid	7664-38-2
sodium hydroxide	1310-73-2

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

California List of Hazardous Substances

phosphoric acid	7664-38-2
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California Permissible Exposure Limits for Chemical Contaminants

phosphoric acid	7664-38-2
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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.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	: US. ACGIH Threshold Limit Values
ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	: J&J OEL/PBOEL HHC
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA P0	: USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	: Time weighted average
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
ACGIH / C	: Ceiling limit
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
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

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NIOSH REL / ST	: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
NIOSH REL / C	: Ceiling value not be exceeded at any time.
OSHA P0 / TWA	: 8-hour time weighted average
OSHA P0 / STEL	: Short-term exposure limit
OSHA P0 / C	: Ceiling limit
OSHA Z-1 / TWA	: 8-hour time weighted average

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; 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

This SDS received a major version update triggered by a change in Section 3.

Revision Date : 2025/04/28

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

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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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