

TOFACITINIB CITRATE
Effective adoption site

Bluepharma, Indústria Farmacêutica, S.A.

1- IDENTIFICATION OF THE SUBSTANCE
Material Name TOFACITINIB TABLETS 5mg / 10mg

CAS Nº 540737-29-9

EINECS Nº. -

Recommended use Pharmaceutical / Human medicinal product

Dosage Form Film-coated tablet

Appearance TOFACITINIB 5MG F.C. TABS. (SUN) US
Tablets are white, round biconvex tablets, embossed on one side with "T5"

TOFACITINIB 10MG F.C. TABS. (SUN) US
Tablets are white, round biconvex tablet, debossed with "T10" on one side

2- COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENT	CAS No.
ACTIVE SUBSTANCE	
TOFACITINIB CITRATE	540737-29-9
EXCIPIENTS	
CELLULOSE MICROCRYSTALLINE	9004-34-6
LACTOSE FAST FLO 100	63-42-3
CROSCARMELOSE SODIUM	74811-65-7
MAGNESIUM STEARATE	91031-63-9
VIVACOAT PC-1P-101	----
OPADRY OY-S-30913 BLUE	----

TOFACITINIB CITRATE
Effective adoption site

Bluepharma, Indústria Farmacêutica, S.A.

3- HAZARD IDENTIFICATION

ACTIVE SUBSTANCE			
SYMBOLS		Specific indications for pregnant and breastfeeding women	IT IS FORBIDDEN TO HANDLE THIS SUBSTANCE
		Signal word(s)	WARNING
		Classification according to Regulation (EC) No. 1272/2008 [CLP]	Acute toxicity, Oral (Category 4), H302 Reproductive toxicity (Category 2), H361fd

DESIGNATION OF HAZARDS	SAFETY WARNINGS
May impair fertility and cause adverse effects on the fetus May cause headaches, chest pain, and dizziness May cause nausea, vomiting, and serious heart problems	H302 - Harmful if swallowed H361d: Suspected of damaging fertility. Suspected of damaging the unborn child P201: Obtain special instructions before use P202: Do not handle until all safety precautions have been read and understood P264: Wash hands and other exposed area thoroughly after handling P280: Wear protective gloves/protective clothing/eye protection/face protection P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell P308+P313: IF exposed or concerned: Get medical advice/ attention P330: Rinse mouth P405: Store locked up P501: Dispose of contents in accordance with local, state or national legislation. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other Hazards: This product is a finished pharmaceutical dosage form (film-coated tablets), and handling this product presents minimal occupational exposure risk.

TOFACITINIB CITRATE
Effective adoption site

Bluepharma, Indústria Farmacêutica, S.A.

EXCIPIENTS (*)

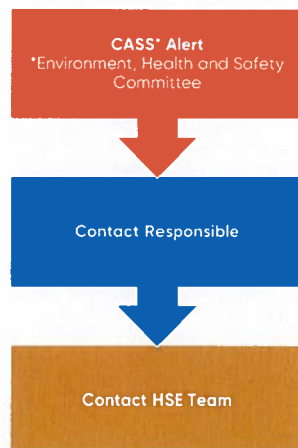
(*) the worst-case scenario for all excipients is assumed.

SYMBOLY		Specific indications for pregnant and breastfeeding women	IT IS FORBIDDEN TO HANDLE THIS SUBSTANCE (OPADRY OY-S-30913 BLUE)
		Signal word(s)	WARNING
		Classification according to Regulation (EC) No. 1272/2008 [CLP]	Carc. 2, H351 (inhalation) The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

DESIGNATION OF HAZARDS	SAFETY WARNINGS
Warning! Hazardous respirable dust may be formed when used. Do not breathe dust. Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.	H351 - Suspected of causing cancer. (inhalation) P201 - Obtain special instructions before use. P280 - Wear protective gloves, protective clothing, eye protection, face protection, or hearing protection. P308 + P313 - IF exposed or concerned: Get medical advice or attention. Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

TOFACITINIB CITRATE
Effective adoption site

Bluepharma, Indústria Farmacêutica, S.A.

4- FIRST-AID MEASURES

EYE CONTACT

Affected individual should remove contact lens, if present. In case of contact with eyes, rinse immediately with plenty of water or saline solution. Get medical attention if irritation occurs.

SKIN CONTACT

Remove/Take off immediately all contaminated clothing. Wash contaminated skin with soap and water. Get medical attention if irritation develops.

INHALATION

If inhaled, remove to fresh air. Get medical attention if symptoms appear. If exposed person is not breathing, give artificial respiration or oxygen applied by trained personnel.

INGESTION

Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. Never give anything by mouth to an unconscious person.

In case of accident or if you feel unwell, seek medical advice immediately.

TOFACITINIB CITRATE*Effective adoption site*

Bluepharma, Indústria Farmacêutica, S.A.

5- FIRE-FIGHTING MEASURES

- **Extinguishing media**

Suitable Extinguishing Media: Foam, dry powder or CO₂, Water spray.

Unsuitable extinguishing media: Do not use a heavy water stream.

- **Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or fire. May include oxides of carbon and Nitrogen.

- **Advice for fire-fighters**

A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

Keep fire exposed containers cool by spraying with water.

6- ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures**

Avoid contact with skin and eyes. Avoid inhalation of dusts. Wear suitable protective clothing, gloves and eyes or face protection. Provide adequate ventilation. Eliminate sources of ignition.

- **Environmental precautions**

Avoid release to the environment.

Spillages or uncontrolled discharges into watercourses must be alerted to the Environment Agency or other appropriate regulatory body.

7- HANDLING AND STORAGE

- **Precautions for safe handling**

Eliminate sources of ignition. Provide adequate ventilation.

Avoid inhalation of vapours. Avoid contact with skin and eyes. Wear suitable protective clothing. Handle the product with good industrial hygiene and safety procedures. Wash thoroughly after handling.

- **Conditions for safe storage**

Store in a well closed container at a temperature of 20°C to 25°C. Keep away from heat and sources of ignition. Avoid reaction with oxidising agents.

TOFACITINIB CITRATE*Effective adoption site*

Bluepharma, Indústria Farmacêutica, S.A.

8- EXPOSURE CONTROLS / PERSONAL PROTECTION

- **Engineering controls**

Provide adequate ventilation, including appropriate local extraction if dust is likely to be evolved.

- **Hand protection**

Double layer of nitrile gloves or chemically resistant material, checking integrity regularly.

- **Eye and face protection**

Sealed safety goggles or full face shield.

- **Body protection**

Laboratory coat or disposable chemical protective suit, fully covering clothing and skin.

- **Respiratory protection**

P3 filter respirator or equivalent, mandatory for any handling, even in small quantities.

9- PHYSICAL AND CHEMICAL PROPERTIES

- **Solubility**

Practically insoluble in water.

Practically insoluble in ethanol and slightly soluble to practically insoluble in methanol.

10- TOXICOLOGICAL INFORMATION

- **Information on toxicological effects**

Acute toxicity

INGESTION: Oral (rat) LD50: 500 mg/kg. May be harmful if swallowed

INHALATION: The material is not thought to produce adverse health effects or irritation of the respiratory tract.

SKIN CONTACT: Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.

EYE CONTACT: Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness. Slight abrasive damage may also result.

TOFACITINIB CITRATE*Effective adoption site*

Bluepharma, Indústria Farmacêutica, S.A.

11- ECOLOGICAL AND DISPOSAL INFORMATION

This substance contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

To be disposed of as hazardous waste. Disposal should be in accordance with local, state or national legislation.

12- TRANSPORT INFORMATION

This product is not classified as dangerous for transport via air (IATA), ground (DOT), or sea (IMDG).

Coimbra, April 07th, 2026

Ana Catarina Gomes
Indústria Farmacêutica, S.A.

Organizational Sustainability –Health & Safety Team Coordinator