XOSPATA® Tablets 40 mg

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Date of issue: 11/29/2018 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Tablet

Product Name: XOSPATA® Tablets 40 mg

Chemical Name: Proprietary

Generic Name: Gilteritinib

Formula: Proprietary

Synonyms: ASP2215

1.2. Intended Use of the Product

Use of the Drug Product, ASP2215: Pharmaceutical research, manufacturing and clinical use. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Astellas US LLC

1 Astellas Way

Northbrook, IL 60062

Tel.: 800-888-7704

www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003

Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

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 labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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).

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Gently wash with plenty of soap and water followed by rinsing with water. Call a POISON CENTER or doctor/physician if you feel unwell.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking, or redness persist.

First-aid Measures After Ingestion: Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

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

Symptoms/Injuries: Pharmaceutical. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.

Symptoms/Injuries After Inhalation: If tablet is crushed: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: If tablet is crushed: May cause skin irritation.

Symptoms/Injuries After Eye Contact: If tablet is crushed: May cause eye irritation.

Symptoms/Injuries After Ingestion: May be harmful if swallowed.

Chronic Symptoms: Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

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

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO_2), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Contact competent authorities after a spill.

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

Additional Hazards When Processed: Avoid breaking or crushing capsules.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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 (59° and 86 °F) [see USP Controlled Room Temperature]. Protect from light. Tight containers.

Incompatible Materials: strong acids, strong bases and strong oxidants.

7.3. Specific End Use(s)

Pharmaceutical research, manufacturing and clinical use. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Iron oxide (Fe2O3) (1309-37-1)		
USA ACGIH	ACGIH TWA (mg/m³)	5 mg/m³ (respirable particulate matter)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m³)	5 mg/m³ (dust and fume)
USA IDLH	US IDLH (mg/m³)	2500 mg/m³ (dust and fume)
USA OSHA	OSHA PEL (TWA) (mg/m³)	10 mg/m³ (fume) 15 mg/m³ (total dust) 5 mg/m³ (respirable fraction)

Titanium dioxide (13463-67-7)		
USA ACGIH	ACGIH TWA (mg/m³)	10 mg/m³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m³)	2.4 mg/m³ (CIB 63-fine)

		0.3 mg/m³ (CIB 63-ultrafine, including engineered nanoscale)
USA IDLH	US IDLH (mg/m³)	5000 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (total dust)

Talc (Mg3H2(SiO3)4) (14807-96-6)		
USA ACGIH	ACGIH TWA (mg/m³)	2 mg/m³ (particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen containing no asbestos fibers
USA NIOSH	NIOSH REL (TWA) (mg/m³)	2 mg/m³ (containing no Asbestos and <1% Quartz-respirable dust)
USA IDLH	US IDLH (mg/m³)	1000 mg/m³ (containing no asbestos and <1% quartz)

Magnesium stearate (557-04-0)		
USA ACGIH	ACGIH TWA (mg/m³)	10 mg/m³ (inhalable particulate matter) 3 mg/m³ (respirable particulate matter)

8.2. Exposure Controls

Appropriate Engineering Controls : Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment : Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical goggles or safety glasses.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : None required under normal product handling conditions. Use NIOSH-approved dust mask if dust has the potential to become airborne.

Environmental Exposure Controls : Do not allow the product to be released into the environment.

Consumer Exposure Controls : Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Solid

Appearance : Light yellow 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

Molecular Weight Of Active Ingredient : Proprietary

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.

10.5. Incompatible Materials: strong acids, strong bases and strong oxidants.

10.6. Hazardous Decomposition Products: Carbon oxides (CO, CO_2). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

XOSPATA® Tablets 40 mg	
ATE (Oral)	1,000.00 mg/kg body weight

ASP2215	
Lethal Oral Dose in Rats	300 mg/kg

Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	22 g/kg

Iron oxide (Fe2O3) (1309-37-1)	
LD50 Oral Rat	> 10000 mg/kg

Titanium dioxide (13463-67-7)	
LD50 Oral Rat	> 10000 mg/kg

Cellulose hydroxypropyl methyl ether (9004-65-3)	
LD50 Oral Rat	>= 4000 mg/kg

D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg

Magnesium stearate (557-04-0)	
LD50 Oral Rat	> 2000 mg/kg

Hydroxypropyl ether of cellulose (9004-64-2)	
LD50 Oral Rat	10200 mg/kg

Skin Corrosion/Irritation: Not classified

ASP2215	
Additional information	No local irritation studies have been conducted. Negative in in vitro 3T3 NRU phototoxicity assay

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Suspected of causing genetic defects.

ASP2215	
Additional information	Bacterial reverse mutation assay: Negative In vitro chromosomal aberration assay: Negative In vivo mouse micronucleus study: Positive

Carcinogenicity: Not classified

Iron oxide (Fe2O3) (1309-37-1)	
IARC group	3

Titanium dioxide (13463-67-7)	
IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Talc (14807-96-6)	
IARC group	3
National Toxicology Program (NTP) Status	Evidence of Carcinogenicity.

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

ASP2215	
Additional information	In a rat embryo-fetal development study, decreased body weight and food consumption in dams, teratogenicity and embryo-fetal deaths were observed at 30 mg/kg/day. The NOAEL was 10 mg/kg/day for dams and embryo-fetal development

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

ASP2215	
Additional information	In a rat 13-week repeated dose toxicity study, mortality was noted at 20 mg/kg/day. At 2.5 mg/kg/day and higher, target organ toxicities and secondary changes included; the eye, gastrointestinal tract, liver, kidney, lung, bone marrow, spleen, pancreas, various lymphoid tissue, and adrenal. After a 4-week recovery period, reversibility was shown. In a dog 4-week repeated dose toxicity study, the NOAEL was 1 mg/kg/day. The lethal dose level was 10 mg/kg/day. At 2.5 mg/kg/day and higher, target organ toxicities and secondary changes included; the eye, gastrointestinal tract, liver, gallbladder, kidney, lung, bone marrow, lymphoid tissue, pancreas, adrenal, testis, epididymis, and oral mucosa. After a 4-week recovery period, reversibility was shown. In a dog 13-week repeated dose toxicity study, the NOAEL was 1 mg/kg/day. The lethal dose level was 5 mg/kg/day. At 2.5 mg/kg/day or more, target organ toxicities and secondary changes were observed in the eye, gastrointestinal tract, liver, gallbladder, kidney, lung, broncus, bone marrow, various lymphoid tissue, pancreas, epithelial tissues including oral mucosa, urinary bladder, lacrimal gland, together with changes in organ weight and/or clinical pathology in some cases. After a 4-week recovery period, reversibility was shown.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: If tablet is crushed: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: If tablet is crushed: May cause skin irritation.

Symptoms/Injuries After Eye Contact: If tablet is crushed: May cause eye irritation.

Symptoms/Injuries After Ingestion: Harmful if swallowed.

Chronic Symptoms: Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Talc (14807-96-6)	
LC50 Fish 1	> 100 g/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])

12.2. Persistence and Degradability

No additional information available.

12.3. Bioaccumulative Potential

Talc (14807-96-6)	
BCF fish 1	(no known bioaccumulation)

12.4. Mobility in Soil

No additional information available.

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents and container according to local, regional, national, and international regulations.

Ecology – Waste Materials: This material is hazardous to the aquatic environment. Keep out of sewers and waterways. Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport.

14.2. In Accordance with IMDG Not regulated for transport.

14.3. In Accordance with IATA Not regulated for transport.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations Not applicable

15.2 US State Regulations Not applicable

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

Date of Preparation or Latest Revision : 11/29/2018

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

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.

Astellas US GHS SDS

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