ajanta pharma limited

# SAFETY DATA SHEET

**Divalproex Sodium delayed-release capsules USP 125 mg**

**EMERGENCY OVERVIEW**

**Divalproex Sodium delayed-release capsules** contain active drug substances Divalproex Sodium and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

**WARNING**: Accidental ingestion of large amounts may be harmful.

## Section 1. Identification of the substance(s)

**Identification of the product**

| | | |
|---|---|---|
| **Product name** | : | Divalproex Sodium delayed-release capsules USP 125 mg |
| **Chemical Formula** | : | Divalproex Sodium: $C_{16}H_{31}NaO_4$ |
| **Chemical Name** | : | **Divalproex Sodium:** Sodium hydrogen bis(2-propylpentanoate) |
| **Therapeutic Category** | : | Anti- epileptic drug |
| **Marketed by** | : | **Ajanta Pharma USA Inc.**<br>440 US Highway 22 East, Bridgewater, NJ 08807.<br>Made in India |
| **Contact Information** | : | 1-855-664-7744 |

## Section 2. Hazard (s) Identification

**Potential Health Effects** :

**Inhalation:** Not expected to be hazardous in final pharmaceutical form.

**Eye Contact:** Not expected to be hazardous in final pharmaceutical form.

**Skin Contact:** Not expected to be hazardous in final pharmaceutical form.

**Indigestion:** Health injuries are not known or expected under normal use. Exposures above clinical dosage could

result in adverse effects. Minor occupational exposures are not expected to be harmful.

**Effects of Overexposure** : The potential for exposure is reduced in finished pharmaceutical dosage form.

## Section 3. Composition / information on ingredients

| Active ingredient | Exposure Limit | CAS No. |
|---|---|---|
| Divalproex Sodium | Not found | [76584-70-8] |

**Inactive ingredients**: 125 mg Divalproex sodium delayed-release capsules, USP (sprinkle): sugar spheres (contains sucrose and maize starch), ethylcellulose, triethyl citrate, talc, silicon dioxide, and magnesium stearate.

The capsule shells contain gelatin, FD&C Blue 1, D&C Red 28, and titanium dioxide.
Each capsule is printed with black pharmaceutical ink which contains: shellac, propylene glycol, black iron oxide and potassium hydroxide

## Section 4. First-aid measures

**General** :

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Never give anything by mouth to an unconscious person.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Overdose Treatment** : Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice

## Section 5. Fire-fighting measures

**Flash Point** : Not Reported

| | | |
|---|---|---|
| **Extinguishing Media** | : | Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material. |
| **Fire and Explosion Hazard** | : | This material is assumed to be combustible. Keep it away from the open fires. |
| **Fire Fighting Procedures** | : | As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing. |
| **Hazardous Combustion by Products** | : | Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, oxides of sodium, hydrogen chloride |

## Section 6. Accidental release measures

| | | |
|---|---|---|
| **Personal Precautions** | : | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. |
| **Environmental Protections** | : | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. |
| **Clean-up Methods** | : | Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains. |
| **Additional Consideration for Large Spills** | : | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. |

## Section 7. Handling and storage

| | | |
|---|---|---|
| **General Handling** | : | Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact to eyes, skin and clothing. When handling, use appropriate personal protective equipment. |
| **Storage** | : | Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. |

## Section 8. Exposure controls / personal protection

| | | |
|---|---|---|
| **Respiratory Protection** | : | Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate. |
| **Skin Protection** | : | Skin protection is not normally necessary, however it is good practice to avoid direct contact with chemical to use suitable gloves when handling. |
| **Eye protection** | : | Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses. |
| **Protective Clothing** | : | Protective clothing is not normally necessary, however it is good practice to use apron. |

## Section 9. Physical and chemical properties

**Appearance** : **125 mg**: Blue transparent/white opaque size "0" hard gelatin capsules, filled with white to off-white colored pellets.

| Presentations and NDC Codes | Strengths |
|---|---|
| | **125 mg** |
| Bottles of 100's pack | 27241-115-01 |
| Bottles of 500's pack | 27241-115-05 |
| Bottles of 1000's pack | 27241-115-10 |

| | | |
|---|---|---|
| **Solubility in water** | : | No Data Available |
| **Odor** | : | Odorless |
| **Boiling point** | : | No Data Available |
| **Melting Point** | : | No Data Available |
| **Evaporation rate** | : | No Data Available |
| **Specific gravity** | : | No Data Available |
| **Vapor density** | : | No Data Available |
| **Reactivity in water** | : | No Data Available |
| **Evaporation rate** | : | No Data Available |
| **Percentage Volatile by volume** | : | No Data Available |
| **Vapor pressure** | : | No Data Available |
| **Other information** | : | No data Available |

## Section 10. Stability and reactivity

| | | |
|---|---|---|
| **Condition to avoid** | : | Avoid exposure to extreme heat, light and moisture. |
| **Stable** | : | Stable under normal ambient and anticipated storage and handling conditions. |
| **Decomposition Products** | : | No data available |
| **Hazardous Reaction** | : | No data available. In finished dosage form there is least possibility that product will undergo any hazardous reaction. |
| **Incompatibilities** | : | No data available. |

## Section 11. Toxicological information

| | | |
|---|---|---|
| **General** | : | Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation. |
| **Target organ** | : | Eye contact, Skin contact and inhalation is not great risk as this product is orally administered tablet formulation. |
| **Acute Toxicity** | : | No data available |

## Section 12. Ecological information

No data available on Ecotoxicity of API. In the finished product form there is no potential for air borne contamination since the product is in compressed tablet form.

## Section 13. Disposal Consideration

**Waste Disposal Considerations:** Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.

**At home:** Discard away from children's reach.

## Section 14. Transport information

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.
**DOT:** Not Regulated
**IATA:** Not Regulated
**IMDG**: Not Regulated

## Section 15. Regulatory information

**DEA:** Divalproex sodium is not a controlled substance.

**FDA:** Divalproex sodium is an approved prescription medication.

## Section 16. Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

**Date:** Apr 22, 2022

## SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION