

Safety Data Sheet
DAPSONE TABLETS USP
Strength: 25mg and 100mg
Pack Size: 30's, 100's Tablets per bottle

EMERGENCY OVERVIEW

Each Dapsone tablets intended for oral administration contains Dapsone and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

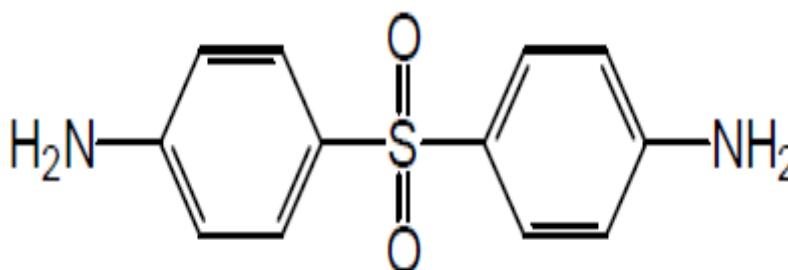
Section 1. Identification

Identification of the product

Product Name: Dapsone USP, 4,4'-diaminodiphenylsulfone (DDS).

Formula: C₁₂H₁₂N₂O₂S

Chemical Name:



Manufacturer / supplier identification

Company: Zydus Pharmaceuticals Ltd. Unit I

Address: Zydus Pharmaceuticals Limited (Unit I), Sub Plot No- 20 &21, Pharmez-Special Economic Zone, Sarkhej- Bavla Road N.H. No. 8A, Village Matoda, Taluka. Sanand, Dist. Ahmedabad-382213, Gujarat State, India

Contact for information: Tel: +91-2717690241

Emergency Telephone No. Tel: +91-2717690300

Recommended use / Therapeutic Category Dapsone Tablets USP is a primary treatment for Dermatitis herpetiformis. It is an antibacterial drug for susceptible cases of leprosy.

Restriction on Use / Contraindications: Dapsone tablets are contraindicated in:
• Patients with Hypersensitivity to Dapsone and/or its derivatives.

Section 2. Hazard(s) Identification

Dose and Administration

Dose Selection

The dosage should be individually titrated starting in adults with 50 mg daily and correspondingly smaller doses in children. If full control is not achieved within the range of 50 mg to 300 mg daily, higher doses may be tried. Dosage should be reduced to a minimum maintenance level as soon as possible.

In responsive patients there is a prompt reduction in pruritus followed by clearance of skin lesions. There is no effect on the

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Adverse Effects	<p>gastrointestinal component of the disease. Dapsone levels are influenced by acetylation rates. Patients with high acetylation rates, or who are receiving treatment affecting acetylation may require an adjustment in dosage.</p> <p>A strict gluten free diet is an option for the patient to elect, permitting many to reduce or eliminate the need for Dapsone; the average time for dosage reduction is 8 months with a range of 4 months to 2 1/2 years and for dosage elimination 29 months with a range of 6 months to 9 years.</p> <p>The following serious adverse reactions are described elsewhere in the labelling:</p> <ul style="list-style-type: none">• Nausea• Vomiting• Abdominal Pain• Pancreatitis• Vertigo• Blurred vision• Tinnitus• Insomnia• Psychosis• Phototoxicity pulmonary eosinophilia,• Tachycardia, albuminuria• Nephrotic syndrome• Hypoalbuminemia without proteinuria• Renal papillary necrosis• Male infertility• D-induced Lupus erythematosus and an infectious• Mononucleosis-like syndrome.
Over Dose Effect	<p>Nausea, vomiting, hyperexcitability can appear a few minutes up to 24 hours after ingestion of an overdosage. Methaemoglobin induced depression, convulsions or severe cyanosis requires prompt treatment. In normal and methaemoglobin reductase deficient patients, methylene blue, 1 mg/kg to 2 mg/kg of body weight, given slowly intravenously, is the treatment of choice. The effect is complete in 30 minutes, but may have to be repeated if methaemoglobin reaccumulates. For non-emergencies, if treatment is needed, methylene blue may be given orally in doses of 3 mg/kg to 5 mg/kg every 4 hours to 6 hours. Methylene blue reduction depends on G6PD and should not be given to fully expressed G6PD deficient patients.</p>
Contraindications	<p>Dapsone tablets are contraindicated in:</p> <ul style="list-style-type: none">• Patients with hypersensitivity to Dapsone and/or its derivatives.
Pregnancy Comments	<p>Teratogenic Effects. Animal reproduction studies have not been conducted with Dapsone. Extensive, but uncontrolled experience and two published surveys on the use of Dapsone in pregnant women have not shown that Dapsone increases the risk of foetal abnormalities if administered during all trimesters of pregnancy or can affect reproduction capacity. Because of</p>

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the lack of animal studies or controlled human experience, Dapsone should be given to a pregnant woman only if clearly needed. In general, for leprosy, USPHS at Carville recommends maintenance of Dapsone. Dapsone has been important for the management of some pregnant D.H. patients

Nursing Mothers

Dapsone is excreted in breast milk in substantial amounts. Haemolytic reactions can occur in neonates.

Pediatric Use

Pediatric patients are treated on the same schedule as adults but with correspondingly smaller doses.

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Dapsone	22 mcg/day	80-08-0
Inactive Ingredients:		
Microcrystalline Cellulose	-	-
Croscarmellose Sodium	-	-
Hydroxypropyl Cellulose	-	-
Colloidal Silicon Dioxide	-	-
Magnesium Stearate	-	-

Section 4. First -aid measures

- Immediately remove any clothing contaminated by the product. Move out of dangerous area. Consult a physician and show this safety data sheet.
- **After inhalation:**
Move person to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical aid
- **After skin contact:**
Immediately flush skin with running water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Obtain medical aid immediately.
- **After eye contact:**
Immediately flush open eyes with running water for at least 15 minutes. Obtain medical aid immediately.
- **After swallowing:**
Do NOT induce vomiting without medical advice. Rinse mouth with water. Never administer anything by mouth to an unconscious person. Obtain medical aid immediately.
- **Most important symptoms and effects, acute and delayed:**
No further relevant information available.

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Overdose
Treatment

Nausea, vomiting, hyperexcitability can appear a few minutes up to 24 hours after ingestion of an overdose. Methemoglobin induced depression, convulsions or severe cyanosis requires prompt treatment. In normal and methemoglobin reductase deficient patients, methylene blue, 1 mg/kg to 2 mg/kg of body weight, given slowly intravenously, is the treatment of choice. The effect is complete in 30 minutes, but may have to be repeated if methemoglobin reaccumulates. For non-emergencies, if treatment is needed, methylene blue may be given orally in doses of 3 mg/kg to 5 mg/kg every 4 hours to 6 hours. Methylene blue reduction depends on G6PD and should not be given to fully expressed G6PD deficient patients.

Section 5. Fire -fighting measures

Extinguishing media

Suitable extinguishing agents: Use water spray, dry chemical, carbon dioxide, or chemical foam.

Special hazards arising from the substance or mixture

Nitrogen oxides, Sulphur oxides, Carbon oxides.

Advice for firefighters

As in any fire, wear a MSHA/NIOSH-approved or equivalent, pressure demand, self-contained breathing apparatus and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Protective equipment:

Hand protection: Gloves Skin and

Body protection: Lab coat

Specific hazards arising from the chemical : Nitrogen oxides, Sulphur oxides, Carbon oxides.

Section 6. Accidental Release Measures

Personal

precautions,

protective equipment

and emergency

procedures

Wear protective equipment and keep unprotected personnel away. Ensure adequate ventilation. Remove all sources of ignition. Prevent further leak or spill if safe to do so.

Environmental

precautions:

Do not let product enter drains, other waterways, or soil.

Methods

material

containment

cleaning up

and

for

and

Prevent further leak or spill if safe to do so. Vacuum, sweep up, or absorb with inert material and place into a suitable disposal container. Consult local regulations for disposal.

Section 7. Handling and Storage

Storage: Store in a tightly-closed container when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep away from sources of ignition. Light sensitive.

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Precautions for safe handling: Avoid contact with skin, eyes, and personal clothing. Wash hands thoroughly after handling. Avoid breathing fumes. Use only with adequate ventilation. Wear suitable protective clothing, gloves, and eye/face protection. Keep away from sources of ignition. Minimize dust generation and accumulation. Keep container tightly closed. Open and handle container with care. Do not eat, drink, or smoke while handling.			
Section 8. Exposure controls / personal protection			
Respiratory Protection	Use NIOSH/MSHA or CEN approved respirator. Wear protective lab coat and boots.		
Skin protection	Wear chemical splash goggles.		
Eye/face protection	Protective clothing is not normally necessary; however, it is good practice to use apron.		
Protective Clothing			
Exposure guidelines	General ventilation normally adequate.		
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.		
Engineering controls	Avoid contact with skin, eyes, and clothing. Wash hands before breaks and immediately after handling the product. Facilities storing or utilizing this material should be equipped with an eyewash fountain. Use adequate ventilation to keep airborne.		
Section 9. Physical and chemical properties			
Appearance	Description of Dapsone Tablets USP 25mg : White to off white, uncoated round shaped tablets, score line on one side and debossed with "1713" on other side. The tablets should be free of all physical defects. Description of Dapsone Tablets USP 100 mg : White to off white, uncoated round shaped tablets, score line on one side and debossed with "1714" on other side. The tablets should be free of all physical defects.		
Solubility	Not available.	Odour	Not available.
Boiling point	Not available.	Melting Point	173-181°C
Evaporation rate	Not available.	Vapour density	Not available.
Reactivity in water	Not available.	Vapour pressure	Not available.
% Volatile by volume	Not available.	Specific gravity	Not available.
Section 10. Stability and Reactivity			
Conditions to avoid	Dust generation. Light.		
Reactivity	Stable		

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Stable	Stable under recommended temperatures and pressures.
Chemical stability	Stable under recommended temperatures and pressures.
Hazardous reactions	No Data available
Decomposition products	No Data available
Incompatible materials	Strong Oxidizing agent
Section 11. Toxicological information	
Symptoms related to the physical, chemical and Toxicological characteristics	Skin contact may result in inflammation characterized by itching, scaling, reddening, blistering, pain or dryness. Eye contact may result in redness, pain or severe eye damage. Inhalation may cause irritation of the lungs and respiratory system. Overexposure may result in serious illness or death.
Information on toxicological effects	
Acute toxicity	No Data available
Further information	NA
Carcinogenicity	Inflammation of the eye is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering.
Section 12. Ecological information	
No data available on ecotoxicity.	
Section 13. Disposal Consideration	
Dispose of product and contaminated packaging in accordance with all local, state, and federal environmental control regulations.	
Section 14. Transport Information	
The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN	
Section 15. Regulatory Information	
Generic Medicine. Under Approval by USFDA & the ANDA Number is 220103	
Section 16. Other information	
None	

Date of issue: 26/02/26

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.