

## SAFETY DATA SHEET



GlaxoSmithKline

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

<b>Material</b>	<b>DORALESE TILTAB TABLETS</b>
<b>Synonyms</b>	DORALESE TABLETS 20 MG * INDORAMIN HYDROCHLORIDE, FORMULATED PRODUCT
<b>Company Name</b>	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK
	UK General Information: +44-20-8047-5000
	Transport Emergency (EU) +44-1865-407333
	Medical Emergency +1-612-221-3999, Ext 221
	Information and Advice: US number, available 24 hours Multi-language response
	 GlaxoSmithKline, Corporate Environment, Health & Safety 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 US
	US General Information: +1-888-825-5249
	Transport Emergency (non EU) +1-703-527-3887
	US number, available 24 hours Multi-language response

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
INDORAMIN HYDROCHLORIDE	38821-52-2	8
NON-HAZARDOUS INGREDIENTS	Unassigned	92

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>* Health</b>	Caution - Pharmaceutical agent. Exposure might occur via skin; eyes. Possible effects of overexposure in the workplace include: dizziness; increased heart rate. Health effects information is based on hazards of components.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### 4. FIRST-AID MEASURES

<b>Ingestion</b>	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS**

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
<b>* Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Antidotes</b>	No specific antidotes are recommended.

**5. FIRE-FIGHTING MEASURES**

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

**6. ACCIDENTAL RELEASE MEASURES**

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.

**7. HANDLING AND STORAGE****HANDLING**

**General Requirements** Avoid breaking or crushing tablets.

**STORAGE**

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

<b>INGREDIENT</b>	INDORAMIN HYDROCHLORIDE
<b>GSK Occupational Hazard Category</b>	2
<b>GSK Occupational Exposure Limit</b>	400 MCG/M3 (8 HR TWA)
<b>* Other Equipment or Procedures</b>	Wear appropriate clothing to avoid skin contact.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

<b>Colour</b>	Light yellow.
<b>Physical Form</b>	Film-coated tablet.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>* Inhalation Toxicity</b>	No studies have been conducted.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Irritation is not expected following direct contact with eyes.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Sensitisation</b>	Sensitisation (allergic skin reaction) is not expected.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
<b>* Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: an anti-adrenergic agent.
<b>* Other Adverse Effects</b>	Overexposure in the workplace might have the following effects: dizziness; increased heart rate.

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
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## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this product.

## 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification and Labelling**

**Transport Information** Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

<b>15. REGULATORY INFORMATION</b>
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The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**\* EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

**US OSHA Standard (29 CFR Part 1910.1200)**

**Classification** This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

**Other US Regulations**

**TSCA Status** Exempt

<b>16. OTHER INFORMATION</b>
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**References** GSK Hazard Determination

**Date Approved/Revised** 17-Aug-2005

**SDS Version Number** 8

**SDS Sections Updated****Sections**

COMPOSITION / INFORMATION ON INGREDIENTS  
EXPOSURE CONTROLS / PERSONAL PROTECTION

FIRST-AID MEASURES

HAZARDS IDENTIFICATION  
REGULATORY INFORMATION  
TOXICOLOGY INFORMATION

**Subsections**

Exposure Controls  
Other Equipment or Procedures  
Health Surveillance Procedures  
Medical Conditions Caused or Aggravated by Exposure  
Health  
  
Inhalation Toxicity  
Other Adverse Effects  
Pharmacological Effects

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.