

SAFETY DATA SHEET



ALKEM

Dronabinol Capsules, USP 2.5 mg, 5 mg and 10 mg

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1. IDENTIFICATION

Material	Dronabinol Capsules, USP 2.5 mg, 5 mg and 10 mg
Recommended Use	Rx Pharmaceutical for human use
Manufacturer	Alkem Laboratories Ltd. Mumbai - 400013, INDIA.
Distributor	Ascend Laboratories, LLC Parsippany, NJ 07054
Contact Phone Number	001-201-476-1977

2. HAZARD(S) IDENTIFICATION

Label elements	
Hazard symbol	None
Signal word	None
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Not applicable.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS No.	Ingredients	CAS No.
Dronabinol	1972-08-3	Sesame Oil	8008-74-0
Gelatin	9000-70-8	Ferrosoferric Oxide	131-761-9
Glycerin	56-81-5	Ferric Oxide Red	1309-37-1
Titanium Dioxide	13463-67-7	Ferric Oxide Yellow	51274-00-1

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4. FIRST-AID MEASURE

Eye contact	– Rinse with water. Get medical attention if irritation develops and persists.
Skin contact	– Wash off with soap and water. Get medical attention if irritation develops and persists.
Inhalation	– Move to fresh air. Call a physician if symptoms develop or persist.
Ingestion	– Rinse mouth. Get medical attention if symptoms occur. Do not induce vomiting.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Treat symptomatically
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. FIRE-FIGHTING MEASURE

Suitable extinguishing media	– Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	– Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards during firefighting	– During fire, gases hazardous to health may be formed.
Special protective equipment for fire-fighters	– Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	– Move containers from fire area if you can do so without risk.
Specific methods	– Use standard firefighting procedures and consider the hazards of other involved materials.

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General fire hazards – No unusual fire or explosion hazards noted.

6. ACCIDENTAL RELEASE MEASURES

**Personal precautions
Protective equipment and
emergency procedure**

Keep unnecessary personnel away.

**Method and material
For containment and
cleaning up**

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. HANDLING AND STORAGE

Handling

Observe good industrial hygiene practices.

**Conditions for safe
storage, including any
incompatibilities**

Dronabinol capsules should be packaged in a well-closed container and stored in a cool environment between 8° and 15°C (46° and 59°F) and alternatively could be stored in a refrigerator. Protect from freezing.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational exposure
limits**

This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.

Biological limit values

No biological exposure limits noted for the ingredient(s).

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Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Hand protection

For prolonged or repeated skin contact use suitable protective gloves.

Other

Wear suitable protective clothing. Use impervious gloves.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Strength	Description	Packs	NDC No
2.5 mg	White capsules (Identified M2)	Bottle of 60 capsules	67877-753-60
5 mg	Dark brown capsules (Identified M5)	Bottle of 60 capsules	67877-754-60
10 mg	Orange capsules (Identified MX)	Bottle of 60 capsules	67877-755-60

10. STABILITY AND REACTIVITY

Reactivity

- The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability

- Stable under normal condition

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Possibility of hazardous reactions	– None known.
Conditions to avoid	– Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible Materials	– Strong oxidizing agents. This product may react with strong alkalies.
Hazardous decomposition products	– No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation.

12. ECOLOGICAL INFORMATION

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	Readily biodegradable
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. DISPOSAL CONSIDERATION

Disposal instructions	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations.

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14. TRANSPORT INFORMATION

Transport in combination with Foodstuffs only, avoiding contact with chemicals, dust and aromas.

15. REGULATORY INFORMATION

This Section Contains Information relevant to compliance with other Federal and/or state laws.

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.

Alkem or Asend shall not be held liable for any damage resulting from handling or from contact with the above product. Alkem or Asend reserves the right to revise this SDS.

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

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