SAFETY DATA SHEET

Strength: 0.1 MG

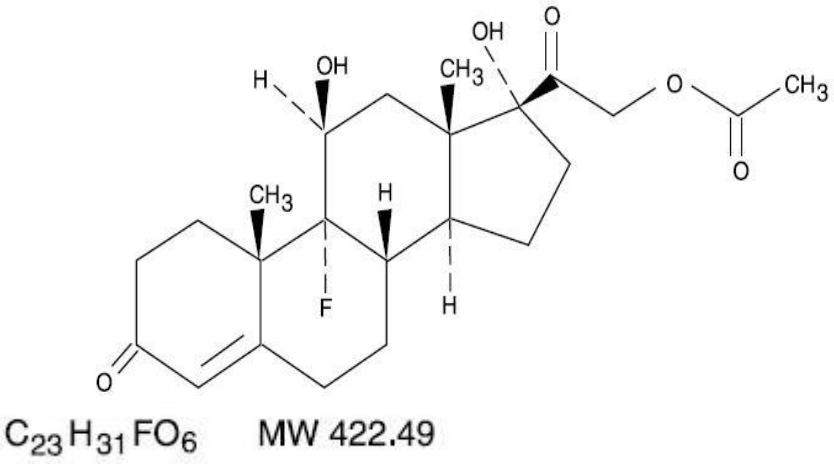
FLUDROCORTISONE ACETATE TABLETS, USP 0.1 MG

Pack Size:100s 500s Tablets per bottle, **Revision No.:** 00

EMERGENCY OVERVIEW

Each **Fludrocortisone Acetate Tablets**, **USP 0.1mg** intended for oral administration contains **Fludrocortisone acetate** and excipients generally considered to be non-toxic and non-hazardous in small amounts under conditions of normal occupational exposure.

Section 1. IDENTIFICATION OF THE PRODUCT

Product Name:	**FLUDROCORTISONE ACETATE TABLETS, USP 0.1 MG**
Active Pharmaceutical Ingredient:	**Fludrocortisone acetate**
Formula:	C23H31FO6
Chemical Name:	9-fluoro-11 β , 17, 21-trihydroxypregn-4-ene-3, 20-dione 21-acetate
Structure:	

$C_{23}H_{31}FO_6$ MW 422.49

Manufacturer / supplier identification

Company:	Zydus Lifesciences Limited
Address:	Survey No. 417, 419 & 420, Sarkhej – Bavla National Highway No. 8A, Village – Moraiya, Taluka – Sanand, Dist.- Ahmedabad - 382 210, Gujarat State, India.
Contact for information:	Tel.: + 91- 2717-666200
Emergency Telephone No.	Tel. : +91-079-71800000
US Customer Service No.	Tel.: + 1 (877) 993 8779
Therapeutic Category:	Corticosteroid
Mechanism of Action:	Fludrocortisone is a synthetic mineralocorticoid used to replace endogenous aldosterone in conditions resulting in missing or inadequate endogenous synthesis. It acts on the kidneys to increase both sodium reabsorption and potassium excretion.
Indications:	Fludrocortisone acetate tablets are indicated as partial replacement therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome.

Recommended usage:

Fludrocortisone can be taken orally with or without a meal. Primary adrenal cortical insufficiency: The usual dosage for primary adrenal cortical insufficiency is 0.1 mg daily, which can be increased to 0.2 mg daily. However, if hypertension develops, the dosage should be reduced to 0.05 mg per day.
The usual dose is 0.1 mg of Florinef (fludrocortisone) Acetate daily, although dosage ranging from 0.1 mg three times a week to 0.2 mg daily has been employed. In the event transient hypertension develops as a consequence of therapy, the dose should be reduced to 0.05 mg daily.

Restriction on Use / Contraindications:

Corticosteroids are contraindicated in patients with systemic fungal infections and in those with a history of possible or known hypersensitivity to these agents.

Section 2. HAZARDS IDENTIFICATION

DOSAGE AND ADMINISTRATION:

Dosage depends on the severity of the disease and the response of the patient. Patients should be continually monitored for signs that indicate dosage adjustment is necessary, such as remission or exacerbations of the disease and stress (surgery, infection, trauma)

Addison's Disease

In Addison's disease, the combination of fludrocortisone acetate tablets with a glucocorticoid such as hydrocortisone or cortisone provides substitution therapy approximating normal adrenal activity with minimal risks of unwanted effects.
The usual dose is 0.1 mg of fludrocortisone acetate tablets daily, although dosage ranging from 0.1 mg three times a week to 0.2 mg daily has been employed. In the event transient hypertension develops as a consequence of therapy, the dose should be reduced to 0.05 mg daily. Fludrocortisone acetate tablets are preferably administered in conjunction with cortisone (10 mg to 37.5 mg daily in divided doses) or hydrocortisone (10 mg to 30 mg daily in divided doses).

Salt-Losing Adrenogenital Syndrome

The recommended dosage for treating the salt-losing adrenogenital syndrome is 0.1 mg to 0.2 mg of fludrocortisone acetate tablets daily.

ADVERSE EFFECTS:

Most adverse reactions are caused by the drug's mineralocorticoid activity (retention of sodium and water) and include hypertension, edema, cardiac enlargement, congestive heart failure, potassium loss, and hypokalemic alkalosis.Other adverse reactions that may occur following the administration of a corticosteroid are necrotizing angiitis, thrombophlebitis, aggravation or masking of infections, insomnia, syncopal episodes, and anaphylactoid reactions.

OVER DOSE EFFECT: Development of hypertension, edema, hypokalemia, excessive increase in weight, and increase in heart size are signs of overdosage of fludrocortisone acetate. When these are noted, administration of drugs should be discontinued, after which the symptoms will usually subside within several days; subsequent treatment with fludrocortisone acetate should be with a reduced dose. Muscular weakness may develop due to excessive potassium loss and can be treated by administering a potassium supplement. Regular monitoring of blood pressure and serum electrolytes can help to prevent overdosage

PREGNANCY COMMENTS:

Pregnancy: Teratogenic Effects

Adequate animal reproduction studies have not been conducted with fludrocortisone acetate. However, many corticosteroids have been shown to be teratogenic in laboratory animals at low doses.

Teratogenicity of these agents in man has not been demonstrated. It is not known whether fludrocortisone acetate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fludrocortisone acetate should be given to a pregnant woman only if clearly needed.

WARNINGS & PRECAUTIONS:

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. If an infection occurs during fludrocortisone acetate therapy, it should be promptly controlled by suitable antimicrobial therapy.

Prolonged use of corticosteroids may produce posterior sub capsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

The use of fludrocortisone acetate in patients with active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant corticosteroids.

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chicken pox or measles and, if exposed, to obtain medical advice.

Advise the patient to use the medicine only as directed, to take a missed dose as soon as possible, unless it is almost time for the next dose, and not to double the next dose.

Inform the patient to keep this medication and all drugs out of the reach of children.

Drug Interactions:

When administered concurrently, the following drugs may interact with adrenal corticosteroids.

Amphotericin B or potassium-depleting diuretics (benzothiadiazines and related drugs, ethacrynic acid and furosemide)—enhanced hypokalemia. Check serum potassium levels at frequent intervals; use potassium supplements if necessary.

Digitalis glycosides—enhanced possibility of arrhythmias or digitalis toxicity associated with hypokalemia. Monitor serum potassium levels; use potassium supplements if necessary.

Oral anticoagulants—decreased prothrombin time response. Monitor prothrombin levels and adjust anticoagulant dosage accordingly.

Antidiabetic drugs (oral agents and insulin)—diminished antidiabetic effect. Monitor for symptoms of hyperglycemia; adjust dosage of antidiabetic drug upward if necessary.

Aspirin—increased ulcerogenic effect; decreased pharmacologic effect of aspirin. Rarely salicylate toxicity may occur in patients who discontinue steroids after concurrent high-dose aspirin therapy. Monitor salicylate levels or the therapeutic effect for which aspirin is given; adjust salicylate dosage accordingly if effect is altered.

Barbiturates, phenytoin, or rifampin—increased metabolic clearance of fludrocortisone acetate because of the induction of hepatic enzymes. Observe the patient for possible diminished effect of steroid and increase the steroid dosage accordingly.

Anabolic steroids (particularly C-17 alkylated androgens such as oxymetholone, methandrostenolone, norethandrolone, and similar compounds)—enhanced tendency toward edema. Use caution when giving these drugs together, especially in patients with hepatic or cardiac disease.

Vaccines—neurological complications and lack of antibody response

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Exposure	CAS No.
Principle Component :		
Fludrocortisone acetate	Not Found	514-36-3
Inactive ingredients :		
croscarmellose sodium	Not Found	74811-65-7
lactose monohydrate	Not Found	10039-26-6
microcrystalline cellulose	Not Found	9004-34-6
Magnesium stearate	Not Found	557-04-0

Section 4. FIRST - AID MEASURES

Description of First Aid Measures

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. 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.

Section 5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all firefighting activities, wear appropriate protective equipment, including self contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

Section 6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.
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

Storage	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat. Dispense in a tightly-closed, light-resistant container (USP).
Specific end use	Pharmaceutical drug product
Precautions for safe handling	If Tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal

protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	**Tablets**
Description	Fludrocortisone Acetate Tablets, USP 0.1 mg — Each white to off-white, round, biconvex, uncoated tablet debossed with ‘1861’ on one side and scored on other side. They are available as follows: Bottles of 100 with child resistant-closure: NDC 72578-164-01 Bottles of 500: NDC 72578-164-05
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

The product is stable

Section 11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility	Adequate studies have not been performed in animals to determine whether fludrocortisone acetate has carcinogenic or mutagenic activity or whether it affects fertility in males or females.

Section 12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number 219251

Section 16. OTHER INFORMATION

Refer Product Packing Insert for more details

Date of issue: 19th Nov , 2024 **Superseded edition:** NA

The information presented in the safety data sheet is, to the best of our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.