

# **SUMMARY OF PRODUCT CHARACTERISTICS**



**ACCRETION PHARMACEUTICALS**

29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, Vasna-Chacharwadi,  
Tal. Sanand, Dist. Ahmedabad, Gujarat-382213

<b>BRAND NAME:</b>	<b>FLUCOXEL</b>
<b>GENERIC NAME:</b>	<b>FLUCONAZOLE DUSTING POWDER 2 % W/W</b>

**Product Characteristic Summary**

Enclosed.



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**1. Name of drug product**

FLUCONAZOLE DUSTING POWDER 2 % W/W

**1.1 (Trade) name of product**

FLUCOXEL

**1.2 Strength**

Each Unit Contains:

Fluconazole BP..... 2 % W/W

Excipients..... Q.S.

**1.3 Pharmaceutical Dosage Form**

Powder for topical application

**ACCRETION PHARMACEUTICALS**29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, Vasna-Chacharwadi,  
Tal. Sanand, Dist. Ahmedabad, Gujarat-382213**BRAND NAME:****FLUCOXEL****GENERIC NAME:****FLUCONAZOLE DUSTING POWDER 2 % W/W****2. Qualitative & Quantitative Composition****2.1 Qualitative Declaration**

Each Unit Contains:

Fluconazole BP..... 2 % W/W

Excipients..... Q.S.

**2.2 Quantitative Declaration****Batch Formula:****Batch Size:450 kg**

Sr. No.	Ingredients	Grade	Rationale	Label Claim	Overages (%)	Quantity/ 100gm jar (in mg)	Quantity/ Batch(Kg)
1.	Fluconazole	BP	Active	2 % w/w	--	2000.000	9.000
2	Starch	BP	Lubricant	--	--	3800.000	17.100
3	Jasmine Flavour	I H S	Fragrance	--	--	200.000	0.900
4.	Purified Talc base	BP	Moisturising agent	--	--	Q.S	Q.S



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### 3. Pharmaceutical Dosage Form

Powder for topical application

### 4. Clinical Particulars

#### 4.1 Therapeutic Indications

FLUCOXEL contains Fluconazole that belong to the group of medicines called Antifungal agents. It is used to treat, control, prevent, & manage fungal infections of skin such as tineapedis (athlete's foot), tineacorporis (ring worm), tineacruris (fungal sweat rash) and tineaversicolor.

#### 4.2 Posology and Method of Administration

FLUCOXEL helps in treat fungal infection where Fluconazole inhibits the synthesis of certain compounds that are essential components of the fungal cell membrane. Moreover, it also impairs various important biological processes inside the fungal cell body required for its survival, thereby killing the killing the fungal cell bodies.

Apply FLUCOXEL as advised by your physician. It is for external use only. Clean and dry up the affected area before applying FLUCOXEL and do not rub. Your doctor will decide the correct dose and duration for you depending upon your age, body weight and severity of disease condition.

#### 4.3 Contraindications

Contraindicated in patients with known hypersensitivity.

#### 4.4 Special Warnings and Precautions for Use

##### Drug Warnings

Let your doctor know if you are allergic to any of the components in FLUCOXEL. Avoid contact of FLUCOXEL with nose, mouth or eyes as it may cause irritation. In case FLUCOXEL comes in contact with these areas accidentally, rinse with water thoroughly. If you are pregnant, planning for pregnancy or breastfeeding, please consult a doctor before using FLUCOXEL. Avoid applying FLUCOXEL on sunburns, lesions, blisters and open wounds.



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### **4.5 Interaction with other medicinal products and other forms of interaction**

Before using FLUCOXEL, inform your doctor if you are taking, have taken or might take any other medicine, including prescription, non-prescription or any herbal medicine.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy**

FLUCOXEL Dusting Powder is unsafe to use during pregnancy as there is definite evidence of risk to the developing baby. However, the doctor may rarely prescribe it in some life-threatening situations if the benefits are more than the potential risks. Please consult your doctor.

#### **Breastfeeding**

FLUCOXEL Dusting Powder is safe to use during breastfeeding. Human studies suggest that the drug does not pass into the breastmilk in a significant amount and is not harmful to the baby.

### **4.7 Effects on ability to drive and operate machine**

Not applicable

### **4.8 Undesirable effects**

Major & minor side effects for FLUCOXEL

Skin irritation

Burning sensation of skin

Redness of skin

Dry or scaly skin

### **4.9 Overdose**

If you or anyone else accidentally ingests or uses too much of FLUCOXEL, consult your doctor immediately or visit the nearby hospital.



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### 5. Pharmacological properties

#### 5.1 Pharmacodynamics property

**Pharmacotherapeutic group:** Antifungal agents,

**ATC Code:**D01AE20

#### Mechanism of Action

Fluconazole interacts with 14-demethylase, a cytochrome P-450 enzyme responsible for catalyzing the conversion of lanosterol to ergosterol. [4] As ergosterol forms a critical part of the fungal cell membrane, fluconazole inhibits the synthesis of ergosterol to increase cellular permeability.

#### 5.2 Pharmacokinetic properties

The pharmacokinetic properties of fluconazole are comparable after administration by the intravenous (IV) and oral (PO) routes. In healthy volunteers, the bioavailability of orally administered fluconazole is measured to be above 90%. It is extensively absorbed in the gastrointestinal tract when an oral dose is taken.

#### 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

### 6. Pharmaceutical particulars

#### 6.1 List of excipients

Purified Talc base

#### 6.2 Incompatibilities

Not Applicable.

#### 6.3 Shelf-Life

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24 months from the date of manufacture.

**6.4 Special Precautions for Storage**

Store below 30°C. Protect from light

**6.5 Nature and Contents of Container**

White powder filled in white moulded round shaped HDPE bottle along with purple colour cap & swivel.

**7. Marketing authorisation holder****ACCRETION PHARMACEUTICALS**

CJ7+PG3, VasnaChacharavadi, Gujarat 382220

**8. Marketing authorisation number(s)****9. Date of first authorisation/renewal of the authorisation****10. Date of revision of the text**






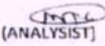

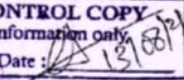


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## CERTIFICATE OF ANALYSIS:

		<b>ACCRETION PHARMACEUTICALS</b>			
		29, Xcelone Industrial Park-1, Behind INTAS Pharmaceuticals, Vasana-Chacharwadi, Ta-Sanand, Dist. Ahmedabad, Gujarat			
<b>CERTIFICATE OF ANALYSIS</b>					
<b>Generic Name</b>	<b>Fluconazole Dusting Powder 2% w/w</b>	<b>A. Report No.</b>	AP/FPE/2108052		
<b>Product Name</b>	FLUCOXEL POWDER	<b>Release Date</b>	: 13.08.2021		
<b>T.R. No.</b>	---	<b>Batch No</b>	: E067		
<b>T.R. Date</b>	10.08.2021	<b>Batch Size</b>	: 450 Kg		
<b>Sample Qty.</b>	2 x 100 GM	<b>Mfg. Date</b>	: 08-2021		
<b>Page No.</b>	: 1 of 1	<b>Exp. Date</b>	: 07-2023		
<b>DESCRIPTION OF TEST</b>		<b>RESULT</b>		<b>LIMITS</b>	
Description		White Powder		White Powder	
Minimum Filled		100.155 gm		NLT Label claim	
Identification		Complies		Positive for Fluconazole	
Assay :					
<b>Ingredient</b>		<b>Label claim</b>	<b>Result</b>	<b>%</b>	<b>Limits</b>
Fluconazole		2.00 w/w	2.0116%	100.58%	90.0 % to 110.0 %
Conclusion : The above sample complies IHS					
 (ANALYST)			 (LAB INCHARGE)		
<b>UNCONTROL COPY</b> For information only QA Sign./Date :  13/08/21					