



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

Product Characteristic Summary

Enclosed.



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

1. Name of drug product

FLUCONAZOLE DUSTING POWDER 2 % W/W

1.1 (Trade) name of product

FLUCOXEL

1.2 Strength

Each Unit Contains:

Excipients......Q.S.

1.3 Pharmaceutical Dosage Form

Powder for topical application



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:

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	IHS	Fragrance			200.000	0.900
4.	Purified Talc base	BP	Moisturising agent			Q.S	Q.S



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

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.



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

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.



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

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



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

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



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

CERTIFICATE OF A PHARMACEUTICAL PRODUCTS:

CERTIFICATE OF A PHAR	MACEUTICAL PRODUCTS
io. of Certificate: Mfg/COPP/ACCRETION/2021/	
Exporting (Certifying) Country: INDIA 17 1 8 Importing (requesting) Country: NIGERIA	8 5
Name and dosage form of products: FLUCOXEL (Fluconazo)	le Dusting Powder 2% W/W)
1.1 Active ingredient (s) and amount (s) per unit dose:	
Composition :	w/w
Complete qualitative composition including excipients, see	attached, N.A.
1.2 Is this product licensed to be placed on the market for	
1.3 Is this product actually on the market in the exporting	
If the answer to 1.2 is yes., continue with section 2 A and 2A.1 Number of product license ⁷ : G/25/2033	d If the answer to 1.2 is no. continue section 2 B 2B.1 Applicant for certificate (name and address) NA
And date of issue : 11.08.2021 21.2 Product license holder : (Name and address) M/S. ACCRETION PHARMACEUTICALS,	2B. 2 Status of applicant : N.A.
29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, At & Po. Vasna-Chacharwadi, Ta - Sanand, Dist - Ahmedabad - 382 213, GUJARAT STATE, INDIA.	2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form
2A.3 Status of product - license Holder *: Manufacturer of the dosage form a b c	2B.3 Why is marketing authorization lacking? N.A. Not Not Not Under Refused Required Requested Consideration
2A.4 Is summary basis of Approval appended? Yes No No	2B. 4 Remarks : N.A
2A.5 Is the attached officially approved product information complete and consonant with the license? res No Not Provided	
2A.6 Applicant for certificate if different from license holder: Not Applicable	CULARAT STATE
Does the certifying authority arrange for periodic inspects produced? Yes No Not applicable If no or not applicable proceed to question 4 3.1 Periodically of routine inspections (Years): Once in a 3.2 Has the manufacture of this type of dosage form been i	year Inspected? Yes No
Does the information submitted by the applicant satisf manufacture of the product? (es No Not applicable	y the certifying authority on all aspects of the
f no, explain: N.A	
This Certificate valid up to 2 Years from Date of Issue Address of certifying authority: The Commissioner Food & Drug Control Administration Block No. 8, Dr. Jivraj Mehta Bhavan, Gujarat State, INDIA	
rel: 91-79-232 53417 Fax: 91-79-232 53400 Date of Approval:	Stamp and date: Assistant Commissioner Food & Drugs Controls Administration Gujarat State
	- 3 SEP 2021



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

CERTIFICATE OF ANALYSIS:

Accreti	n	29, Xc	elone Industrial Par	RETION PH k-1, Behind IN Sanand, Dist.	TAS Pharmace	uticals, Va	asana-Chacharwadi,
			CERTIFI	CATE OF ANAL	Veie		
Seneric Name		Fluconazol	e Dusting Powder 2	and the principle of the latest section of	A. Repo	ort No.	AP/FPE/2108052
Product Name		FLUCOXEL P			Release		: 13.08.2021
.R. No.			OWDER		Batch 1		: E067
r.R. Date		10.08.2021			Batch S		: 450 Kg
Sample Qty.		2 x 100 GM	7-7-1		Mfg. D		: 08-2021
Page No.	:	1 of 1			Exp. Da		: 07-2023
DESCRIPTI	ON	OF TEST		RESULT	100		LIMITS
Description		-	White Powder				Powder
Minimum Filled			100.155 gm		111	NLT Lal	bel claim
Identification		7- 72 (5)	Complies		1-15 14-5	Positiv	e for Fluconazole
Assay :					E THE STATE		
Ingredient			Label claim	Result	%	Limits	Part and the same
	_		2.00 w/w	2.0116%	100.58%	90.0%	to 110.0 %
Fluconazole			2.00 W/W	2.0110%	100.30%	30.0%	10.10.0%
Fluconazole			2.00 W/W	2.0110%		30.0%	10.10.0%
Fluconazole			2.00 w/w	2.0110%	XXXX	30.0%	10.10.0 %
	on	: The above	sample complies li		XXXX	33.0 %	10.10.0 %
	on	: The above			Add to	33.0 %	10.10.0 %
Conclusi	(In	: The above				33.0 %	[LAB INCHARGE]