

# **SUMMARY OF PRODUCT CHARACTERISTICS**



**ACCRETION PHARMACEUTICALS**

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

**BRAND NAME:**

**ITRACOXEL**

**GENERIC NAME:**

**ITRACONAZOLE DUSTING POWDER 1 % W/W**

**Product Characteristic Summary**

Enclosed.



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**1. Name of drug product**

ITRACONAZOLE DUSTING POWDER 1 % W/W

**1.1 (Trade) name of product**

ITRACOXEL

**1.2 Strength**

Each Unit Contains:

Itraconazole BP..... 1 % 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:****ITRACOXEL****GENERIC NAME:****ITRACONAZOLE DUSTING POWDER 1 % W/W****2. Qualitative & Quantitative Composition****2.1 Qualitative Declaration**

Each Unit Contains:

Itraconazole BP..... 1 % 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.	Itraconazole	BP	Active	1 % w/w	--	1000.000	4.500
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**

For the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: pulmonary and ectrapulmonaryblastomycosis, hystoplasmosis, asperrgillosis, and onychomycosis.

#### **4.2 Posology and Method of Administration**

ITRACOXEL works by inhibiting ergosterol synthesis (an organic compound responsible for maintaining cell membrane integrity of fungi cell) that leads to fungal cell membrane abnormalities (marked with increased permeability and disruption of fungi cell) thus causing destruction to the fungi cell and preventing the occurrence of fungal infections in affected individuals.

Use ITRACOXEL as advised by your physician. It is for external use only. Clean and wipe to dry the affected area before applying the medicine. Sprinkle enough powder over the infected area. Avoid rubbing it and avoid contact with the eyes, mouth, nose and ears.

Your doctor will decide the correct dose, frequency and duration of ITRACOXEL for you depending upon your age and type or severity of the infection.

#### **4.3 Contraindications**

It is contraindicated for patients who have shown hypersensitivity to itraconazole.

#### **4.4 Special Warnings and Precautions for Use**

None.

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



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### A. Drug-Drug Interactions

Before using ITRACOXEL, inform your doctor, if you are taking any of the following medicines:

- Rifampicin (used to treat tuberculosis)
- Phenytoin, carbamazepine, phenobarbital (used to treat epilepsy)

### 4.6 Fertility, pregnancy and lactation

#### **Pregnancy**

ITRACOXEL is not recommended to be used in pregnant women. Consult your doctor before using ITRACOXEL.

#### **Breastfeeding**

ITRACOXEL should be used with caution in breastfeeding women only if it is considered clearly necessary. Consult your doctor before using ITRACOXEL.

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

Not applicable

### 4.8 Undesirable effects

#### COMMON

- Skin irritation
- Redness or itching at the application site
- Burning sensation and rashes

#### RARE

Stop using ITRACOXEL and contact your doctor if you experience any of the following side effects:

- Signs of allergic reactions (such as rashes, swelling of the lips, throat or face, swallowing or breathing problems, feeling dizzy or faint and nausea)

### 4.9 Overdose



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If you or anyone else accidentally use too much of ITRACOXEL, consult your doctor immediately or visit the nearby hospital.

### 5. Pharmacological properties

#### 5.1 Pharmacodynamics property

**Pharmacotherapeutic group:** Antifungal agents,

**ATC Code:** D01AC02

Itraconazole is an imidazole/triazole type antifungal agent. Itraconazole is a highly selective inhibitor of fungal cytochrome P-14 sterol C-14  $\alpha$ -demethylation via the inhibition of the enzyme cytochrome P450 14 $\alpha$ -demethylase. This enzyme converts lanosterol to ergosterol, and is required in fungal cell wall synthesis. The subsequent loss of normal sterol correlates with the accumulation of 14  $\alpha$ -methyl sterols in fungi and may be partly responsible for the fungistatic activity of fluconazole.

#### 5.2 Pharmacokinetic properties

##### Absorption:

Itraconazole is rapidly and almost completely absorbed with maximum plasma concentration (C<sub>max</sub>) achieved 1-2 hours after dosing.

##### Protein binding:

99.8 %

##### Metabolism:

Itraconazole is extensively metabolized by the liver into a large number of metabolites, including hydroxyitraconazole, the major metabolite. The main metabolic pathways are oxidative scission of the dioxolane ring, aliphatic oxidation at the 1-methylpropyl substituent, N-dealkylation of this 1- methylpropyl substituent, oxidative degradation of the piperazine ring and triazoloneacission.

#### 5.3 Preclinical safety data

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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**

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**





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**10. Date of revision of the text**



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**CERTIFICATE OF A PHARMACEUTICAL PRODUCTS:**

**CERTIFICATE OF A PHARMACEUTICAL PRODUCTS**

3. of Certificate: Mfg/COPP/ACCRETION/2021/

Exporting (Certifying) Country: **INDIA**  
Importing (requesting) Country: **NIGERIA**      **071893**

1. Name and dosage form of products: **ITRACOXEL**  
(Itraconazole Dusting Powder 1% W/W)

1.1 Active ingredient (s) and amount (s) per unit dose :  
Composition :  
Itraconazole B.P.                                      1% w/w  
Excipients    Q.S.

Complete qualitative composition including excipients, N.A.

1.2 Is this product licensed to be placed on the market for use in the exporting country?    Yes     No

1.3 Is this product actually on the market in the exporting country ?    Yes     No     Unknown

If the answer to 1.2 is yes., continue with section 2 A and If the answer to 1.2 is no. continue section 2 B

<p>2A.1 Number of product license : N.A. And date of issue : N.A.</p>	<p>2B.1 Product license holder : (Name and address) <b>M/S. ACCRETION PHARMACEUTICALS,</b> 29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, At &amp; Po. Vasna-Chacharwadi, Ta- Sanand, Dist - Ahmedabad - 382 213, <b>GUJARAT STATE, INDIA.</b></p>
<p>2A.2 Product license holder : (Name and address) N.A.</p>	<p>2B.2 Status of applicant : Manufacturer of the dosage form a <input checked="" type="checkbox"/>    b <input type="checkbox"/>    c <input type="checkbox"/>    d <input type="checkbox"/></p>
<p>A.3 Status of product - license Holder : N.A.</p>	<p>2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form</p>
<p>2A.4 Is summary basis of Approval appended? Yes <input type="checkbox"/>    No <input type="checkbox"/></p>	<p>2B.3 Why is marketing authorization lacking? Not <input type="checkbox"/>    Not <input checked="" type="checkbox"/>    Under <input type="checkbox"/>    Refused <input type="checkbox"/> Required    Requested    Consideration</p>
<p>2A.5 Is the attached officially approved product information complete and consonant with the license ? Yes <input type="checkbox"/>    No <input type="checkbox"/>    Not Provided <input type="checkbox"/></p>	<p>2B.4 Remarks : Number of product license : <b>G/25/2033</b> And date of issue : <b>25.08.2021</b></p>
<p>2A.6 Applicant for certificate if different from license holder : Not Applicable</p>	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?  
Yes     No     Not applicable

If no or not applicable proceed to question 4

3.1 Periodically of routine inspections (Years) : Once in a year

3.2 Has the manufacture of this type of dosage form been inspected?    Yes     No

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?  
Yes     No     Not applicable

If no, explain: N.A

This Certificate valid up to **2 Years from Date of Issue**

Address of certifying authority :    Name of the Authorized Person : **C.U.Chodvadiya**  
**The Commissioner Food & Drug Control Administration**  
1<sup>st</sup> Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,  
Gandhinagar, Gujarat State, INDIA    Signature: *[Signature]*  
Tel: 91-79-232 53417 Fax: 91-79-232 53400    Stamp and date:    Assistant Commissioner  
Date of Approval:    Food & Drugs Controls Administration  
Gujarat State

**3 SEP 2021**



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## CERTIFICATE OF ANALYSIS:

DESCRIPTION OF TEST		RESULT		LIMITS
Description	White Powder			White Powder
Minimum Filled	100.256 gm			NLT Label claim
Identification	Complies			Positive for Itraconazole
Assay :				
Ingredient	Label claim	Result	%	Limits
Itraconazole	1.00 w/w	1.0165%	101.65%	90.0 % to 110.0 %

Conclusion : The above sample complies IHS

(ANALYSIST)

[LAB INCHARGE]

**UNCONTROL COPY**  
For information only  
QA Sign./Date : *[Signature]* 13/08/21