



<b>Brand Name</b> : AGOVIR	2021
<b>Generic Name</b> : Aciclovir Tablets BP 200 mg	
<b>Module 1</b> Administrative Information and Product Information	
<b>1.5</b> Product Information	<b>Confidential</b>

## 1.5 PRODUCT INFORMATION

### 1.5.1 Prescribing information (Summary of products characteristics)

#### SUMMARY PRODUCT CHARACTERISTICS

#### 1. Name of drug product:

AGOVIR (Aciclovir Tablets BP 200 mg)

#### 2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Aciclovir BP 200 mg

#### 3. Pharmaceutical form:

White, circular, Flat, uncoated tablets having embossed 'A/200' on one side of breakline & 'AGOG' on other side of each tablets.

#### 4. Clinical particulars:

##### 4.1 Posology and Method of Administration:

###### *Dosage in adults*

Herpes simplex: 200 mg 5 times daily at 4 hrs interval for 5 days. Herpes zoster: 800 mg 5 times daily at 4 hrs interval for 7 days. Prophylaxos or suppression: 200 mg 4 times daily.

###### *Dosage in children*

Below 2 hrs: Herpes Simplex: 100 mg 5 times at 4 hrs. interval. Children above 2 yrs: 100 mg 4 times daily at 6 hrs intervals and over 2 yrs: same as adult

Method of administration : Oral.

##### 4.3 Contraindications:



Hypersensitivity, glaucoma, psychiatric diseases depression

#### 4.3 Special Warnings and Precautions for Use :

Renal impairment, necessitates dose reduction, maintain adequate hydration  
Paediatrics: Reduce dose necessary. Not recommended in age below 2 years

#### 4.4 Interaction with other medicinal products, and other forms of interaction:

Probenecid decreases the renal tubular secretion of acyclovir leading to increased concentration in serum, prolonged half life and increased toxicity.  
Nephrotoxic agent like paracetamol, aminoglycosides amphotericin B, lithium, methotrexate and methoxyflurane may increase the potential for nephrotoxicity of aciclovir when concurrently administered.

#### 4.5 Pregnancy and Lactation:

##### *Pregnancy*

Contraindicated orally and parentally

##### *Lactation*

May reduce lactation.

### 5. Pharmacological properties:

#### 5.1 Pharmacokinetic Properties:

Aciclovir is poorly water-soluble and has poor oral bioavailability (15–30%), hence intravenous administration is necessary if high concentrations are required. When orally administered, peak plasma concentration occurs after 1–2 hours. According to the Biopharmaceutical Classification System (BCS), aciclovir falls under the BCS Class III drug i.e. soluble with low intestinal permeability. Aciclovir has a high distribution rate; protein binding is reported to range from 9 to 33% The elimination half-life ( $t_{1/2}$ ) of aciclovir depends according to age group; neonates have a  $t_{1/2}$  of 4 hours, children 1–12 ye



## 6. **Pharmaceutical particulars:**

### 6.1 **List of Excipients:**

Lactose	BP
Microcrystalline cellulose	BP
Sodium starch Glycolate	BP
Colloidal silicon dioxide	BP
Maize starch	BP
Sodium methyl paraben	BP
Sodium propyl paraben	BP
Polyvinyl pyrrolidone K-30 (Povidone)	BP
Purified talc	BP
Cross Carmellose sodium	BP
Magnesium stearate	BP
Polyplasdone XL-10	BP

### 6.2 **Incompatibilities:**

None Reported

### 6.3 **Shelf-Life:**

36 months from the date of manufacture.

### 6.4 **Special Precautions for Storage:**

Store in a cool, dry and dark place. Protect from light.

### 6.5 **Nature and Contents of Container:**

10 tablets packed in one blister. Such 10 blisters packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

### 6.6 **Special precautions for disposal:**

None reported.

## 7. **Registrant:**

**AGOG PHARMA LTD.**

Plot No. 33, Sector II,  
The Vasai Taluka Industrial  
Co-Op. Estate Ltd., Gauraipada,  
Vasai (E), Dist. Thane, India.

## 8. **Manufacturer:**

**AGOG PHARMA LTD.**

Plot No. 33, Sector II,  
The Vasai Taluka Industrial  
Co-Op. Estate Ltd., Gauraipada,  
Vasai (E), Dist. Thane,  
India.

## 9. **Date of revision of the text :**