

# Axlovir™ Combipack

Nirmatrelvir 150 mg Tablet & Ritonavir 100 mg Tablet

#### Composition:

**Axlovir™ Combipack:** Each Combipack contains (02) two Nirmatrelvir INN 150 mg tablet & (01) one Ritonavir USP 100 mg tablet.

#### Pharmacology:

**Axlovir™ Combipack** consists of nirmatrelvir, which inhibits a SARS-CoV-2 protein to stop the virus from replicating, and ritonavir, which slows down nirmatrelvir's breakdown to help it remain in the body for a longer period at higher concentrations.

#### Emergency use authorization:

EUA of Nirmatrelvir, a SARS-CoV-2 main protease (Mpro; also referred to as 3CLpro or nsp5 protease) inhibitor and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death

#### Limitation of authorized use:

- Axlovir is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- Axlovir is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- Axlovir is not authorized for use longer than five consecutive days.

#### Dosage & Administration:

**Axlovir™ Combipack** is administered as three tablets (two tablets of nirmatrelvir and one tablet of ritonavir) taken together orally twice daily for five days, for a total of 30 tablets.

#### Contraindication:

It is contraindicated with drugs that are potent CYP3A inducers where significantly reduced Nirmatrelvir or Ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance

#### Precaution:

Ritonavir may cause liver damage, so caution should be exercised when giving **Axlovir™ Combipack** to patients with preexisting liver diseases, liver enzyme abnormalities or liver inflammation.

#### Side Effect:

Impaired sense of taste, diarrhea, high blood pressure and muscle aches

#### Drug Interaction:

Initiation of medications that inhibit or induce CYP3A may increase or decrease concentrations of **Axlovir™ Combipack**, respectively. These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications
- Clinically significant adverse reactions from greater exposures.
- Loss of therapeutic effect and possible development of viral resistance

#### Use in Renal patient:

Mild renal impairment: No dosage adjustment is needed in patients with mild renal impairment.  
Moderate renal impairment: In patients with moderate renal impairment (eGFR  $\geq 30$  to  $< 60$  mL/min), reduce the dose of **Axlovir™ Combipack** to 150 mg Nirmatrelvir and 100 mg Ritonavir twice daily for 5 days.  
Severe renal impairment: Not recommended in patients with severe renal impairment

#### Use in Hepatic patient:

No dosage adjustment of **Axlovir™ Combipack** is needed for patients with either mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. No pharmacokinetic or safety data are available regarding the use of Nirmatrelvir or Ritonavir in subjects with severe hepatic impairment (Child-Pugh Class C); therefore, not recommended for use in patients with severe hepatic impairment.

#### Pregnancy & lactation:

There are no available human data on the use of **Axlovir™ Combipack**  
Pediatric patients: 12 years of age and older weighing at least 40 kg with positive results of direct SARS-cov-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

#### Storage:

Store below 25°C, protected from light and moisture.  
Keep out of reach of children.

#### How supplied:

**Axlovir™ Combipack:** Each Combipack contains 3 tablets (02 Nirmatrelvir 150 mg Tablet & 01 Ritonavir 100 mg Tablet- in Alu-Alu blister pack.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH