

150 mm

90 mm

**Damid™**

Darolutamide INN Film Coated Tablet

**DESCRIPTION**  
**Damid™** is a preparation of Darolutamide. Darolutamide is an androgen receptor (AR) inhibitor. Darolutamide competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. A major metabolite, keto-darolutamide, exhibited similar in vitro activity to Darolutamide. In addition, Darolutamide functioned as a progesterone receptor (PR) antagonist in vitro (approximately 1% activity compared to AR). Darolutamide decreased prostate cancer cell proliferation in vitro and tumor volume in mouse xenograft models of prostate cancer.

**INDICATIONS**  
 Darolutamide is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer.

**DOSAGE AND ADMINISTRATION**  
 The recommended dose of Damid™ is 600 mg (two 300 mg tablets) administered orally twice daily, equivalent to a total dose of 1200 mg. Swallow tablets whole with food.

- Advice patients to take any missed dose as soon as they remember prior to the next scheduled dose, and not to take two doses together to make up for a missed dose.

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

**CONTRAINDICATIONS**  
 None

**SIDE EFFECTS**

- Fatigue
- Pain in extremity
- Rash

**WARNINGS & PRECAUTIONS**  
 Darolutamide can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception.

**DRUG INTERACTIONS**

- Combined P-gp and Strong or Moderate CYP3A Inducers: Avoid concomitant use of Darolutamide with combined P-gp and strong or moderate CYP3A4 Inducers.
- Combined P-gp and Strong CYP3A4 Inhibitors: Concomitant use of Darolutamide with a combined P-gp and strong CYP3A4 inhibitor increases Darolutamide exposure which may increase the risk of Darolutamide adverse reactions. Monitor patients more frequently for Darolutamide adverse reactions and modify Darolutamide dosage as needed.
- BCRP (Breast Cancer Resistant Protein) Substrates: Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions and consider dose reduction of the BCRP substrate drug.

**OVERDOSE**  
 There is no known specific antidote for Darolutamide overdose. The highest dose of Darolutamide studied clinically was 900 mg twice daily, equivalent to a total daily dose of 1800 mg. No dose limiting toxicities were observed with this dose.

Considering the saturable absorption and the absence of evidence for acute toxicity, an intake of a higher than recommended dose of Darolutamide is not expected to lead to systemic toxicity in patients with intact hepatic and renal function.

In the event of intake of a higher than recommended dose in patients with severe renal impairment or moderate hepatic impairment, if there is suspicion of toxicity, interrupt **Damid™** treatment and undertake general supportive measures until clinical toxicity has been diminished or resolved. If there is no suspicion of toxicity, **Damid™** treatment can be continued with the next dose as scheduled.

**USE IN PREGNANCY AND LACTATION**  
 The safety and efficacy of Darolutamide have not been established in females. Based on its mechanism of action, Darolutamide can cause fetal harm and loss of pregnancy. Animal embryo-fetal developmental toxicology studies were not conducted with Darolutamide. There are no human data on the use of Darolutamide in pregnant females.

**PHARMACEUTICAL PRECAUTION**  
 Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

**PACKAGING**  
**Damid™ Tablet:** Box containing 3 strips of 10 tablets each. Each film coated tablet contains Darolutamide INN 300 mg.

**SK+F ONCOLOGY**  
 Manufactured by  
**ESKAYEF PHARMACEUTICALS LIMITED**  
 RUPGANJ, NARAYANGANJ, BANGLADESH  
 TM TRADEMARK  
 R/PM2118 V01

## PM SPECIFICATION

Creative ID: CSD\_02

<b>Job Name:</b> Damid FCT Insert	<b>Size:</b> L - 90 mm, W - 150 mm	<b>Paper:</b> 70 gsm Offset Paper
<b>No. of Color:</b> 2 Extra	<b>Pantone Color Code</b> <span style="display: inline-block; width: 15px; height: 15px; background-color: #4b0082; border: 1px solid black; margin-right: 5px;"></span> Violet C	<span style="display: inline-block; width: 15px; height: 15px; background-color: #e31a1c; border: 1px solid black; margin-right: 5px;"></span> 2347 C

	Creative Service Department	Marketing Department	PD/QC/Contract Customer	Approved By
Comments				
Signature & Date				