▼Joenja (leniolisib) PRESCRIBING INFORMATION for United Kingdom (UK)

Please consult the Summary of Product Characteristics (SPC) before prescribing.

Joenja (leniolisib) film-coated tablet. Each film coated tablet contains leniolisib phosphate equivalent to 70 mg leniolisib.

Indication: Treatment of activated phosphoinositide 3 kinase delta *(P13Kδ*) syndrome (APDS) in adult and paediatric patients 12 years of age and older.

Dosage and administration: Recommended dosage of Joenja in adult and paediatric patients 12 years of age and older weighing 45 kg or greater is 70 mg administered orally twice daily approximately 12 hours apart, with or without food. There is no recommended dosage for patients weighing less than 45 kg. Tablets should be swallowed whole. *Testing prior to treatment:* Verify the pregnancy status in females of reproductive potential prior to treatment. *Hepatic impairment:* Use of Joenja in patients with moderate to severe hepatic impairment is not recommended.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Precautions: *Embryo-foetal toxicity:* Joenja may cause foetal harm when administered to a pregnant woman. *Vaccinations:* Live, attenuated vaccinations may be less effective if administered during Joenja treatment. *Lactose excipient:* Joenja contains lactose and should not be taken by patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose galactose malabsorption.

Interactions: The use of Joenja is not recommended concomitantly with strong or moderate CYP3A4 inhibitors (e.g., clarithromycin, diltiazem, erythromycin, ketoconazole, ritonavir, verapamil, grapefruit juice); strong or moderate CYP3A4 inducers (e.g., carbamazepine, efavirenz, nevirapine, phenobarbital, phenytoin, rifabutin, rifampin, St. John's Wort); or CYP1A2 metabolized drugs with a narrow therapeutic index (e.g., theophylline, tizanidine). *Avoid concomitant use:* Concomitant use of Joenja with drugs that are primarily metabolized by isoenzyme CYP1A2 and have a narrow therapeutic index (e.g., alosetron, caffeine, duloxetine, melatonin, ramelteon, tasimelteon, theophylline, tizanidine) should be avoided. Concomitant use of Joenja with drugs that are BCRP, OATP1B1, and OATP1B3 substrates (e.g., rosuvastatin, pitavastatin, letermovir) should be avoided.

Pregnancy and Lactation: *Women of childbearing potential/contraception in females:* Women of childbearing potential should use highly effective methods of contraception during treatment with Joenja and for 1 week after the last dose. Leniolisib may cause foetal harm. Pregnant women should be advised of the potential risk to a foetus. Pregnancy status in females of reproductive potential should be verified prior to initiating treatment. *Pregnancy and lactation:* Joenja is not recommended.

Adverse Reactions: *Very Common (≥ 1/10)*: sinusitis, headache, tachycardia (e.g., tachycardia and sinus tachycardia), diarrhoea, atopic dermatitis (e.g., atopic dermatitis and eczema, alopecia, back pain, neck pain, fatigue, pyrexia. See Summary of Product Characteristics for full list of adverse reactions.

Legal category: POM

Presentation and basic NHS cost: Joenja tablets - £29,000 per 1 bottle (60 tablets).

Marketing Authorisation number: PLGB 33010/0001.

MA holder: Pharming Technologies B.V., Darwinweg 24, 2333 CR Leiden, The Netherlands.

Joenja is a registered trademark of Pharming Technologies B.V.

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellowcard in the Google Play or Apple App store.