



XOSPATATM

gilteritinib 40 mg
film-coated
tablets



XOSPATATM Patient Access Initiative (AARAMBH)

Please contact AARAMBH contact centre at

Toll Free Number: 18002038711

Mail id : aarambh.x@medybizpharma.com

Working Hrs

9.30 AM to 6.00 PM (Monday to Saturday)

PAP: Patient Access Program

Note: Patient Access Initiative (PAI) is referred as Patient Access Program (PAP)

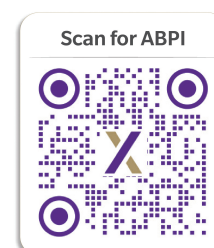
ABBREVIATED PRESCRIBING INFORMATION OF XOSPATA™ 40 mg film coated tablets
(Please refer the full prescribing information for further details)

1. Name of the medicinal product: XOSPATA™ 40 mg film coated tablets **2. QUALITATIVE AND QUANTITATIVE COMPOSITION:** Each film coated tablet contains 40 mg gilteritinib (as fumarate). **3. PHARMACEUTICAL FORM:** Film coated tablet (tablet). **4. CLINICAL PARTICULARS**

4.1 Therapeutic indication: Xospata is indicated as monotherapy for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. **4.2 Posology and method of administration** **Posology:** The recommended starting dose is 120 mg gilteritinib (three 40 mg tablets) once daily. Blood chemistries and ECG monitoring should be performed before initiation and during the treatment as recommended. Treatment should continue until the patient is no longer clinically benefiting from Xospata or until unacceptable toxicity occurs. Response may be delayed; therefore, continuation of treatment at the prescribed dose for up to 6 months should be considered to allow time for a clinical response. In the absence of a response after 4 weeks of treatment, the dose can be increased to 200 mg once daily, if tolerated or clinically warranted. *Dose modifications:* Xospata should be administered at about the same time each day. If a dose is missed or not taken at the usual time, the dose should be administered as soon as possible on the same day, and patients should return to the normal schedule the following day. If vomiting occurs after dosing, patients should not take another dose but should return to the normal schedule the following day. *Elderly:* No dose adjustment is required in patients ≥65 years of age. *Hepatic impairment:* No dose adjustment is required for patients with mild or moderate hepatic impairment. Xospata is not recommended for use in patients with severe hepatic impairment, as safety and efficacy have not been evaluated in this population. *Renal impairment:* No dose adjustment is necessary in patients with mild or moderate renal impairment. There is no clinical experience in patients with severe renal impairment. *Paediatric population:* The safety and efficacy of Xospata in children aged below 18 years has not yet been established. No data is available. Due to in vitro binding to 5HT_{2B}, there is a potential impact on cardiac development in patients less than 6 months of age. **4.3 Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 (Kindly refer full prescribing information). **4.4 Special warnings and precautions for use:** Differentiation syndrome: If differentiation syndrome is suspected, corticosteroid therapy should be initiated along with hemodynamic monitoring until symptom resolution. If severe signs and/or symptoms persist for more than 48 hours after initiation of corticosteroids, Xospata should be interrupted until signs and symptoms are no longer severe. Corticosteroids can be tapered after resolution of symptoms and should be administered for a minimum of 3 days. Symptoms of differentiation syndrome may recur with premature discontinuation of corticosteroid treatment. Posterior reversible encephalopathy syndrome: There have been reports of posterior reversible encephalopathy syndrome (PRES) in patients receiving Xospata (see section 4.6). If PRES is suspected, it should be confirmed by brain imaging, preferably magnetic resonance imaging (MRI). Discontinuation of Xospata in patients who develop PRES is recommended. Prolonged QT interval: QT prolongation can be observed in the first three months of treatment with gilteritinib. Therefore, electrocardiogram (ECG) should be performed prior to initiation of treatment, on day 8 and 15 of cycle 1, and prior to the start of the next three subsequent months of treatment. Caution is warranted in patients with relevant cardiac history. Hypokalaemia or hypomagnesaemia may increase the QT prolongation risk. Hypokalaemia or hypomagnesaemia should therefore be corrected prior to and during Xospata treatment. Xospata should be interrupted in patients who have a QTcF >500 msec. The decision to re-introduce gilteritinib treatment after an event of QT prolongation should be based on a careful consideration of benefits and risks. If Xospata is re-introduced at a reduced dose, ECG should be performed after 15 days of dosing, and prior to the start of the next three subsequent months of treatment. In clinical studies, 12 patients had QTcF >500 msec. Three patients interrupted and re-initiated treatment without recurrence of QT prolongation. Pancreatitis: Xospata should be interrupted and can be resumed at a reduced dose when the signs and symptoms of pancreatitis have resolved. Interactions: Co-administration of CYP3A/P gp inducers may lead to decreased gilteritinib exposure and consequently a risk for lack of efficacy. Therefore, concomitant use of gilteritinib with strong CYP3A4/P gp inducers should be avoided. Caution is required when concomitantly prescribing gilteritinib with medicinal products that are strong inhibitors of CYP3A, P gp and/or breast cancer resistant protein (BCRP) because they can increase gilteritinib exposure. In situations where satisfactory therapeutic alternatives do not exist, patients should be closely monitored for toxicities during administration of gilteritinib. Concomitant use of gilteritinib with medicinal products that target 5HT_{2B} receptor or sigma nonspecific receptors should be avoided unless use is considered essential for the care of the patient since gilteritinib may reduce the effect of these drugs. Embryofoetal toxicity and contraception: Pregnant women should be informed of the potential risk to a foetus. Females of reproductive potential should be advised to have a pregnancy test within seven days prior to starting treatment with Xospata and to use effective contraception during treatment with Xospata and for at least 6 months after stopping treatment. Women using hormonal contraceptives should add a barrier method of contraception. Males with female partners of reproductive potential should be advised to use effective contraception during treatment and for at least 4 months after the last dose of Xospata. **4.5 Effects on ability to drive and use machines:** Dizziness has been reported in patients taking Xospata and should be considered when assessing a patient's ability to drive or use machines. **4.6 Undesirable effects:** Summary of the safety profile: The safety of Xospata was evaluated in 319 patients with relapsed or refractory AML who have received at least one dose of 120 mg gilteritinib. The most frequent adverse reactions with gilteritinib were alanine aminotransferase (ALT) increased (82.1%), aspartate aminotransferase (AST) increased (80.6%), blood alkaline phosphatase increased (68.7%), blood creatine phosphokinase increased (53.9%), diarrhoea (35.1%), fatigue (30.4%), nausea (29.8%), constipation (28.2%), cough (28.2%), peripheral oedema (24.1%), dyspnoea (24.1%), dizziness (20.4%), hypotension (17.2%), pain in extremity (14.7%), asthenia (13.8%), arthralgia (12.5%) and myalgia (12.5%). The most frequent serious adverse reactions were acute kidney injury (6.6%), diarrhoea (4.7%), ALT increased (4.1%), dyspnoea (3.4%), AST increased (3.1%) and hypotension (2.8%). Other clinically significant serious adverse reactions included differentiation syndrome (2.2%), electrocardiogram QT prolonged (0.9%) and posterior reversible encephalopathy syndrome (0.6%). **OVERDOSE:** There is no known specific antidote for Xospata. In the event of an overdose, treatment with Xospata should be stopped. Patients must be closely monitored for signs or symptoms of adverse reactions, and appropriate symptomatic and supportive treatment initiated, taking into consideration the long half life estimated at 113 hours. **For full prescribing information please write to: MARKETING AUTHORISATION HOLDER: Astellas Pharma India Private Limited, 301,3rd Floor, C and B Square, 127 Andheri Kurla Road, Chakala, Andheri (East), Mumbai - 400 069. (Version: XOSPATA/aPI/India/Ver.2.0/Apr2024).**

Only for the use of Medical Practitioner.

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