Summary of prescribing information for DYFIRA Capsules

Active Ingredient: each delayed-release capsules of DYFIRA contains: dimethyl fumarate 120mg, 240mg. **Indication:** For Relapsing remitting multiple sclerosis. **Dosage:** Starting dose: 120 mg twice a day, orally, for 7 days. Maintenance dose after 7 days: 240 mg twice a day, orally. Swallow dimethyl fumarate capsules whole and intact. Do not crush, chew, or sprinkle capsule contents on food. Take dimethyl fumarate with or without food. **Contraindications:** Known hypersensitivity to dimethyl fumarate or any of the excipients. **Warning and precautions:** Anaphylaxis and angioedema: Discontinue and do not restart dimethyl fumarate if these occur. Progressive multifocal leukoencephalopathy (PML): Withhold dimethyl fumarate at the first sign or symptom suggestive of PML. Herpes zoster and other serious opportunistic infections: Consider withholding dimethyl fumarate in cases of serious infection until the infection has resolved. Lymphopenia: Obtain a CBC including lymphocyte count before initiating dimethyl fumarate, after 6 months, and every 6 to 12 months thereafter. Consider interruption of TECFIDERA if lymphocyte counts $<0.5 \times 10^9/L$ persist for more than six months. Liver injury: Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating dimethyl fumarate and during treatment, as clinically indicated. Discontinue dimethyl fumarate if clinically significant liver injury induced by dimethyl fumarate is suspected. **Pregnancy & Lactation:** Pregnancy: Based on animal data, may cause fetal harm. Lactation: There are no data on the presence of dimethyl fumarate or monomethyl fumarate (MMF, metabolite) in human milk. The effects on the breastfed infant and on milk production are unknown. **Interaction:** Aspirin, when administered approximately 30 minutes before dimethyl fumarate did not alter the pharmacokinetics of MMF. **Adverse reactions:** Most common flushing, abdominal pain, diarrhea, and nausea. **Overdose:** symptoms consistent with the known adverse event profile of dimethyl fumarate. There are no known therapeutic interventions to enhance elimination of dimethyl fumarate nor is there a known antidote. In the event of overdose, initiate symptomatic supportive treatment as clinically indicated.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com