SANDOZ A Novartis Division

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High-quality and affordable Anastrozole Sandoz IS NOW AVAILABLE!

We sold approximately 200,000 boxes in Japan and Australia in Year 2022[2]

Anastrozole Sandoz Bioequivalent (BE) Fasting Study Report[1]

Randomised, 2-way Crossover Bioequivalence Study of Two Different Anastrozole 1 mg Film-Coated Tablets Comparing the Pharmacokinetic Properties After Single dose in Healthy Volunteers under Fasting Conditions

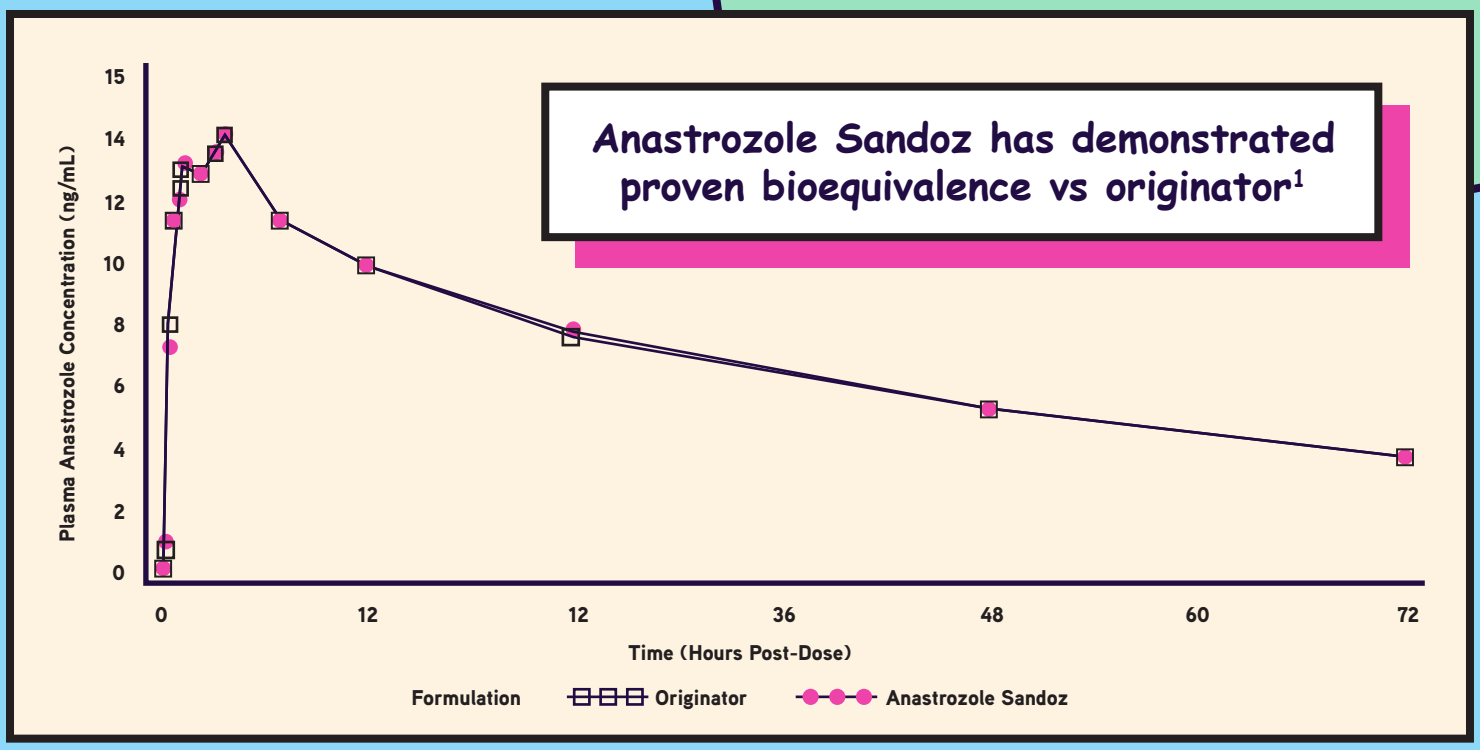

Figure I: Mean Anastrozole Plasma Concentration (ng/mL) - Linear Scale

ANASTROZOLE SANDOZ FILM COATED TABLETS 1MG

Important note: Before prescribing, please consult full prescribing information. **Presentation:** One film-coated tablet contains 1 mg Anastrozole. White, round and biconvex film-coated tablet with embossment "A1" on one side. **Indications:** • Adjuvant treatment of postmenopausal women with hormone receptor positive early invasive breast cancer. • Treatment of advanced breast cancer in postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. Efficacy has not been demonstrated in oestrogen receptor negative patients unless they had a previous positive clinical response to tamoxifen. **Dosage:** One 1mg tablet to be taken orally once a day. No dose change is recommended in patient with mild or moderate renal impairment and mild hepatic disease. For early disease, the recommended duration of treatment should be 5 years. **Contraindications:** Hypersensitivity to anastrozole or excipients. Premenopausal women; pregnancy; lactation; patients with severe renal impairment (creatinine clearance less than 20ml/min); with moderate or severe hepatic disease. Oestrogen-containing therapies should not be co-administered with Anastrozole as they would negate its pharmacological action. **Warnings/Precautions:** • Anastrozole is not recommended for use in children as safety and efficacy have not been established in this group of patients. • Women with osteoporosis or at risk of osteoporosis should have their bone mineral density formally assessed by bone densitometry at the commencement of treatment and at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and carefully monitored. • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine • Caution when driving and using machines. **Adverse reactions:** • ***Very common adverse reactions (≥ 10%):*** Hot flushes, asthenia, arthralgia/joint stiffness, arthritis, osteoporosis, headache, nausea, rash, depression. • ***Common adverse reactions (≥ 1% and < 10%):*** Vaginal dryness, Vaginal bleeding, Hair thinning (alopecia), allergic reactions, diarrhoea, vomiting, somnolence, Carpal Tunnel Syndrome, sensory disturbances (including paraesthesia, taste loss and taste perversion), increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, anorexia, hypercholesterolemia, bone pain, myalgia. • ***Uncommon (≥0.1% and <1%):*** Hypercalcaemia (with or without an increase in parathyroid hormone), increases in gamma-GT and bilirubin, hepatitis, urticaria, trigger finger. • ***Rare (≥0.01% and <0.1%):*** Erythema multiformae, anaphylactoid reaction, cutaneous vasculitis (including some reports of Henoch- Schönlein purpura). • ***Rare (<0.01%):*** Stevens-Johnson syndrome, angioedema. November 2022.SIN

References: 1. Anastrozole Sandoz Bioequivalent (BE) Fasting Study Report. **2.** Data on File Sandoz International Region, IQVIA MATQ4 2022 **3.** Anastrozole Sandoz Package Insert version Nov2022

Information for Healthcare Professionals only

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