RXADVANCE
2 Park Central Drive
Southborough, MA 01772

CLINICAL UPDATE

Brand Name	ORTIKOS®
Generic Name	budesonide
Drug Manufacturer	Sun Pharma Global FZE

Clinical Update

ORTIKOS® is a corticosteroid indicated for:

- Treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years and older.
- Maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.

FDA Approval Date: 6/13/2019

Safety

ADVERSE EVENTS

Most common adverse reactions (≥ 5%) in adults are: headache, respiratory infection, nausea, back pain, dyspepsia, dizziness, abdominal pain, flatulence, vomiting, fatigue, and pain.

WARNINGS & PRECAUTIONS

- Hypercorticism and Adrenal Axis Suppression: Follow general warnings concerning corticosteroids and paediatrics and patients with hepatic impairment may be at increased risk.
- Symptoms of Steroid Withdrawal in Patients Transferred from Other Systemic Corticosteroids: Taper slowly from corticosteroids with high systemic effects; monitor for withdrawal symptoms and unmasking of allergies (rhinitis, eczema).
- Increased Risk of Infection, including Serious and Fatal Chicken Pox and Measles: Monitor patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral or parasitic infections, or ocular herpes simplex.
- Other Corticosteroid Effects: Monitor patients with concomitant conditions where corticosteroids may have unwanted effects (e.g., hypertension, diabetes mellitus).

Drug Interactions

- CYP3A4 Inhibitors (e.g., ketoconazole, grapefruit juice): Can increase systemic budesonide concentrations: avoid use.

Special Population Considerations

PEDIATRICS

The observed safety profile of oral budesonide in pediatric patients (8 to 17 years of age) is consistent with its known safety profile in adults and no new safety concerns were identified. The safety and effectiveness of ORTIKOS® have not been established in pediatric patients less than 8 years of age.

GERIATRICS

CLINICAL UPDATE

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

PREGNANCY

Based on animal data, may cause fetal harm.

HEPATIC IMPAIRMENT

Avoid use of ORTIKOS® in patients with moderate and severe hepatic impairment. No dosage adjustment is needed in patients with mild hepatic impairment Pregnancy

LACTATION

Lactation studies have not been conducted with oral budesonide, including ORTIKOS®, and no information is available on the effects of the drug on the breastfed infant or the effects of the drug on milk production.

Product Availability

DOSAGE FORM(S) & STRENGTH(S)

Extended-Release Capsules: 6 mg and 9 mg