ANZUPGO (DELGOCITINIB) CREAM – THERAPEUTIC CHEAT SHEET

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TRADE NAME[1-2]

- ANZUPGO® (delgocitinib 2% cream)

MECHANISM OF ACTION[1,3]

- In inflammatory skin disorders, the binding of inflammatory cytokines to receptors on cell membranes triggers Janus kinases (JAKs) to phosphorylate intracellular receptor domains. This prompts the recruitment, activation, and nuclear localization of signal transducers and activators of transcription (STATs), which regulate the transcription of cytokine-responsive genes that drive inflammation and contribute to skin barrier dysfunction.
  - The JAK-STAT pathway plays a role in each of the Th1, Th2, Th17, and Th22 inflammatory responses.
- As a pan-JAK inhibitor, delgocitinib inhibits the activity of all four members of the JAK family: JAK1, JAK2, JAK3, and tyrosine kinase 2 (TYK2).
  - Delgocitinib acts in a concentration-dependent manner, with a stronger inhibitory effect on JAK1 & JAK2.
  - Of the downstream STAT isoforms (STAT1-6), delgocitinib preferentially suppresses STAT3 activity, which is known to play a key role in driving keratinocyte hyperproliferation and proinflammatory gene expression.

FDA-APPROVED FOR[2]

- Topical treatment of moderate to severe chronic hand eczema (CHE) refractory to topical corticosteroids in adult patients (18 years and older)
- Topical treatment of moderate to severe chronic hand eczema (CHE) in adult patients (18 years or older) with contraindications to topical corticosteroids
- Approved for ages 18 years and older; safety and efficacy not yet established for pediatric patients.

OFF-LABEL DERMATOLOGIC USES[1,3]

- Atopic dermatitis
  - Approved as ointment formulation in Japan since 2020 without requirement for prior failure of corticosteroids.
    - Delgocitinib 0.25% ointment for pediatric patients (≥2 years old)
    - Delgocitinib 0.5% ointment for both children & adults
- Evidence supporting the use of topical delgocitinib in other conditions is limited at this time, though there have been several case reports, small case series, and phase II trials looking at potential uses for delgocitinib in other inflammatory skin disorders, such as frontal fibrosing alopecia, alopecia areata, vitiligo, lichen planus pigmentosus, and subacute cutaneous lupus erythematosus.

DOSING[2]

- Apply a thin layer to affected areas on the hands and wrists twice daily.
- Do not use more than 30 grams per 2 weeks or 60 grams per month.
- Avoid contact with eyes, mouth, and other mucous membranes.

SIDE EFFECTS[3,4,5,6,7,8,9]

- Topical delgocitinib was well-tolerated in phase 3 trials, with most adverse events were mild-to-moderate severity and considered unrelated to treatment.
  - The most frequently reported adverse events in trials were COVID-19, nasopharyngitis/upper respiratory tract infections, and headache.
  - Adverse event rates in the treatment group were comparable to in the vehicle-only group. Discontinuation due to adverse events was actually lower with delgocitinib than vehicle.
  - No serious adverse events (venous thromboembolism or major adverse cardiovascular events) associated with delgocitinib were reported in major phase 3 clinical trials.
  - In the DELTA 3 trial, there was one reported case of eczema herpeticum, considered possibly related to the trial drug by the investigator. No events of eczema herpeticum were reported in the DELTA 1, DELTA 2, DELTA FORCE, or DELTA TEEN trials.
- Local tolerability was favorable in clinical trials:
  - More than half of patients reported no local irritation (stinging/burning sensation).
  - Of the patients who did report a stinging/burning sensation, the majority rated it as “mild”, and tolerability scoring improved throughout treatment.
- NOTE: Topical delgocitinib was formulated specifically to minimize systemic absorption. As a result, delgocitinib cream was approved by the FDA without requiring the class-wide JAK inhibitor Boxed Warning label.
  - Delgocitinib cream was formulated with minimal penetration-enhancing excipients and without propylene glycol (PG) or polyethylene glycol (PEG).
    - PG is a common ingredient used to enhance skin penetration of medications, which is found in ruxolitinib cream (a JAK1+2 inhibitor) as well as in nearly two-thirds of topical corticosteroid formulations.
    - PEG is another ingredient commonly used in topical formulations to enhance drug delivery.
  - Pharmacokinetic studies suggest minimal/negligible systemic exposure when applied as FDA-approved for chronic hand dermatitis, with a relative bioavailability of ~0.6% compared with oral administration.

GENERAL PRECAUTIONS[2,3]

- Do not use in combination with other JAK inhibitors or potent immunosuppressing agents.
- Not recommended in patients with active hepatitis B or C infection (patients with active hepatitis B or C infection were excluded from clinical trials)
- Current prescribing guidelines recommend completion of all age-appropriate immunizations (including herpes zoster) prior to initiating therapy, and suggest avoiding live vaccine administration immediately before, during, and after treatment.
- Recommend that breastfeeding women avoid direct contact with the nipple/areola and surrounding areas immediately after application to the hands in order to minimize risk of infant exposure.

PREGNANCY AND BREASTFEEDING[2,3]

- There is insufficient data on the use of topical delgocitinib in pregnant or breastfeeding women to draw conclusions regarding drug-associated risks on maternal or fetal outcomes.
- Animal studies on embryofetal development have focused on oral delgocitinib.
- One study demonstrated delgocitinib in the milk of lactating rats after oral administration; there are no similar studies at this time using topical delgocitinib.
  - Current prescribing guidelines recommend that breastfeeding women avoid direct contact with the nipple/areola and surrounding areas immediately after application to the hands in order to minimize risk of infant exposure.

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