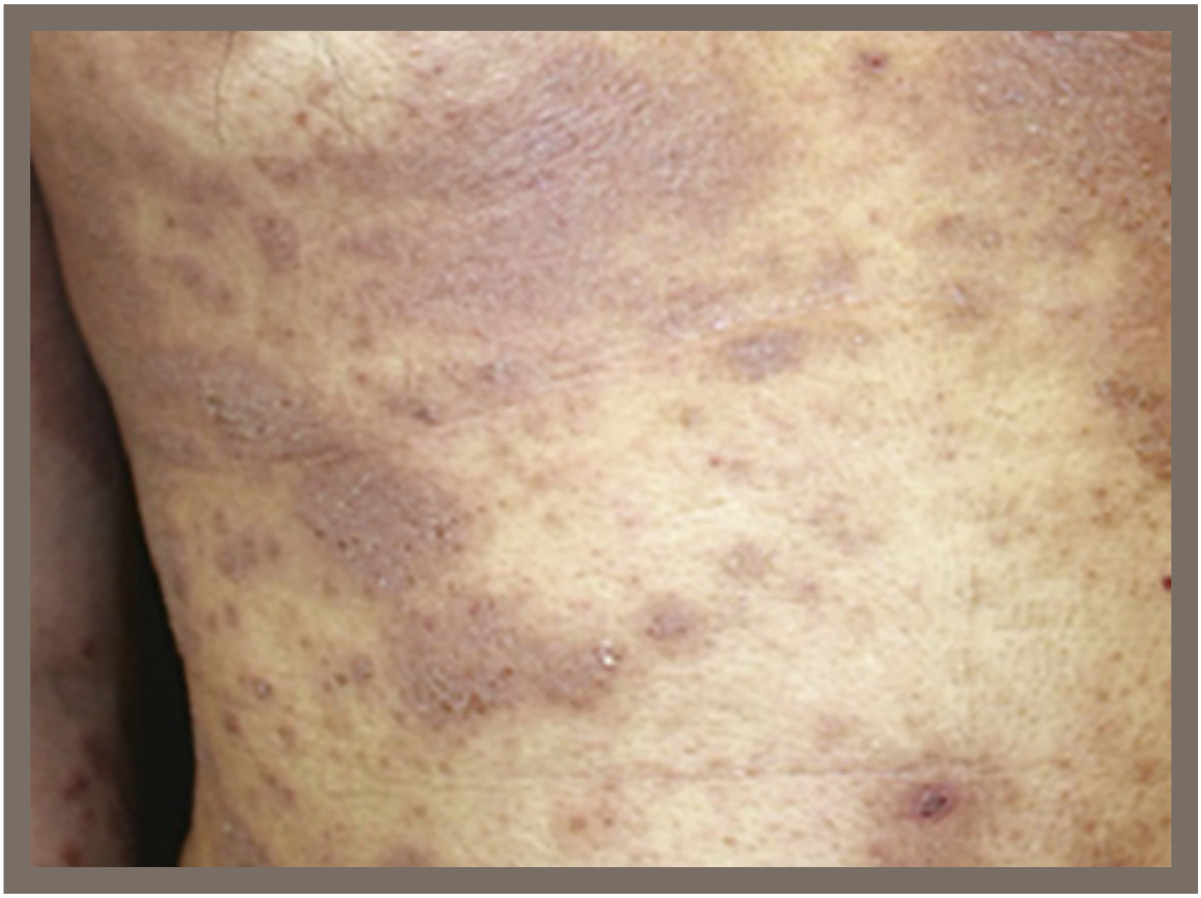
MODERATE-TO-SEVERE ATOPIC DERMATITIS AFFECTS ALL TYPES OF SKIN—BUT NOT ALL SKIN TYPES ARE THE SAME

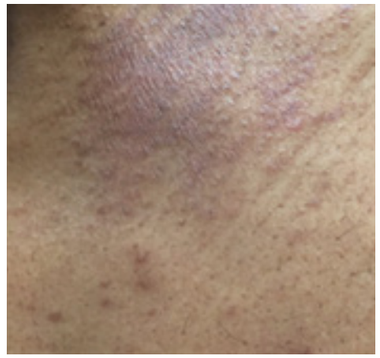
See how the signs of atopic dermatitis can distinctively manifest in skin of color

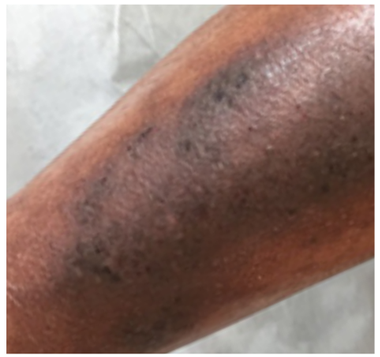


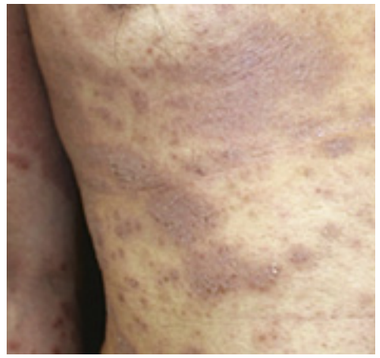
ATOPIC DERMATITIS SEVERITY CAN BE UNDERESTIMATED IN PATIENTS OF COLOR[1,2]

Underestimation of erythema in darker skin may delay diagnosis with presenting patients having more severe disease[1,2]

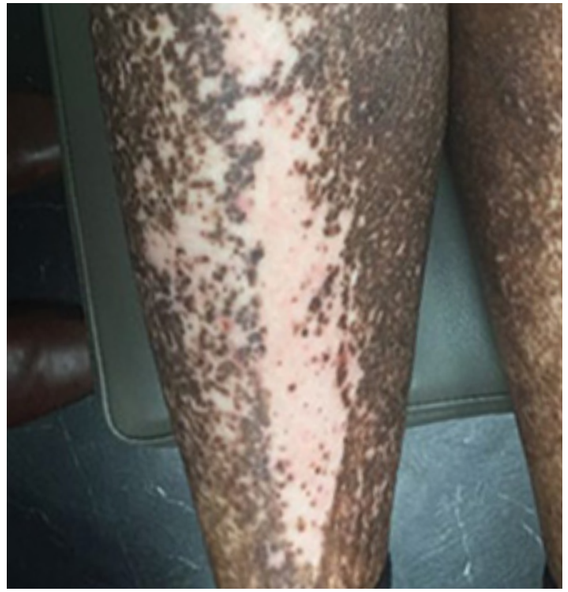
- In lighter skin, erythema appears pink or red. In darker skin types, erythema may appear **violet or dark violet**[3]

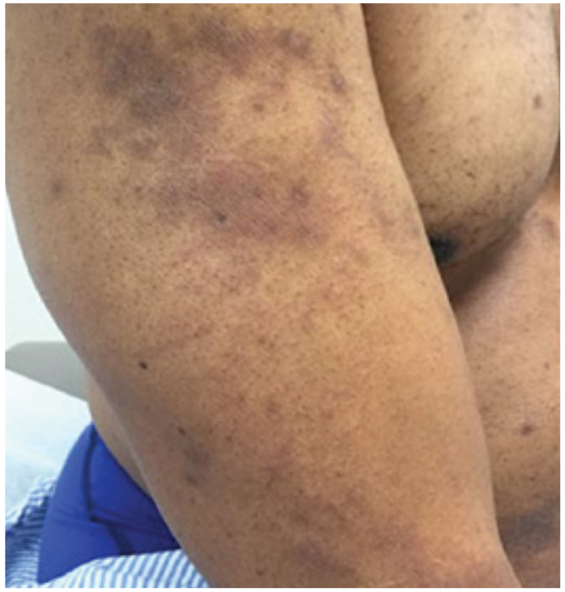






Temporary, or even permanent, hyper- or hypopigmentation following skin inflammation occurs most commonly in skin of color[1,3-5]

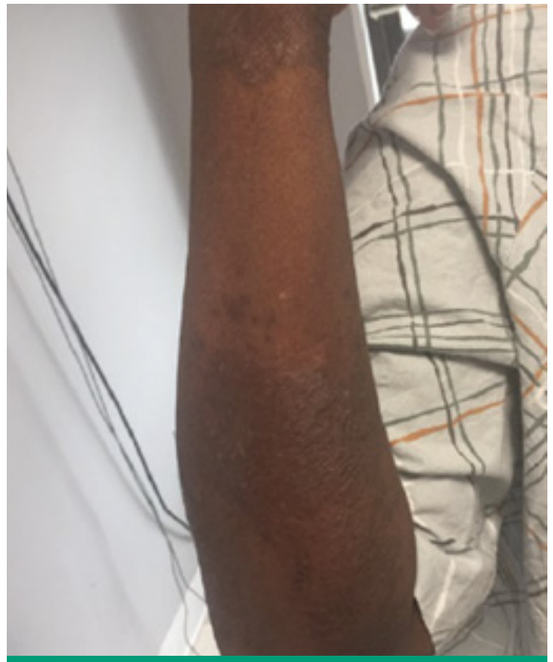




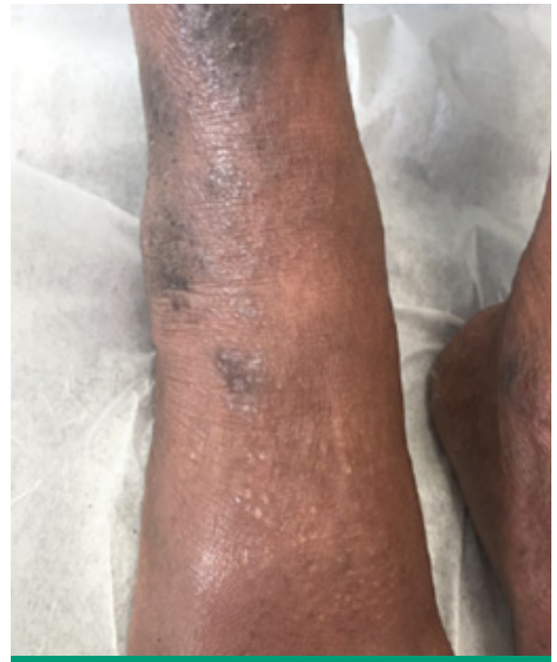
PROLONGED USE OF TOPICAL CORTICOSTEROIDS MAY CONTRIBUTE TO A GREATER RISK OF HYPER- OR HYPOPIGMENTATION IN SKIN OF COLOR[3,6]

RECOGNIZE HOW CLINICAL SIGNS MAY PRESENT IN SKIN OF COLOR

Marked lichenification, hyperpigmentation, and follicular accentuation are also common atopic dermatitis features in skin of color[3,7]



Marked lichenification and hyperpigmentation[3,7]



Follicular accentuation[3,7]

A study[a] has shown a diversity of atopic dermatitis presentations in skin of color—examples in patients of African origin include:

A study has shown a diversity of[7]:

- Papular lichenoid lesions
- Infraorbital folds
- Palmar hyperlinearity
- Ichthyosis

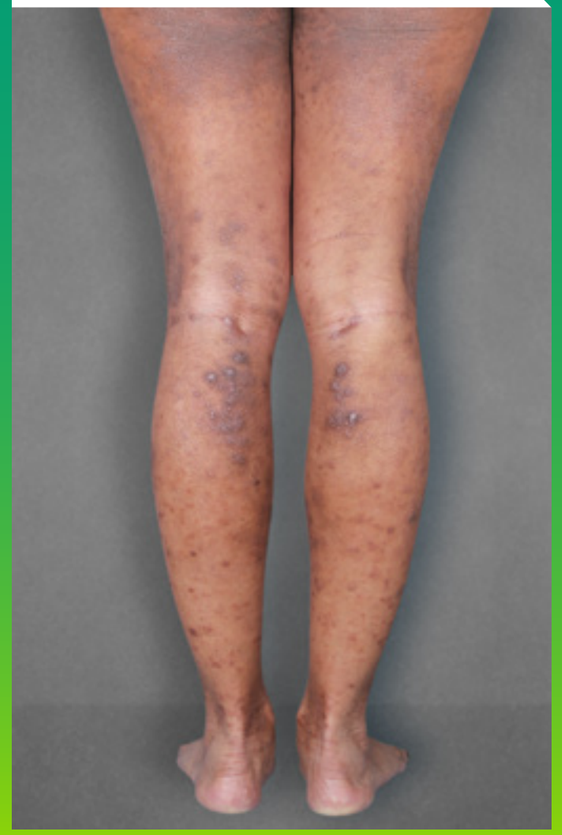
[a]In a prospective study of Nigerian atopic dermatitis patients over a 2-year period (N=1019)[7]

DUPIXENT—SEE VISIBLE RESULTS IN ADULT PATIENTS OF COLOR

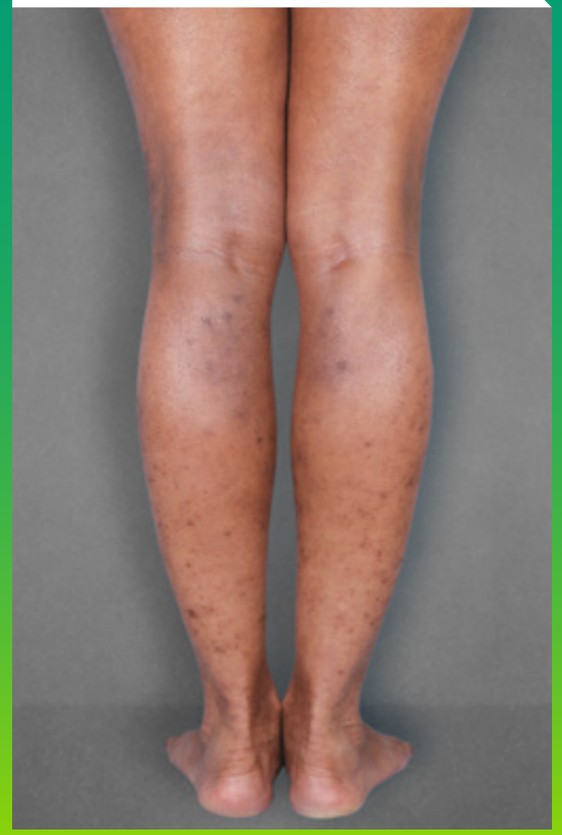
Actual patient treated with DUPIXENT. Note that this patient was on concomitant therapies, such as TCS, phototherapy, etc, at their prescribing physician's discretion. Scoring was designated by the treating physician. Because this was a real-world patient, there may be other factors influencing their treatment results, and individual results may vary.

Note: No active lesions were present at Week 16, only post-inflammatory hyperpigmentation.

BASELINE: IGA 4 (severe)



WEEK 16: IGA 0 (clear)



INDICATION

DUPIXENT is indicated for the treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

CONSIDER DUPIXENT FOR SKIN CLEARANCE AND ITCH REDUCTION IN ADULTS

>3X as many adult patients achieved clear or almost-clear skin (IGA 0 or 1) with DUPIXENT + TCS than with placebo + TCS at Week 16 (Trial 3; 39% vs 12%, *P*<0.0001; primary endpoint)[8,9,a,b]

Significant itch reduction (Peak Pruritus NRS) at Week 2 (9% vs 3%; *P*=0.0097) and Week 16 (41% vs 12%, *P*<0.001) with DUPIXENT in Trial 1 (secondary endpoint)[8,10,11]

In a post hoc analysis of 3 pooled trials (2 monotherapy and 1 concomitant TCS trial) in adults

ITCH REDUCTION AND SKIN CLEARANCE WAS GENERALLY CONSISTENT ACROSS ALL TESTED RACIAL GROUPS VS COMPARATOR[12]

- Black/African American
- Asian
- White

Definitive conclusions cannot be made as this analysis was performed on only 16-week data, did not directly compare dose regimens, and only a small number of black/African American patients were available for analysis.

TRIAL DESIGNS: A total of 917 adults in Trials 1 and 2 (16 weeks each) and 421 adults in Trial 3 (52 weeks) with moderate-to-severe atopic dermatitis inadequately controlled with topical prescription therapies were randomized to DUPIXENT or placebo. All patients in Trial 3 were treated with concomitant TCS. All patients received 300 mg Q2W after a 600 mg loading dose. Patients had an IGA score ≥3 (overall atopic dermatitis lesion severity scale of 0 to 4), an EASI score ≥16 on a scale of 0 to 72, and BSA involvement of ≥10%. At baseline, 52% had an IGA score of 3 (moderate), 48% had an IGA of 4 (severe), mean EASI score was 33, and weekly averaged Peak Pruritus NRS was 7 on a scale of 0 to 10.[8]

TRIAL RESULTS: The primary endpoint was change from baseline in the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) and ≥2-point improvement at Week 16 (38% and 36% of patients treated with DUPIXENT vs 10% and 9% with placebo in Trials 1 and 2, respectively, *P*<0.001; 39% of patients treated with DUPIXENT + TCS vs 12% with placebo + TCS in Trial 3, *P*<0.0001). Other endpoints included change from baseline in the proportion of subjects with EASI-75 at Week 16 (improvement of ≥75%; 51% and 44% of patients treated with DUPIXENT vs 15% and 12% with placebo in Trials 1 and 2, respectively, *P*<0.001; 69% of patients treated with DUPIXENT + TCS vs 23% with placebo + TCS in Trial 3, *P*<0.0001) and itch reduction defined by ≥4-point improvement in the Peak Pruritus NRS at Week 16 (41% and 36% of patients treated with DUPIXENT vs 12% and 10% with placebo in Trials 1 and 2, respectively, *P*<0.001; 59% of patients treated with DUPIXENT + TCS vs 20% with placebo + TCS in Trial 3, *P*<0.0001).[8-11]

AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numerical rating scale; Q2W, once every 2 weeks; TCS, topical corticosteroids.

[a] Responder defined as IGA 0 or 1 (clear or almost clear) with a reduction of ≥2 points on a 0-4 IGA scale at Week 16 in all trials (primary efficacy outcome) and at Week 52 in Trial 3 (other endpoint)

[b] Emollient background regimen/therapy was required.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity: Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum, anaphylaxis and serum sickness or serum sickness-like reactions, were reported in <1% of subjects who received DUPIXENT in clinical trials. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

DUPIXENT® (dupilumab) Injection
200mg · 300mg
REVOLUTIONIZING AD

DEMONSTRATED SAFETY ACROSS 52 WEEKS

The Week 52 safety profile of DUPIXENT + TCS in adults was generally consistent with the Week 16 adult safety profile[8]

Adverse reactions occurring in ≥1% of adult patients through Week 16[8]

Adverse reaction	DUPIXENT monotherapy[a]		DUPIXENT + TCS[b]	
	DUPIXENT[c] (n=529) n (%)	PLACEBO (n=517) n (%)	DUPIXENT + TCS[c] (n=110) n (%)	PLACEBO + TCS (n=315) n (%)
Injection site reaction	51 (10)	28 (5)	11 (10)	18 (6)
Conjunctivitis[d]	51 (10)	12 (2)	10 (9)	15 (5)
Blepharitis	2 (<1)	1 (<1)	5 (5)	2 (1)
Oral herpes	20 (4)	8 (2)	3 (3)	5 (2)
Keratitis[e]	1 (<1)	0	4 (4)	0
Eye pruritus	3 (1)	1 (<1)	2 (2)	2 (1)
Other herpes simplex virus infections[f]	10 (2)	6 (1)	1 (1)	1 (<1)
Dry eye	1 (<1)	0	2 (2)	1 (<1)

[a] Pooled analysis of Trials 1, 2, and 4 (phase 2 dose-ranging study).
[b] Analysis of Trial 3 in which subjects were on background TCS therapy.
[c] DUPIXENT 600 mg at Week 0, followed by 300 mg every 2 weeks.
[d] Conjunctivitis cluster includes conjunctivitis, allergic conjunctivitis, bacterial conjunctivitis, viral conjunctivitis, giant papillary conjunctivitis, eye irritation, and eye inflammation.
[e] Keratitis cluster includes keratitis, ulcerative keratitis, allergic keratitis, atopic keratoconjunctivitis, and ophthalmic herpes simplex.
[f] Other herpes simplex virus infection cluster includes herpes simplex, genital herpes, herpes simplex otitis externa, and herpes virus infection, but excludes eczema herpeticum.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical or inhaled corticosteroids abruptly upon initiation with DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Atopic Dermatitis Patients with Comorbid Asthma: Advise patients not to adjust or stop their asthma treatments without consultation with their physicians.

Parasitic (Helminth) Infections: It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1% at Week 16) in adult patients with atopic dermatitis are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, and dry eye. The safety profile in children and adolescents through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile of DUPIXENT in adolescents and children observed through Week 52 was consistent with that seen in adults with atopic dermatitis.

DRUG INTERACTIONS: Avoid use of live vaccines in patients treated with DUPIXENT.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. Healthcare providers and patients may call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/ to enroll in or obtain information about the registry. Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus.
- **Lactation:** There are no data on the presence of DUPIXENT in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

Please click here for full Prescribing Information.

References: 1. Vachiramon V, Tey HL, Thompson AE, Yosipovitch G. Atopic dermatitis in African American children: addressing unmet needs of a common disease. *Pediatr Dermatol.* 2012;29(4):395-402. **2.** Ben-Gashir MA, Hay RJ. Reliance on erythema scores may mask severe atopic dermatitis in black children compared with their white counterparts. *Br J Dermatol.* 2002;147(5):920-925. **3.** Kaufman BP, Guttman-Yassky E, Alexis AF. Atopic dermatitis in diverse racial and ethnic groups—variations in epidemiology, genetics, clinical presentation and treatment. *Exp Dermatol.* 2018;27(4):340-357. **4.** Davis EC, Callender VD. Postinflammatory hyperpigmentation: a review of the epidemiology, clinical features, and treatment options in skin of color. *J Clin Aesthet Dermatol.* 2010;3(7):20-31. **5.** Eichenfield LF, Stein Gold LF. Practical strategies for the diagnosis and assessment of atopic dermatitis. *Sem Cutan Med Surg.* 2017;36(2 suppl 2):S35-S38. doi:10.12788/j.sder.2017.009 **6.** Hengge UR, Ruzicka T, Schwartz RA, Cork MJ. Adverse effects of topical glucocorticosteroids. *J Am Acad Dermatol.* 2006;54(1):1-15. **7.** Nnoruka EN. Current epidemiology of atopic dermatitis in south-eastern Nigeria. *Int J Dermatol.* 2004;43(10):739-744. **8.** DUPIXENT Prescribing Information. **9.** Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet.* 2017;389(10086):2287-2303. **10.** Simpson EL, Bieber T, Guttman-Yassky E, et al; SOLO 1 and SOLO 2 Investigators. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med.* 2016;375(24):2335-2348. **11.** Data on file, Regeneron Pharmaceuticals, Inc. **12.** Alexis AF, Rendon M, Silverberg JI, et al. Efficacy of dupilumab in different racial subgroups of adults with moderate-to-severe atopic dermatitis in three randomized, placebo-controlled phase 3 trials. *J Drugs Dermatol.* 2019;18(8):804-813.

DUPIXENT® (dupilumab) Injection
200mg · 300mg
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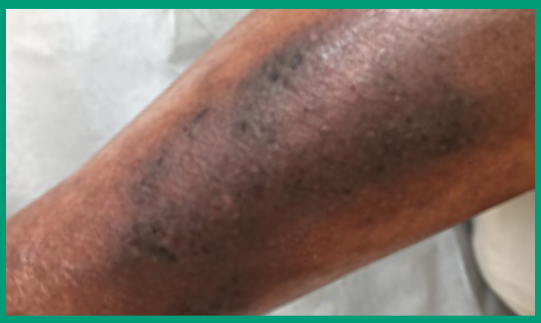
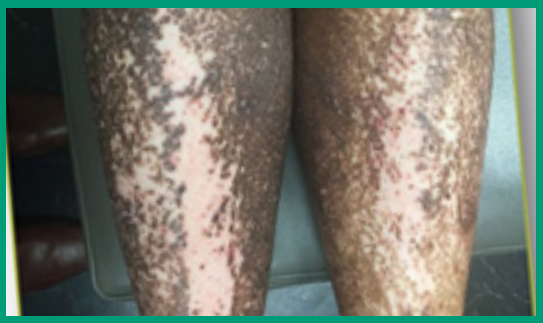
NOT ALL SKIN TYPES ARE THE SAME

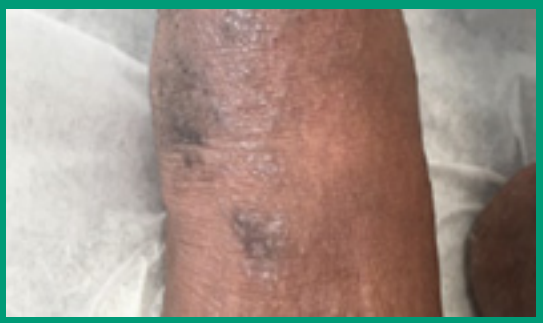
Moderate-to-severe atopic dermatitis severity may present distinctively in skin of color[1,2]



Erythema, which appears pink or red in lighter skin, may appear violet or dark violet in skin of color[3]



Hyper- or hypopigmentation following skin inflammation occurs most commonly in skin of color[1,3-5]



Other common atopic dermatitis features in skin of color include marked lichenification and follicular accentuation[3,7]

CONSIDER A NOVEL BIOLOGIC THAT PROVIDES SIMILAR EFFICACY ACROSS RACIAL GROUPS[1,2]

SANOFI GENZYME

REGENERON

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