

JCMS

JOURNAL OF CUTANEOUS MEDICINE AND SURGERY

Volume 24 ▪ Number 4 ▪ July/August 2020



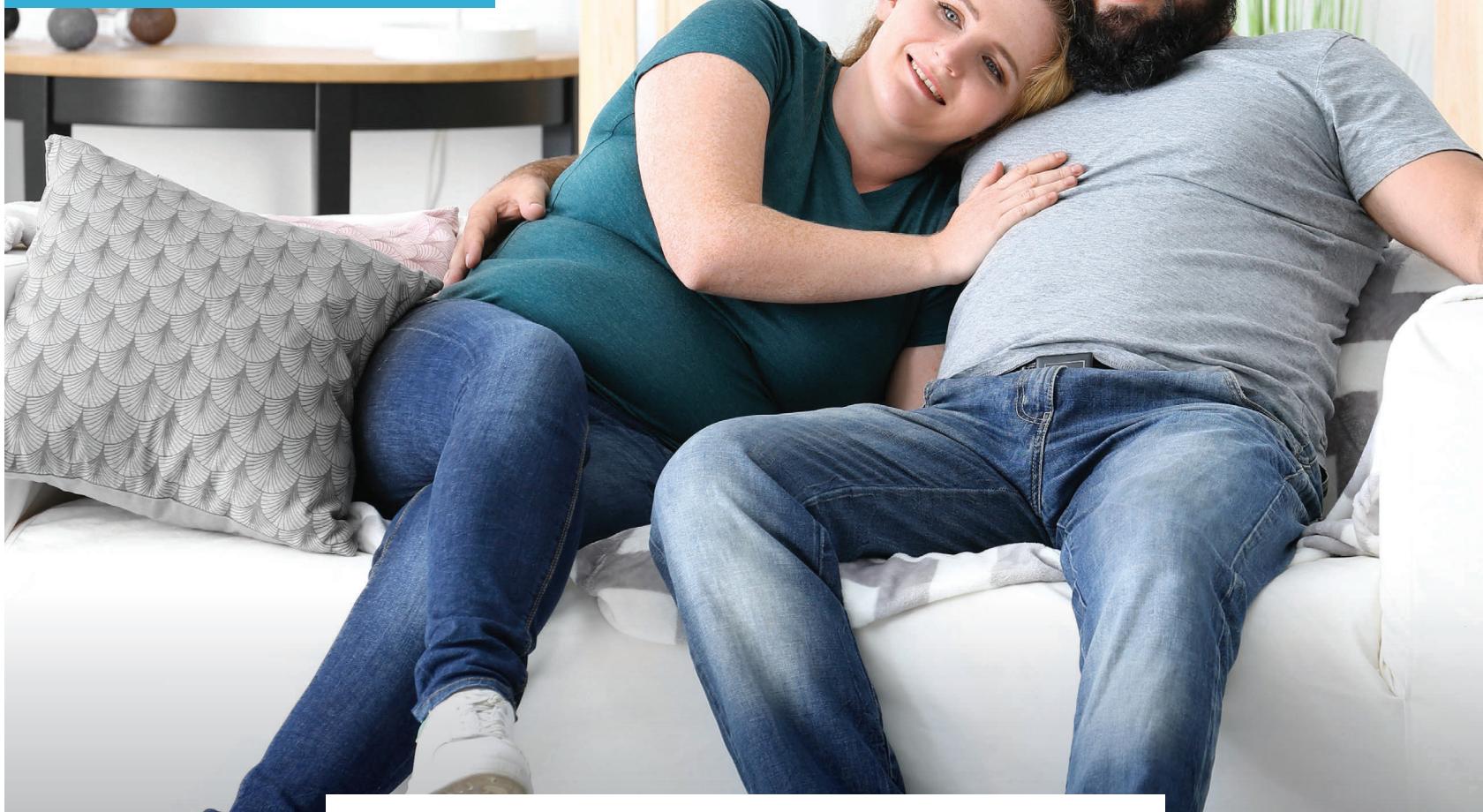
Skin Manifestations in Pediatric Patients Treated With a TNF-Alpha Inhibitor for Inflammatory Bowel Disease: A Retrospective Study

Utility of Preinjection Aspiration for Hyaluronic Fillers: A Novel In Vivo Human Evaluation

The Impact of Suspension of Dermatology On-Call Services

HUMIRA

The first and only
treatment indicated in
moderate to severe HS^{1*}



See what HUMIRA can do for your patients

THE HUMIRA Dermatology Portfolio – Established Experience*

DATES OF INTRODUCTION in Canadian practice:

2006 PsA 2008 Ps 2015 HS[†]

* Comparative clinical significance has not been established.
† Available for use in adolescents with HS as of 2018.

Reference: 1. HUMIRA Product Monograph. AbbVie Corporation. June 25, 2019.

HUMIRA is indicated for:

- Reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis (PsA) patients. Can be used in combination with methotrexate (MTX) in patients who do not respond adequately to MTX alone.
- Treatment of adult patients with chronic moderate to severe plaque psoriasis (Ps) who are candidates for systemic therapy. For patients with chronic moderate plaque Ps, HUMIRA should be used after phototherapy has been shown to be ineffective or inappropriate.
- Treatment of active moderate to severe hidradenitis suppurativa (HS) in adult and adolescent patients (12 to 17 years of age weighing ≥ 30 kg), who have not responded to conventional therapy (including systemic antibiotics).

Consult the Product Monograph at abbvie.ca/content/dam/abbviecorp/ca/en/docs/HUMIRA_PM_EN.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing, conditions of clinical use, and storage and handling. The Product Monograph is also available by calling 1-888-703-8271.

abbvie

© AbbVie Corporation
Printed in Canada
HUM/4432A – December 2019

MEMBER OF
INNOVATIVE MEDICINES CANADA

PAAB

abbvie.ca
1-888-703-3006

 **HUMIRA**[®]
adalimumab
destination you™

UNCOVER TREMFYA®

POWERFUL EFFICACY DEMONSTRATED in moderate to severe psoriasis

Improvements in the Dermatology Life Quality Index from baseline were observed in patients treated with TREMFYA® compared to placebo at Week 16.^{1,†}

**PASI
90**

73% (241/329) of patients achieved **PASI 90 at Week 16** with TREMFYA® vs. 3% with placebo (co-primary endpoint) and 50% with adalimumab (secondary endpoint) (TREMFYA® 100 mg at Weeks 0 and 4, then every 8 weeks [n=329]; placebo at Weeks 0, 4, and 12 [n=174]; adalimumab 80 mg at Week 0, 40 mg at Week 1, then 40 mg every 2 weeks [n=334]; p<0.001, NRI)^{1,*}

**PASI
90**

76% (47/62) of patients achieved **PASI 90 at Week 16** with TREMFYA ONE-PRESS™ vs. 0% (0/16) with placebo (co-primary endpoint, p<0.001)^{1,†}

**PASI
100**

50% (31/62) of patients achieved **PASI 100 at Week 16** with TREMFYA ONE-PRESS™ vs. 0% (0/16) with placebo (secondary endpoint, p<0.001)^{1,†}

No new safety signals were observed at **up to 3 years** in the uncontrolled extension phase of VOYAGE 1 and VOYAGE 2 (N=1221; median duration of follow-up: 156 weeks [range: 1–161])

- Safety profile was **consistent** with that observed in the controlled periods¹

The most frequently reported adverse drug reaction (>10%) through the 16-week, placebo-controlled period of the pooled VOYAGE 1 and VOYAGE 2 clinical trials in TREMFYA®-treated patients was upper respiratory infections (14.3% vs. 12.8% placebo).

Indication:

TREMFYA®/TREMFYA ONE-PRESS™ (guselkumab injection) is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Relevant warnings and precautions:

- Do not initiate treatment in patients with any clinically important active infections until the infection resolves or is adequately treated
- Discontinue treatment if patient develops a serious infection or is not responding to standard therapy for infection
- Evaluate patients for tuberculosis infection prior to therapy and monitor for active tuberculosis during and after treatment
- Consider completion of all immunizations prior to treatment
- Concurrent use with live vaccines is not recommended
- Discontinue treatment in cases of serious hypersensitivity reactions, including urticaria and dyspnea, and institute appropriate therapy
- Women of childbearing potential should use adequate contraception

- Use during pregnancy only if clearly needed

- The benefits of breastfeeding should be considered along with the mother's clinical needs
- Effect on human fertility has not been evaluated
- Safety and efficacy in pediatric patients have not been evaluated
- Data in patients ≥65 years of age are limited

For more information:

Please consult the Product Monograph at www.janssen.com/canada/products for important information relating to adverse reactions, drug interactions, and dosing that has not been discussed in this piece.

The Product Monograph is also available by calling 1-800-567-3331.

* VOYAGE 1: A multicentre, randomized, double-blind, placebo- and active comparator-controlled phase 3 study in 837 adult patients with moderate to severe plaque psoriasis (body surface area involvement ≥10%, PASI score ≥12, Investigator's Global Assessment ≥3) with or without psoriatic arthritis who were candidates for systemic therapy or phototherapy. Patients were randomized to receive subcutaneous injections of TREMFYA® 100 mg at Weeks 0 and 4, then every 8 weeks (n=329); adalimumab 80 mg at Week 0, 40 mg at Week 1, then 40 mg every 2 weeks (n=334); or placebo at Weeks 0, 4, and 12 (n=174). At Week 16, patients receiving placebo crossed over to TREMFYA® 100 mg at Weeks 16 and 20, then every 8 weeks.

† ORION Multicentre, phase 3, double-blind, placebo-controlled study to evaluate TREMFYA® administered with the patient-controlled One-Press injector in adults with moderate to severe plaque psoriasis (i.e., IGA score ≥3; PASI score ≥12; BSA involvement ≥10% for ≥6 months prior to screening). Patients were randomized 4:1 to either TREMFYA® 100 mg at Weeks 0, 4, and every 8 weeks thereafter, or placebo at Weeks 0, 4, and 12, with crossover to TREMFYA® 100 mg at Week 16. SC injections for both treatment arms done with One-Press device. Co-primary endpoints: Proportion of patients achieving IGA 0/1 and PASI 90 responses at Week 16.

PASI=Psoriasis Area Severity Index; NRI=non-responder imputation; IGA=Investigator's Global Assessment; BSA=body surface area; SC=subcutaneous.

References: 1. TREMFYA®/TREMFYA ONE-PRESS™ (guselkumab injection) Product Monograph. Janssen Inc. November 27, 2019. 2. Ferris LK, Ott E, Jiang J, et al. Efficacy and safety of guselkumab, administered with a novel patient-controlled injector (One-Press), for moderate-to-severe psoriasis: results from the phase 3 ORION study. *J Dermatolog Test* 2019; doi: 10.1080/09546834.2019.1587145.



REACH FOR SKYRIZI

SKYRIZI (risankizumab injection) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.



In the ULTIMMA-1 and ULTIMMA-2 studies, the percentage of patients with DLOI of 0/1 (no impact on health-related quality of life) at Week 16 were 65.8% ($p<0.0001$ vs. placebo and ustekinumab) and 66.7% ($p<0.0001$ vs. placebo; $p=0.0004$ vs. ustekinumab), respectively, in the SKYRIZI groups, 7.8% and 4.1%, respectively, in the placebo groups, and 43.0% and 46.5%, respectively, in the ustekinumab groups.^{1,2*}

Demonstrated efficacy

In the ULTIMMA-2 study, 74.8% (n=220/294) and 80.6% (n=237/294) of patients on SKYRIZI achieved PASI 90 vs. 47.5% (n=47/99) and 50.5% (n=50/99) of patients on ustekinumab at Weeks 16 and 52, respectively (secondary endpoints).^{1,*}

- Treatment difference at Week 16: 27.6% (95% CI: 16.7, 38.5)
- Treatment difference at Week 52: 30.2% (95% CI: 19.6, 40.9)

Generally well-established safety profile

The most common ($\geq 10\%$) adverse reaction through Week 16 was upper respiratory tract infections (13.0% with SKYRIZI vs. 9.7% with placebo).¹

Clinical use:

Efficacy and safety in pediatric population (<18 years of age) have not been evaluated. Limited data available for geriatrics (≥ 65 years of age).

Relevant warnings and precautions:

- Infections including tuberculosis
- Pregnant or nursing women
- Vaccinations
- Women of childbearing potential
- Hypersensitivity

PASI: Psoriasis Area and Severity Index; sPGA: static Physician Global Assessment; DLQI: Dermatology Life Quality Index.

* The efficacy and safety profile of SKYRIZI were assessed in 997 patients with moderate to severe plaque psoriasis in two multicentre, randomized, double-blind studies (ULTIMMA-1 and ULTIMMA-2). 598 patients were randomized to SKYRIZI 150 mg, 199 to ustekinumab 45 mg (<100 kg body weight) or 90 mg (>100 kg body weight) and 200 to placebo. Patients received treatment at Week 0, Week 4, and every 12 weeks thereafter.

References: 1. SKYRIZI Product Monograph. AbbVie Corporation. April 17, 2019. 2. Gordon KB, et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (ULTIMMA-1 and ULTIMMA-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet* 2018;392(10148):650-61.

Convenient every-12-week dosing

following initial doses at Week 0 and Week 4

The recommended dose is 150 mg (two 75 mg injections) administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.¹

For more information:

Please consult the Product Monograph at www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/SKYRIZI_PM_EN.pdf for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-888-704-8271.



© AbbVie Corporation
Printed in Canada
RIS/0040A – September 2019

MEMBER OF
INNOVATIVE MEDICINES CANADA



abbvie.ca
1-888-703-3006

Skyrizi®
(risankizumab) injection

JOURNAL OF CUTANEOUS MEDICINE AND SURGERY

Volume 24 ■ Number 4 ■ July/August 2020

