

# Mask wearing may be a cause for rosacea flare-ups<sup>1</sup>



## Rosacea patients are affected in a number of ways<sup>2</sup>

Irrespective of disease severity, rosacea patients (n=300) can be greatly impacted by **invisible symptoms**, which can **worsen with flares**<sup>2\*</sup>



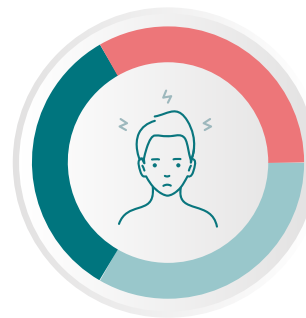
of rosacea patients report **not being in control** of their disease<sup>2</sup>



Furthermore,



patients report suffering from **moderate depression**<sup>2</sup>



patients report suffering from **moderate anxiety**<sup>2</sup>

It's not all 'maskne'... recent mask wearing has increased rosacea flare-ups<sup>1,3,4</sup>

## The current pandemic may be impacting rosacea patients further<sup>1,3,4</sup>



During the current Covid-19 pandemic, reports of mask-related facial dermatoses, such as well-known '**maskne**', have increased. Mask wearing can also cause **mask-related rosacea**<sup>1,3</sup>

**Mask-related rosacea may cause rosacea patients to experience a high burden**<sup>5,6</sup>



**NEW EVIDENCE** presented at the 2020 European Academy of Dermatology and Venereology Congress (EADV) highlighted that mask wearing by rosacea patients **significantly increased their disease severity** and had a **negative impact on their quality of life**:<sup>5†</sup>

### Rosacea severity assessed at Baseline (T<sub>0</sub>) and at Week 6 (T<sub>1</sub>) of quarantine:<sup>5</sup>

	Papulopustular rosacea (PPR) n=23 median [IQR]		Erythematotelangiectatic rosacea (ETR) n=13 median [IQR]	
	T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>
Clinician's Erythema Assessment (CEA)	1 [0-2]	2 [0-3] <sup>†</sup>	2 [2-3]	4 [3-4] <sup>5</sup>
Dermatology Life Quality Index (DLQI)	7 [6-9]	11 [9-12] <sup>†</sup>	6 [4-6]	9 [8-9] <sup>†</sup>
Investigator's Global Assessment (IGA)	1 [0-2]	3 [0-3.5] <sup>†</sup>	2 [2-3]	4 [3-4] <sup>5</sup>

**Act now** and help your rosacea patients reduce the risk of flares during these times...



### Help your patients continue their rosacea treatment journey

Although flare-ups seem likely, the National Rosacea Society (NRS) has provided guidance on how to avoid worsening the impact of rosacea during these times:<sup>4</sup>

- Stick to a skincare routine
- Apply a fragrance-free moisturizer under masks
- Try to use a new or clean mask in public



During the current pandemic, patient **self-medication** and **poor compliance** to prescribed treatments among patients are a **serious concern**<sup>7</sup>

### Help your patients avoid rosacea flares by providing them with advice during these times



- Ask about how the pandemic may be impacting their rosacea

# WHEN TREATING ROSACEA WHY COMPROMISE?

ORACEA® (doxycycline, USP) 40mg<sup>††</sup> Capsules  
The only FDA-approved oral treatment for  
papulopustular rosacea

- › Specifically designed to treat only papulopustular rosacea<sup>8</sup>
- › Proven tolerability<sup>9,10</sup>
- › Safe for long-term use<sup>11††</sup>



## RAPID RESULTS CLEARER SKIN IN JUST 3 WEEKS<sup>9,10</sup>

### CLINICAL RESULTS OF ORACEA CAPSULES VS PLACEBO<sup>9</sup>

	STUDY 1		STUDY 2	
	ORACEA Capsules (40 mg) n=127	Placebo n=124	ORACEA Capsules (40 mg) n=142	Placebo n=144
Mean change in lesion count from baseline to week 16	-11.8	-5.9	-9.5	-4.3
No. (%) of subjects clear or almost clear on the IGA <sup>†††</sup>	39 (30.7%)	24 (19.4%)	21 (14.8%)	9 (6.3%)

### MOST COMMON ADVERSE EVENTS IN BOTH STUDIES (%)<sup>10</sup>

	ORACEA Capsules n=269	Placebo n=268
Nasopharyngitis	4.8 %	3.3 %
Diarrhea	4.4 %	2.6 %
Hypertension	2.9 %	0.7 %
Sinusitis	2.6 %	0.7 %
Elevated AST	2.2 %	0.7 %

No photosensitivity or vaginal candidiasis reported in controlled clinical trials (vs placebo)<sup>9</sup>

**Study Design:** The safety and efficacy of ORACEA Capsules in the treatment of inflammatory lesions (papules and pustules) of rosacea was evaluated in two randomized, placebo-controlled,

multicenter, double-blind, 16-Week Phase 3 trials involving 537 subjects (total of 269 subjects on ORACEA Capsules from the two trials) with rosacea (10 to 40 papules and pustules and two or fewer nodules)<sup>9</sup>

When treating moderate to severe papulopustular rosacea, the 30 mg immediate release and 10 mg delayed release mechanism makes ORACEA Capsules just as powerful as doxycycline 100 mg, without crossing the antimicrobial threshold<sup>9-18</sup>

This means that, ORACEA Capsules are safe for long-term use, as found in a 9-month clinical study<sup>11</sup>

## IMPORTANT SAFETY INFORMATION

**Indication:** ORACEA® (doxycycline, USP) 40 mg<sup>††</sup> Capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. ORACEA Capsules do not lessen the facial redness caused by rosacea. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with ORACEA Capsules were nasopharyngitis, sinusitis, diarrhea, hypertension and aspartate aminotransferase increase. **Warnings/Precautions:** ORACEA Capsules should not be used to treat or prevent infections. ORACEA Capsules should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ORACEA Capsules should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Although photosensitivity was not observed in clinical trials, ORACEA Capsules patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ORACEA Capsules treatment beyond 16 weeks and safety beyond 9 months have not been established

You are encouraged to report negative side effects of prescription drugs to the FDA

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088

## FOOTNOTES

AST, aspartate aminotransferase; IQR, interquartile range

\*Beyond the visible: rosacea and psoriasis of the face report is based on a self-administered online survey covering 361 physicians, 300 rosacea patients and 318 psoriasis patients with facial involvement from France, Germany, Italy, Poland, Canada and the United States. Inclusion criteria for patients: adults suffering from at least a moderate disease impact (DLQI  $\geq 6$ ) with a diagnosis of rosacea or psoriasis on the face, taken a prescribed treatment in the past 12 months, and visited a physician at least once for their disease in the past 12 months<sup>2</sup>

<sup>†</sup>Multicenter, observational study conducted in Italy. Phase 2 assessed the impact of mask use in patients with pre-existing acne or rosacea over 3 months<sup>5</sup>

<sup>†</sup>P<0.015

<sup>§</sup>P<0.00015

<sup>††</sup>30 mg immediate release and 10 mg delayed release beads

<sup>††</sup>As found in a 9-month clinical study<sup>12</sup>

<sup>†††</sup>IGA, Investigator's Global Assessment

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