
**International Journal of Innovative Technologies in Social Science**

e-ISSN: 2544-9435

**Operating Publisher**
**SciFormat Publishing Inc.**
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
Calgary, Alberta, T3E0A7,
Canada
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| **ARTICLE TITLE** | SUMMARY OF THE LATEST REPORTS ON ROSACEA TREATMENT WITH TOPICAL PREPARATIONS CONTAINING MINOCYCLINE |
| **DOI** | https://doi.org/10.31435/ijitss.1(49).2026.4908 |
| **RECEIVED** | 21 January 2026 |
| **ACCEPTED** | 06 March 2026 |
| **PUBLISHED** | 18 March 2026 |
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# SUMMARY OF THE LATEST REPORTS ON ROSACEA TREATMENT WITH TOPICAL PREPARATIONS CONTAINING MINOCYCLINE

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**ABSTRACT**

**Introduction and Objective:** Rosacea is a chronic inflammatory disease of the facial skin. The main symptoms include erythema, papules, and pustules. It affects approximately 5.5% of the adult population and occurs more frequently in women. Its aetiology is complex. Genetic, immunological, and environmental factors are involved in the pathogenesis. Treatment options include topical and systemic antibiotic therapy and the elimination of aggravating factors. Among drugs used with a good therapeutic effect, minocycline can be mentioned. This study aims to review the current scientific literature and summarise the latest findings on the treatment of rosacea with topical minocycline formulations.
**Review Methods:** The literature review was conducted based on scientific publications from 2017 to 2025. The PubMed and Google Scholar databases were used for the search. English-language publications meeting the thematic and substantive criteria were analysed.
**Brief description of the state of knowledge:** Tetracycline antibiotics, including minocycline, are the mainstay of rosacea treatment. Minocycline is highly lipophilic and has the highest efficacy among tetracyclines. Clinical studies confirm its effectiveness in both oral and topical forms. Modern topical formulations enable effective therapy.
**Summary:** Rosacea is a chronic inflammatory facial skin disease that significantly reduces patients' quality of life. Minocycline, due to its anti-inflammatory and antibacterial properties, is effective in treating moderate to severe forms of the disease. Topical formulations, particularly the 1,5% concentration foam, demonstrate high efficacy and good tolerability.

**KEYWORDS**

Rosacea, Minocycline, Skin, Topical Drug Administration

**CITATION**

Małgorzata Muszyńska, Paulina Małyszczak, Dawid Nowicki, Katarzyna Karaś, Sylwia Mroszczyk. (2026) Summary of the Latest Reports on Rosacea Treatment with Topical Preparations Containing Minocycline. *International Journal of Innovative Technologies in Social Science*. 1(49). doi: 10.31435/ijitss.1(49).2026.4908

**Abbreviations:** IGA- Investigator's Global Assessment; PPR- Papulopustular Rosacea; RR-Relative Risk

**Introduction and Aim of the Study**

Rosacea is a chronic inflammatory dermatosis that most commonly affects the central areas of the face. The condition is characterised by the presence of erythema, telangiectasia, papules, and pustules, as well as phymatous changes [1-3]. In some patients, ocular manifestations may also occur, including blepharitis, conjunctivitis, or keratitis [4]. The course of the disease is often associated with subjective symptoms such as increased skin sensitivity and sensations of burning, stinging, or pruritus [5-7].

Since 2017, the ROSacea COnsensus (ROSCO) Panel has recommended a rosacea classification system based on the assessment of clinical features. This classification considers both primary and secondary criteria that reflect clinical manifestations of the disease. The system is modular and flexible, allowing for a more accurate representation of the heterogeneous clinical profile of rosacea. In the presence of phymatous changes or persistent facial erythema, a diagnosis can be established based on a single clinical feature. Otherwise, rosacea can be diagnosed when at least two primary features are present, including flushing or erythema, papules, pustules, teleangiectasia, and ocular manifestations. Secondary features include sensations of burning or stinging, oedema or swelling and skin dryness. Additionally, individual features are assessed in terms of their frequency, severity, duration, and extent of involvement, enabling a more precise evaluation of disease severity [8].

Rosacea constitutes a significant health problem due to both its chronic course and its substantial impact on patients' quality of life [2]. The cutaneous manifestations characteristic of the condition may lead to reduced self-esteem and the development of emotional disorders, such as anxiety and depression, as well as contribute to social isolation [5,9,10]. According to epidemiological data, rosacea may affect up to 5,5% of the global population [11]. It occurs most frequently in adults aged 30-50 years; however, initial symptoms may appear before the age of 20. Women are affected more often than men [3,11], although men more commonly develop more severe, hypertrophic forms of the disease [12].

The aetiology of rosacea remains incompletely understood; however, its pathogenesis is thought to involve a complex interplay of genetic, environmental and immunological factors. The most important determinants of disease development include genetic predisposition, immune system dysregulations, abnormal dilation of blood vessels, as well as the influence of external factors such as ultraviolet radiation, stress, certain medications and microorganisms, including the human demodex mite (*Demodex folliculorum*) and Cutibacterium acnes. The complexity of these mechanisms makes it difficult to identify a single primary causative factor [6,9,14,15].

Treatment of rosacea has long been considered challenging due to the recurrent nature of the disease and the associated tendency of the skin to irritation [16]. Therapeutic management of rosacea involves the use of topical and systemic treatments, appropriate skincare, laser therapies, and light-based therapies, as well as the elimination of factors that trigger symptoms. In the treatment of the papulopustular subtype, agents such as metronidazole, azelaic acid, ivermectin, modified-release doxycycline, as well as brimonidine and oxymetazoline for the reduction of erythema, are commonly used [5,8,14,17]. One of the drugs also employed in the management of this disease subtype is minocycline. It is a semi-synthetic antibiotic from the tetracycline group, exhibiting both antibacterial and anti-inflammatory properties. Minocycline can be administered both systemically and topically [6,8]. Topical application of minocycline allows high drug concentrations to be achieved in the skin while simultaneously limiting the risk of systemic adverse effects [1,2]. This paper aims to review the current scientific literature to summarise the most recent reports on the treatment of rosacea using topical minocycline formulations.

**Methodology**

The literature review was conducted based on an analysis of available scientific articles concerning the treatment of rosacea with topical preparations containing minocycline. The following keywords and their combinations were used: rosacea, minocycline, skin, and topical drug administration. Data sources included the electronic databases PubMed and Google Scholar.

Initially, a preliminary selection was performed based on keywords and abstracts. Publications not directly related to the research topic were excluded. Ultimately, 27 studies describing the use of minocycline in the treatment of rosacea published between 2017 and 2025 were included in the review. Only publications in Polish and English were considered.

Publications published before 2017 and those not related to rosacea or to the mechanism of action or evaluation of the efficacy of topical minocycline preparations used in the treatment of rosacea were excluded from the analysis. Article selection was carried out independently, beginning with an analysis of keywords and abstracts, followed by a detailed assessment of full texts meeting the inclusion criteria. Finally, the selected publications were evaluated in terms of their currency, relevance to the topic of the study, and scientific merit.

**Discussion**

**The use of tetracyclines, with particular emphasis on minocycline, in the treatment of rosacea**

Antibiotics from the tetracycline, doxycycline and minocycline, constitute the cornerstone of pharmacological treatment of inflammatory lesions in the course of rosacea [1-2]. These agents exhibit both antibacterial activity and strong anti-inflammatory properties, which make them first-line drugs in the management of moderate and severe forms of the disease [6]. The mechanism of action of tetracyclines involves the inhibition of lipase activity produced by *Cutibacterium acnes*, which prevents the release of free fatty acids from sebaceous follicles. In addition, these antibiotics reduce neutrophil chemotaxis and inhibit phospholipase A2 activity, thereby exerting an effect on the reduction of inflammatory response intensity. An important aspect of their action is also the reduction of metalloproteinase activity and nitric oxide production. Tetracyclines suppress the production of pro-inflammatory cytokines such as tumour necrosis factor alpha, interleukin-1, interleukin-1β and interleukin-6, resulting in an overall reduction of the inflammatory response [15,18-20]. Their anti-inflammatory and antioxidant properties, as well as their ability to inhibit collagenase activity, make this group of drugs particularly desirable in the treatment of skin diseases associated with collagen structure damage and pronounced inflammation [10,20].

Minocycline exhibits the highest lipophilicity among tetracyclines, which enables the achievement of higher therapeutic concentrations within the sebaceous glands. Clinical studies have demonstrated its superior efficacy compared with doxycycline in the treatment of rosacea [15,21]. The results of numerous studies indicate that minocycline constitutes an effective and generally well-tolerated therapeutic option in the management of rosacea, particularly in moderate to severe forms of the disease. Its broad spectrum of activity, including anti-inflammatory, antioxidant and immunomodulatory properties, allows for its use in both systemic and topical therapies, resulting in clinically significant improvement [10,20].

**Types of topical preparations containing minocycline**

The most common problem associated with long-term systemic use of minocycline is the development of microbial resistance. It is worth noting, however, that *Cutibacterium acnes* exhibits a lower level of resistance to minocycline compared with doxycycline and tetracycline. Other important complications resulting from prolonged oral minocycline therapy include intestinal dysbiosis and excessive overgrowth of yeasts, leading to fungal infections such as vulvovaginal and oral candidiasis. Long-term systemic therapy with minocycline may also induce adverse effects involving the nervous, musculoskeletal, gastrointestinal, genitourinary, respiratory, and cutaneous systems [16,18,22].

Topical minocycline formulations allow high drug concentrations to be achieved within the skin while simultaneously limiting systemic exposure, which significantly reduces the incidence of general adverse effects [2,10,22]. Table 1 presents a summary of topical preparations containing minocycline. Despite the well-recognised benefits of topical administration, this form was not available until 2020, when the FMX103 foam was approved. Two additional formulations are currently in advanced clinical trials and may in the future represent an important addition to topical treatment strategies: HY01 as well as BPX-01 and BPX-04 [18,23]. A summary of the basic information on these preparations is provided in Table 1.

**Table 1.** Summary of topical minocycline preparations

| Name of preparation | Pharmaceutical form | Minocycline concentration | Manufacturer or company | Status |
|---|---|---|---|---|
| **FMX103** | Foam | 1,5% | — | Approved in 2020 |
| **HY01** | Anhydrous gel | 1% and 3% | Hovione | In an advanced phase of clinical trials |
| **BPX-01 and BPX-04** | Hydrophilic gel | 1% and 2% | BioPharmax | In an advanced phase of clinical trials |

Source: [18,22-24]

**Comparison of topical minocycline preparations**

FMX103 was developed for the treatment of moderate to severe papulopustular rosacea. The foam combines the efficacy of minocycline with a simultaneous minimisation of the risk of systemic adverse effects. The formulation is unique, as it uses a micronised form of the active substance suspended in a foam, which enables improved skin penetration and eliminates the unpleasant gritty sensation. It contains excipients such as soybean oil, coconut oil, light mineral oil, and cyclomethicone-5. These substances possess moisturising properties and exhibit high chemical compatibility with minocycline [22,25,26]. The formulation developed by Hovione contains a patented excipient with emollient properties, composed of anhydrous hydrocarbon-based gelling agents. This composition promotes water retention and supports the restoration of the epidermal barrier, which is of particular importance for patients with barrier impairment caused by papulopustular rosacea. The Hovione gel stabilises a novel free-base form of minocycline, which, due to its higher pH (6.0-6.5) compared with 3.5-4.5 in other formulations, may reduce skin irritation. In addition, it is characterised by higher lipophilicity and greater stability than minocycline hydrochloride [18,23,27].

BiopharmaX employs a patented technology based on an anhydrous, hydrophilic gel, HyantX™, which completely dissolves minocycline hydrochloride and enables rapid transdermal absorption [18,24]. The company conducted an evaluation of clinical studies on topical minocycline gels, BPX-01 and BPX-04. Clinical trials of the minocycline gels BPX-01 and BPX-04 demonstrated a significant reduction in inflammatory lesions and an improvement in the global assessment of skin condition, as measured by the Investigator Global Assessment (IGA), compared with placebo. For both formulations, a reduction in inflammatory lesions was observed [6,18,24].

Hovione conducted a phase IIb study, the Minocycline Against Rosacea Study (MARS), in which the efficacy of 1% and 3% minocycline gel was evaluated. After 12 weeks of therapy, a statistically significant, dose-dependent reduction in inflammatory lesions was observed. Improvement was also noted on the Investigator Global Assessment (IGA) scale, with a reduction of ≥2 grades [6,18]. A summary of the results obtained by both companies is presented in Table 2.

**Table 2.** Comparison of BPX-01, BPX-04 and HY01 formulations

| Formulation and manufacturer | Number of participants | Dose and formulation | Primary endpoints | Efficacy outcomes | p* |
|---|---|---|---|---|---|
| **BPX-01 (BiopharmX)** | 226 patients, 15 centres | Minocycline gel 1% and 2% | Reduction in the number of inflammatory lesions; number of non-inflammatory lesions; improvement in skin quality assessed using the Investigator Global Assessment (IGA); subjective assessment of symptom severity | **Reduction in inflammatory lesions: 58.5% (BPX-01 2%) vs 43.8% (placebo)** | **p = 0,0256** |
| **BPX-04 (BiopharmX)** | 206 patients, 11 centres | Minocycline gel 1% | Change in the number of inflammatory lesions; improvement in skin quality of ≥2 grades as measured by the IGA | **Mean change in lesion count: -13.6 (BPX-04) vs -10.3 (placebo); improvement in skin quality measured by IGA: 52.3% vs 32.3%** | **p = 0.004** (for mean change in lesion count); **p = 0.018** (for improvement in skin quality measured by IGA) |
| **HY01- Hovione gel** | 270 patients, 26 centres | Minocycline gel 1% and 3% | Mean change in the number of inflammatory lesions; proportion of patients with an improvement of ≥2 grades in skin quality measured by the IGA | **Reduction in inflammatory lesions: -12.6 (1%), -13.1 (3%), -7.9 (placebo); improvement in skin quality measured by IGA: 39% (1%), 46% (3%), 31% (placebo)** | **p = 0.01 (for reduction in inflammatory lesions); p = 0.038 (for improvement in skin quality measured by IGA)** |

*p - probability value
Source: [18,24]

Alamari *et al.* conducted a systematic review and meta-analysis that included only randomised controlled trials (RCTs) evaluating the efficacy and safety of topical minocycline in the form of a 1.5% foam and gels at concentrations of 1% and 3% in patients with moderate-to-severe papulopustular rosacea. Five RCTs were included in the analysis, comprising a total of 2,453 participants, of whom 70% were women. Four of the five analysed studies investigated the use of 1.5% minocycline foam, while one study assessed the efficacy of 1% and 3% minocycline gel [2]. Table 3 presents a summary of the results of studies evaluating the efficacy of the aforementioned formulations.

**Table 3.** Comparison of the efficacy of topical formulations

| Formulation and concentration | Effect measured by IGA (Week 12) | Relative risk (95% CI) | p* | I²** | Notes |
|---|---|---|---|---|---|
| **Minocycline foam 1.5%** | Significant improvement | 1,31 (1,12-1,53) | 0,0008 | 33% | Most effective formulation; superior to 1% and 3% gels |
| **Minocycline gel 1%** | Non-significant improvement | 1,26 (0,83-1,93) | 0,28 | – | No significant efficacy |
| **Minocycline gel 3%** | Cut-off point and borderline improvement | 1,50 (1,01-2,24) | 0,05 | – | Borderline significant effect |

p* - probability value
I²** - heterogeneity
Source: [2]

The meta-analysis by Alamri *et al.* demonstrated that minocycline foam was more effective in reducing the number of inflammatory lesions. The best outcomes were observed with the 1.5% formulation. Both the foam and minocycline gels at concentrations of 1% and 3% improved the IGA score after 12 weeks of treatment; however, minocycline foam showed greater efficacy than the gel formulations [2].

**Adverse effects during the use of topical preparations**

**Table 4.** Adverse effects observed during the use of 1.5% minocycline foam

| Cutaneous symptom | Relative risk (95% CI) | p* | I²** | Statistical significance | Severity assessment |
|---|---|---|---|---|---|
| **Moderate erythema** | 0,77 (0,62-0,96) | 0,02 | 0% | Yes | Mild |
| **Mild erythema** | 0,95 (0,78-1,15) | 0,59 | 43% | No | Mild |
| **Severe erythema** | 0,51 (0,16-1,16) | 0,25 | 0% | No | Mild |
| **Telangiectasia** | 1,02 (0,94-1,11) | 0,36 | 0% | No | High |
| **Burning or stinging** | 0,99 (0,62-1,56) | 0,95 | 53% | No | Moderate |
| **Redness or flushing** | 1,07 (0,71-1,60) | 0,75 | 77% | No | Moderate |
| **Dryness or xerosis** | 0,89 (0,74-1,06) | 0,20 | 0% | No | High |
| **Pruritus** | 0,97 (0,79-1,20) | 0,79 | 0% | No | High |
| **Scaling or desquamation** | 0,85 (0,70-1,03) | 0,10 | 0% | No | High |
| **Hyperpigmentation** | 0,88 (0,68-1,13) | 0,30 | 19% | No | High |

p* - probability value
I²** - heterogeneity
Source: [2]

An analysis of the available clinical data on the use of topical minocycline formulations demonstrated that all evaluated formulations are characterised by a favourable safety profile and good local tolerability. In the case of 1.5% minocycline foam, the most frequently reported adverse events were pruritus and viral upper respiratory tract infections. The results of studies conducted by Alamari *et al.* indicated an association between the use of 1.5% minocycline foam and moderate erythema. However, no statistically significant association

was observed between these formulations and the occurrence of other symptoms, such as mild or severe erythema, telangiectasia, burning, skin dryness, pruritus, or hyperpigmentation. These events occurred sporadically and did not reach statistical significance. The vast majority of patients (>80%) rated the adverse events as mild or negligible. These adverse effects are presented in Table 4 [2].

**Table 5.** Comparison of adverse effects of 1.5% foam, BPX-01/04 gel, and HY-01 1% and 3%

| Formulation and concentration | Most common adverse effects | Severity | Remarks |
|---|---|---|---|
| **1.5% minocycline foam (rosacea, Phase III)** | Pruritus, viral upper respiratory tract infections | Mild–moderate | Only one patient discontinued treatment due to pruritus; skin-related application-site issues were reported as absent or mild in >80% of participants |
| **BPX-01** | No significant adverse effects | Well tolerated | No photosensitivity, hyperpigmentation, or skin discolouration were reported |
| **BPX-04** | Upper respiratory tract infections (5.3%), gastroenteritis (2.4%), headache (2.4%) | Mostly unrelated to treatment | — |
| **HY-01 minocycline 1%** | Dermatitis, application-site pruritus | Isolated cases | — |
| **HY-01 minocycline 3%** | Nausea, erythema, application-site pruritus, hypersensitivity, headache, exacerbation of rosacea, urticaria | Isolated cases | — |

Source: [6,18,24]

In studies evaluating the HY-01 gel containing minocycline at concentrations of 1% and 3%, only isolated and transient adverse events were reported. For the 1% concentration, these included cases of dermatitis and application-site pruritus, whereas for the 3% concentration, the reported adverse events comprised nausea, erythema, hypersensitivity, headache, exacerbation of rosacea, and urticaria [6,18]. No significant cutaneous reactions or cases of photosensitivity or hyperpigmentation were observed during the use of the modern BPX-01 and BPX-04 formulations. Among the most frequently observed adverse events were mild upper respiratory tract infections, sporadic gastrointestinal complaints, and headaches. These formulations were well tolerated, and the majority of reported symptoms were mild in nature and did not require discontinuation of treatment. The results of these studies are summarised in Table 5 [18,24].

## Conclusions

Rosacea represents a significant health problem due to its chronic course and its negative impact on quality of life, including reduced self-esteem, emotional disturbances, and social isolation. It is a chronic inflammatory dermatosis primarily affecting the central areas of the face and is characterised by the presence of erythema, telangiectasia, and papular and pustular lesions. According to epidemiological data, the disease affects approximately 5.5% of the global population.

Tetracycline-class antibiotics, including tetracycline, doxycycline, and minocycline, constitute the cornerstone of pharmacotherapy for inflammatory lesions in rosacea due to their antibacterial and anti-inflammatory properties. Owing to its anti-inflammatory, antioxidant, and immunomodulatory effects, minocycline is effective in the treatment of this condition.

Topical minocycline formulations allow high drug concentrations to be achieved in the skin while limiting systemic absorption, thereby reducing the risk of systemic adverse effects. Topical minocycline preparations, particularly 1.5% minocycline foam, represent a promising and effective therapeutic option for the treatment of moderate to severe papulopustular rosacea. Both the 1.5% foam and the HY-01 and BPX-01/04 gels are characterised by a high safety profile and good tolerability. Adverse effects are generally mild and local in nature.

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