SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

PanOxyl Aquagel 5, PanOxyl 5 Aquagel 5%w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl peroxide 5% w/w. Also contains propylene glycol.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The product is indicated for use in the topical treatment of acne vulgaris.

4.2 Posology and method of administration

Treatment should normally begin with PanOxyl Aquagel 2.5. The reaction of the skin to benzoyl peroxide differs in individual patients. The higher concentration in PanOxyl Aquagel 5 or 10 may be required to produce a satisfactory response.

Adults and adolescents
Apply a thin film to the whole of the affected area once daily preferably after washing and drying the skin.
If excessive dryness or peeling occurs application should be temporarily interrupted as per physician instruction or patient tolerability.

Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continued use is normally required to maintain a clinical response.

Elderly Patients
There are no specific recommendations for use in the elderly.

Paediatric Population
Safety and effectiveness of topical benzoyl peroxide in children under the age of 12 has not been established.

4.3 Contraindications

Patients with a known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes, eyelids, mouth, lips, and other mucous membranes. Contact with broken skin should be avoided. Care should be taken when applying the product to the neck and other sensitive areas.

During the first weeks of treatment a sudden increase in peeling and reddening will occur in most patients and will normally subside in a day or two if treatment is temporarily discontinued.

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.
Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents.

If severe local irritancy occurs (e.g. severe erythema, severe dryness and itching, severe stinging/burning sensation), benzoyl peroxide should be discontinued.

As benzoyl peroxide may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight should be avoided or minimised. When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.
The product may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

PanOxyl 5 Aquagel contains propylene glycol. Propylene glycol may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant application of PanOxyl with tretinoin, isotretinoin,and tazarotene should be avoided since it may reduce their efficacy and increase irritation. If combination treatment is required, the products should be applied at different times of the day (e.g., one in the morning and the other in the evening.)

Using topical PanOxyl at the same time as topical sulfonamide-containing products may cause skin and facial hair to temporarily change colour (yellow/orange).

4.6 Fertility, Pregnancy and lactation

Fertility
There are no data on the effect of topical benzoyl peroxide on fertility.

Pregnancy
There are limited data on the use of topical benzoyl peroxide in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see Section 5.3). No effects during pregnancy are anticipated since systemic exposure to benzoyl peroxide is very limited. However, benzoyl peroxide should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Lactation
Percutaneous absorption of benzoyl peroxide is very limited; however, it is not known whether benzoyl peroxide is excreted in human milk after topical application.
Topical benzoyl peroxide should be used during lactation only if the expected benefit justifies the potential risk to the infant.
If used during lactation, benzoyl peroxide should not be applied to the breast area to avoid accidental ingestion by the infant.

4.7 Effects on ability to drive and use machines

Not Relevant.

4.8 Undesirable effects

Adverse reactions are classified by System Organ Class. Adverse reactions that occurred either during clinical studies or that were spontaneously reported are presented below:

Frequencies were defined as follows:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known* (cannot be estimated from the available data).

Immune System Disorders

Not known:	Allergic reactions, including application site hypersensitivity and anaphylaxis

Skin and Subcutaneous Tissue Disorders

Very Common:	Peeling, application site erythema
Common:	Dryness, pruritus and contact sensitisation reactions
Uncommon:	Burning sensation
Not known:	Application site rash

General Disorders and Administration Site Conditions

Not known:	Application site discoloration and application site reactions such as irritation and pain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms and signs
Topically applied benzoyl peroxide is not generally absorbed in sufficient amounts to produce systemic effects.
Excessive application may result in severe irritation. In this event, discontinue use and wait until the skin has recovered.

Treatment
Cold compresses can provide relief from irritation due to excessive application.

Accidental ingestion of topical benzoyl peroxide should be managed clinically or as recommended by the National Poisons Centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Benzoyl peroxide

ATC code: D10AE01

Mechanism of action

Benzoyl peroxide is a highly lipophilic oxidizing agent with bacteriocidal and keratolytic effects.

Pharmacodynamic effects

The effectiveness of benzoyl peroxide in the treatment of acne vulgaris is primarily attributable to its antibacterial activity, especially with respect to Propionibacterium acnes. The antibacterial activity of benzoyl peroxide is due to the release of active or free-radical oxygen capable of oxidising bacterial proteins. Benzoyl peroxide is also believed to be effective in the treatment of acne on account of its anti-inflammatory and mild keratolytic properties.

5.2 Pharmacokinetic properties

Absorption/Distribution/Metabolism
Benzoyl peroxide is absorbed by the skin where it is metabolised to benzoic acid. Following topical application, less than 5% of the dose enters systemic circulation as benzoic acid.

Elimination
Benzoyl peroxide is excreted as benzoic acid in the urine.

5.3 Preclinical safety data

Carcinogenesis/mutagenesis
Both the carcinogenicity and photocarcinogenicity of benzoyl peroxide have been extensively assessed in both mice and hamsters, by various routes of administration, in studies ranging from 42 to 100 weeks in duration. The

overall conclusion is that benzoyl peroxide is considered to be generally recognized as a neither carcinogenic nor photocarcinogenic and safe in topical acne products at a concentration of 2.5% to 10%.
The genotoxicity of benzoyl peroxide was extensively assessed in vitro and in vivo. While in a few in vitro studies benzoyl peroxide showed weak mutagenicity, the overall genotoxicity profile did not indicate significant biological relevance.

Reproductive Toxicology

Fertility and Pregnancy
In a combined repeat- dose and reproduction/development toxicity study, benzoyl peroxide (250, 500 or 1,000 mg/kg/day) was administered orally to male rats for 29 days and female rats for 41-51 days. There were no treatment-related changes observed in the mating period, mating rate, conception rate, delivery rate, birth rate, pregnancy period, luteinization number, implantation number and the rate of losing embryos and foetuses after implantation. In pups, body weight was significantly decreased in the high-dose group. The no-observed-adverse-effect-level (NOAEL) for reproductive toxicities was considered to be 500 mg/kg/day.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 940
Di-isopropanolamine
Propylene glycol
Macrogol lauryl ether
Sodium laurilsulfate
Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium tube, fitted with a High Density Polyethylene screw cap.

Licenced pack sizes: 40g and 50g. Not all pack sizes may be marketed

6.6 Special precautions for disposal

There are no special instructions for use or handling of PanOxyl Aquagel 5.

7 MARKETING AUTHORISATION HOLDER

Avianta Pharma Limited,
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England,
CV31 3SS,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 49226/0014

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/06/2016

10 DATE OF REVISION OF THE TEXT

06/11/2025

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)