SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Blemish 0.1% + 1.0 % Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains:

Adapalene BP	1.0 mg
Clindamycin Phosphate USP equivalent to Clindamycin	10 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel
Description: White to off white translucent homogenous gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Local treatment for acne (acne vulgaris).

4.2 Posology and method of administration

Apply a thin layer of gel on clean dry skin in places of rashes once a day, at night.
During the first week of treatment, acne may be exacerbated by the effects of the active substance on the lesions, which were invisible before. In this case, treatment should not be discontinued, the therapeutic effect is observed 8-12 weeks after starting the treatment.

Children: Use in children above 12 years.

4.3 Contraindications

Hypersensitivity to adapalene, clindamycin or to other components of the drug, as well as to lincomycin. Enteritis, ulcerative colitis, colitis, associated with antibiotics (in history), Crohn's disease.

4.4 Special warnings and precautions for use

The drug is for topical use only.
Avoid contact of gel with eyes, lips, areas of the nose and skin around the eyes, and also mucous membranes. If accidentally gel gets into these areas, thoroughly rinse them with warm water.
Do not apply gel to eczematous skin lesions, sunburns, cuts or other skin lesions.
During treatment, excessive exposure to sunlight and ultraviolet light, including lamps, should be avoided due to increased skin sensitization and increased risk of solar erythema.
Using during the treatment period with cosmetic products that dry the skin (abrasive or healing soaps, skin cleansers, excessive amounts of alcohol, astringent, creams or lotions for or after shaving, products, detergents) can lead to irritative effect.
In the event of an allergic reaction to any component of the drug, therapy should be discontinued and appropriate measures taken.
With topical application of clindamycin, absorption of antibiotics from the skin surface occurs. Diarrhea, diarrhea with blood admixtures and colitis (including pseudomembranous colitis) with external and systemic application of clindamycin has been reported.

Studies show that the main cause of colitis associated with the use of antibiotics is the toxin produced by clostridia. Usually colitis is characterized by severe persistent diarrhea and severe colic in the stomach and may be accompanied by blood and mucus secretion. Pseudomembranous colitis can be detected by endoscopic examination.

Finding *Clostridium difficile in feces*, and fecal analysis for the presence of *C. difficile* toxin can help with the diagnosis of this disease.
In case of significant diarrhea drug use should be discontinued. In cases of severe diarrhea, it is necessary to consider the possibility of an endoscopic examination of the large intestine to establish an accurate diagnosis.
The use of peristalsis-suppressing agents, such as opiates and difenoxylate with atropine, may prolong and / or worsen this condition. It was determined that vancomycin is effective in the treatment of pseudomembranous colitis associated with the use of antibiotics caused by *Clostridium difficile*. The usual dose for adult patients is from 500 mg to 2 g of vancomycin per day orally, divided into 3-4 doses, for 7-10 days.

Resins of cholestyramine or colestipol bind vancomycin in vitro.
If it is necessary to use concomitantly resin and vancomycin, it is advisable to use each of these drugs at different times.
Considering the potential development of diarrhea, diarrhea with blood admixtures and pseudomembranous colitis, the physician should decide whether to use other drugs (see "Contraindications", "Side effects").
It is necessary to avoid getting the drug on the mucous membrane of the eyes and into the oral cavity. When applying the gel, it is necessary to wash hands thoroughly. In case of accidental contact with sensitive surfaces (eyes, bruises on the skin, mucous membranes), it is necessary to thoroughly rinse this area with cool water.
Oral and parenteral use of clindamycin was associated with the development of severe colitis, which could lead to a lethal outcome. Caution is required to prescribe clindamycin phosphate dosage forms for external use in patients with atopy.

4.5 Interaction with other medicinal products and other forms of interaction

Since some patients may have a local irritation effect, the co-administration of other potentially irritating topical preparations increases the risk of side effects on the skin.
Care should be taken to use gel with preparations containing sulfur, resorcinol or salicylic acid.
If it is necessary to use the drug together with other drugs, use gel once a day for the night and use other drugs in the morning.
Clindamycin has the ability to block neuromuscular transmission, which can lead to increased effects of other drugs with similar properties. Therefore, it should be used with caution in patients who receive such medications. There is cross-resistance between clindamycin and lincomycin. Antagonism between erythromycin and clindamycin was also noted.

4.6 Pregnancy and lactation

Since adequate clinical trials on the safety of the use of the drug in pregnant women have not been performed, gel should not be used during this period.
The use of the drug during breastfeeding is contraindicated.

4.7 Effects on ability to drive and use machines

Does not affect.

4.8 Undesirable effects

Redness, peeling, dryness, itching and burning of the skin at the place of application of the gel, immediately after application, which recovers later. Allergic reactions, photosensitivity reactions, acne, sensation of tingling, gram-negative folliculitis, gastrointestinal disorders, abdominal pain,

urticaria, increased oiliness of the skin, contact dermatitis, burning eyes, occasional side effects like diarrhea, diarrhea with admixture of blood and Colitis (including pseudomembranous colitis).

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Possible redness and peeling of the skin when excessive amounts of gel are applied.
Therapy is symptomatic.

5. PHARMACOLOGICAL PROPERTIES.

Pharmacotherapeutic group: Anti-acne preparations for topical use**.**
Code ATC: D10AD53

5.1 Pharmacodynamics.

Adapalene is a derivative of naphthoic acid, a retinoid-like substance that modulates the processes of cell differentiation and keratinization, as well as inflammatory processes of the skin, which form the main pathogenetic links in the development of acne. Adapalene binds to the retinoid receptors of the cell nucleus and thus contributes to the normal differentiation of the epithelial cells of the follicles, which leads to a decrease in the formation of microcomedones and prevents the development of acne, contributes to the preservation of intact skin.
The therapeutic effect of the drug usually manifests itself within 8-12 weeks of starting treatment. When using adapalene in the form of a gel, absorption of the drug through the skin into the blood is extremely low.

Clindamycin phosphate is a semi-synthetic antibiotic that acts as an inhibitor of the synthesis of bacterial proteins by binding to a 50S subunit of ribosomes and inhibiting the process of initiating the formation of a peptide chain. Clindamycin inhibits all *Propionibacteriumacnes,* that are subjected to testing with a minimum inhibitory concentration of 0.4 µg / ml. Cross- resistance between clindamycin and erythromycin was detected.

5.2 Pharmacokinetics.

Not investigated.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carbomer 980, polysorbate-80, propylene glycol, polyethylene glycol, methyl paraben, phenoxyethanol, disodium edentate, sodium hydroxide, purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C in a cool place. Do not freeze. Keep all the medicines out of reach of children.

6.5 Nature and contents of container

15 g gel is packed in Lami tube and such 1 tube is packed in a carton with pack insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan) India

8. MARKETING AUTHORISATION NUMBER(S)

04976/07180/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 August 2020

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines