

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BenGay® Ultra Strength

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl Salicylate 30% w/w

Menthol 10% w/w

Camphor 4% w/w

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

This medicine is indicated for the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, strains, bruises and sprains.

4.2. Posology and method of administration

Check with the doctor or pharmacist if you are uncertain. The usual dosage is generally: Apply 3-4 times a day, as needed.

Directions for use: Apply a thin layer on the achy area only and gently massage until the cream disappears (is absorbed).

Do not exceed the recommended dose.

Do not swallow! For external use only.

If there is no improvement in your condition within 10 days, refer to a doctor.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.
- Damaged skin or on sores.
- In children and infants under 12 years of age without a doctor's instructions.

4.4. Special warnings and precautions for use

Special warnings

- Excessive use may result in salicylate toxicity (salicylates have been associated with Reye's syndrome).
- Do not use with a heating pad or bandage with a tight dressing.
- Avoid contact of the preparation with the eyes. In case of contact, wash immediately with water.
- Avoid contact of the preparation with mucosal tissues (e.g., the mouth and nose).
- If hyperirritation occurs, stop use. See section 4.8 "Undesirable Effects".

Precautions for use

Before treatment with BenGay, tell the doctor if:

- You are sensitive to any food or medicine, especially to salicylates.
- You use this medicine frequently or for a prolonged period.

4.5. Interaction with other medicinal products and other forms of interaction

- Products containing salicylates (e.g., aspirin): concomitant use may lead to salicylate poisoning.
- Anticoagulants, such as Coumadin: the combination may increase the potential for bleeding, since BenGay contains salicylate..

4.6. Fertility, pregnancy and lactation

There is not enough information for safe use during pregnancy or breastfeeding. Use during pregnancy

and/or breastfeeding must be under medical supervision.

4.7. Effects on ability to drive and use machines

This medicine has no effect on ability to drive or operate machines.

4.8. Undesirable effects

Discontinue use and refer to a doctor as soon as possible if the following occur:

- Irritation (rare)
- Rash (rare)
- Local inflammation (rare)

Additional side effects

Occurring rarely:

- Eyes: ocular irritation
- Immune system disorders: angioedema
- Respiratory system: shortness of breath (associated with hypersensitivity)
- Application site: skin edema, blisters, burning, sensation, redness, irritation, pain, tingling, itching, and rash. In addition, urticaria, cold sensation.
- Application site sores or toxicity: burns

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

4.9. Overdose

If you took an overdose, or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Methyl salicylate belongs to the salicylate group, which are non-steroidal anti-inflammatory agents.

Methyl salicylate, Menthol and Camphor belong to topical analgesic group.

5.2. Pharmacokinetic properties

Not stated.

5.3. Preclinical safety data

Not stated.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Purified Water, Stearic Acid, Glyceryl Stearate SE, Tween 80 (Polysorbate 80), Lanolin, Triethanolamine (Trolamine), Carbomer, Potassium Hydroxide, Edetate Disodium.

6.2. Incompatibilities

Not known.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25°C.

6.5. Nature and contents of the outer packaging

A plastic tube containing 57 gram, 113 gram, 170 gram.

Not all presentations may be marketed.

6.6. Special precautions for disposal and other handling

Not stated.

7. REGISTRATION HOLDER

Kenvue Hellas Commercial Single Member S.A., Yakum, 6097200, Israel

8. MANUFACTURER

JNTL Consumer Health I (Switzerland) GmbH, Zug, Switzerland

9. REGISTRATION NUMBER

133-94-27518-00

Revised in 11.2025.