PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed without a doctor's prescription

BenGay[®] Greaseless Pain Relieving Cream Cream

Active ingredients - each unit contains: Methyl Salicylate 15% w/w Menthol 10% w/w

BenGay[®] Ultra Strength Cream

Active ingredients - each unit contains: Methyl Salicylate 30% w/w Menthol 10% w/w Camphor 4% w/w

Inactive ingredients and allergens: see section 6 *"Further Information"*.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine is not intended for conditions similar to arthritis in infants and children under 12 years of age. Under this age, refer to a doctor.

Use correctly. Consult a pharmacist if you need further information. Refer to the doctor if the signs of the disease (symptoms) worsen or if they do not improve after 10 days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

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.

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

2. BEFORE USING THE MEDICINE:

Do not use this medicine:

- if you are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in the medicine.
- · on damaged skin or on sores.
- in children and infants under 12 years of age without a doctor's instructions.

Special warnings regarding use of the medicine

- 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 "Side Effects".

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.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- other preparations 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.

Pregnancy and breastfeeding

There is not enough information for safe use during pregnancy or breastfeeding. Use during pregnancy and/or breastfeeding must be under medical supervision.

Driving and use of machinery

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

3. HOW SHOULD THE MEDICINE BE USED?

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.

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.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of BenGay may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

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:

Eves: ocular irritation

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

If a side effect occurs, if one of the side effects worsens, if you suffer from a side effect not mentioned in this leaflet, or if there is a change in your general feeling, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects,

or by entering the link: https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in the original package. Do not store different medicines in the same package.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

- BenGay Greaseless Pain Relieving Cream: Purified Water, Stearic Acid, Glyceryl Stearate, Glycerin, Isopropyl Palmitate, Cetyl Alcohol, Methylparaben, Phenoxyethanol, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylparaben, Xanthan Gum
- BenGay Ultra Strength:

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

What the medicine looks like and the contents of the package:

- BenGay Greaseless Pain Relieving Cream: A plastic tube containing 57 gram.

- BenGay Ultra Strength:

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

Not all pack sizes may be marketed.

Registration Holder and address:

J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer and address:

Johnson & Johnson Consumer Inc., NJ, USA.

Revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

- BenGay Greaseless Pain Relieving Cream: 133-96-23330-00
- BenGay Ultra Strength: 133-94-27518-00