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

The medicine is dispensed with a doctor's prescription only

## **LESHCUTAN® OINTMENT**

15%

#### Composition Paromomycin (as sulfate)

Methylbenzethonium chloride 12%

For information on inactive ingredients, see section 6 - "Further Information"

Read the 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. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to

#### others. It may harm them even if it seems to you that their medical condition is similar. 1. WHAT IS THE MEDICINE INTENDED FOR?

Topical treatment of cutaneous leishmaniasis.

Therapeutic group: Paromomycin: aminoglycoside antibiotic. Methylbenzethonium chloride: quaternary

### ammonium with antimicrobial activity. 2. BEFORE USING THE MEDICINE

#### Do not use this medicine:

If there is a known sensitivity to any of its

- ingredients or to neomycin.
- Do not use in the eyes. Do not use in the external ear in case of a
- perforated eardrum.

#### Special warnings regarding use of the medicine: Do not use the medicine without consulting

a doctor before starting treatment: If you are pregnant or breastfeeding.

- If you are suffering, or have suffered in the past, from impaired function of the liver,
- kidney/urinary system or hearing. If you are sensitive to any food or medicine,
- such as neomycin, inform the doctor before taking the medicine.
- Drug interactions:
- If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell
- the doctor or pharmacist.
- Pregnancy, breastfeeding and fertility Do not use the preparation if you are pregnant or
- breastfeeding without consulting a doctor before starting treatment. 3. HOW SHOULD YOU USE THE MEDICINE?
- Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and
- treatment regimen of the preparation. The dosage and treatment regimen will be

# determined by the doctor only.

Directions for use:

- 1- Clean the affected area and completely cover
- with the ointment. A sterile dressing can be used to dress the area. 2- Apply the ointment twice a day, for about 10
- will consider administration of an additional 10-day course of treatment. Use this medicine at set time intervals, as

days. If full recovery is not achieved, the doctor

determined by the attending doctor.

### Do not exceed the recommended dose.

only.

Complete the entire medicinal treatment. Even if there is an improvement in your health condition, do not stop using the medicine unless instructed to do so by a doctor.

Mode of administration This medicine is intended for external use Avoid contact with the eyes or external ear If you accidentally took a higher dosage

If you took an overdose, or if a child has accidentally swallowed the ointment, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Adhere to the treatment regimen as recommended

by the doctor. Do not take medicines in the dark! Check the label and the 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 Leshcutan ointment may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of

them.

Discontinue treatment and refer to the doctor immediately if a severe local reaction occurs (rare). Additional side effects

Redness

- Irritation
- Local inflammation

doctor.

- Local burning sensation
- Local pain or swelling

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the

doctor. Reporting of side effects

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

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

- medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the
  - 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 this medicine below 25°C.
  - Do not discard medicines in wastewater or waste. Ask the pharmacist how to dispose of
- medicines no longer in use. These measures will help to protect the environment. 6. FURTHER INFORMATION

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

Light mineral oil, White petrolatum What the medicine looks like and the contents

of the package: An ointment in a white-yellowish color.

Manufacturer and license holder:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in November 2021 according to MOH guidelines.

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

138 89 27616

Health:

