

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is to be supplied according to doctor's prescription only

## **TaroClindin Gel**

TaroClindin Gel contains 2 active ingredients:

clindamycin (as phosphate) 1% w/w

benzoyl peroxide (as hydrous) 5% w/w

Inactive ingredients and allergens in the medicine – see section 6 of the leaflet.

**Read the entire leaflet carefully before using the medicine.**

This leaflet contains concise information about the medicine. If you have further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

### **1. What is the medicine intended for?**

For the treatment of mild to moderate acne (acne vulgaris), especially acne with inflammatory sores.

#### **Therapeutic group:**

clindamycin – antibiotic agent of the lincosamides class

benzoyl peroxide – disinfectant of the peroxides class

Both TaroClindin Gel substances act together to:

- Fight bacteria which may cause acne.
- Reduce the number of red and inflamed pimples caused by acne.

### **2. Before using the medicine**

#### **Do not use the medicine if:**

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| <ul style="list-style-type: none"><li>• You are sensitive (allergic) to clindamycin, lincomycin, benzoyl peroxide or to any of the other ingredients contained in the medicine (see section 6).</li></ul> |
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#### **Special warnings regarding the use of this medicine**

- **Use TaroClindin Gel only on the skin.** Keep away from areas such as eyes, lips, mouth or the inner part of your nose.
- **Do not use TaroClindin Gel on irritated skin regions**, such as cuts, scratches, sunburns or damaged skin.
- In case of contact with eyes, lips, mouth or the inner part of your nose, wash thoroughly with plenty of water.
- Most patients will experience some skin redness and peeling during the first weeks of treatment. If your skin is irritated, you may need an oil-free moisturizing cream. In such case, use TaroClindin Gel less frequently or stop the treatment for a short period to allow skin healing and then resume the treatment.

- Stop the treatment and contact the doctor if the skin irritation is severe (manifested by severe redness, dryness, itching, tingling or burning), or if the skin condition does not improve.
- Do not enable contact between the medicine and colored fabrics such as clothes, towels, bedding, furniture or carpets. **TaroClindin Gel may bleach these fabrics or woven materials.**
- TaroClindin Gel may bleach hair.
- TaroClindin Gel may make your skin more sensitive to the harmful effect of sun. Avoid using tanning beds/lamps and reduce the time of sun exposure. Use a sunscreen and wear protective clothes while using the medicine.

**Contact your doctor or pharmacist prior to using this medicine if:**

- You have previously had any intestinal problem such as regional enteritis, ulcerative colitis or antibiotic associated colitis.
- **You develop abdominal cramps or severe or persistent diarrhea; immediately stop the treatment and contact your doctor.** Antibiotics may cause a condition leading to severe diarrhea or abdominal cramps, although this is unlikely to happen with a topical antibiotic.
- If you have recently used other medicines containing clindamycin or erythromycin, there is an increased chance that TaroClindin Gel will not act on you as required. **Tell your doctor or pharmacist** if you have recently used any other medicine containing clindamycin or erythromycin.

**If you are taking or have recently taken any other medicines, including over-the-counter medicines and food supplements, tell your doctor or pharmacist.** Especially if you are taking:

- Any other topical antibiotic treatment for acne.
- Medical soaps or cleansing substances causing skin erosion.
- Soaps or cosmetic products causing excessive skin dehydration.
- Products containing a high amount of alcohol or disinfectants.

Since using these products in combination with TaroClindin Gel may cause skin irritation over time.

**TaroClindin Gel may reduce the efficacy of other medicines for skin treatment taken simultaneously, including certain medicines for the treatment of acne containing tretinoin, isotretinoin or tazarotene.** Tell your doctor if you are taking these medicines; you may have to use the two products at different times of the day (e.g. one in the morning and the other at night).

**Using several products together for the treatment of acne increases the risk of skin irritation.** Use of TaroClindin Gel together with medicines such as dapsone and sulfacetamide may lead to temporary discoloration of facial skin and/or hair. Consult your doctor if you are planning to undergo surgery, since TaroClindin Gel may affect the activity of certain general anesthetics.

**Pregnancy and breastfeeding**

The information regarding the safety of the medicine in pregnant women is limited. If you are pregnant or breastfeeding, consult your doctor or pharmacists prior to using medicines. Your doctor will consider the benefit relative to the risk for you associated with using TaroClindin Gel during pregnancy. It is **unknown** whether TaroClindin Gel ingredients may pass to the breast milk. One of the active ingredients of the medicine is clindamycin, which may pass to the breast milk when taken orally or injected. If you are breastfeeding, do not apply TaroClindin Gel on your breasts.

## Children and adolescents

The medicine is intended for children and adolescents above the age of 12 years. Do not administer this medicine to children below the age of 12 years since no information regarding the safety and efficacy of this medicine in children is available.

### 3. How to use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and manner of treatment will be determined by the doctor only. The standard dose is once a day in the evening. 2-5 weeks may pass until you notice the effect of the medicine.

#### **Do not exceed the recommended dose.**

#### **Instructions for use:**

1. Remove your makeup completely.
2. Wash the treatment area thoroughly and then wash it with some warm water and dry gently.
3. Apply a thin layer of the gel over the entire treatment area using the fingertips.
4. Apply to all the skin areas with acne, not only the pimples. If the gel is not easily absorbed in the skin, you are using an excessive amount.
  - In the facial area only, extract from the tube an amount of gel equivalent to the length from the fingertip to the first phalanx, i.e. a fingertip.
  - For the face and back areas, use a total amount of 2.5 fingertips.
5. If the skin is very dry or peeling, you can use a hypoallergenic oil-free and perfume-free moisturizing cream. In addition, use TaroClindin Gel less frequently or stop the treatment for a short period to allow your skin to adapt to the treatment. The medicine may not be as effective as required if not applied daily.
6. **Wash your hands** after using the gel.
7. After the gel has dried, you can use oil-free makeup.

**Do not swallow, for external use only.** Treatment duration – do not use for a period exceeding 12 weeks without consulting your doctor. Your doctor will instruct you regarding the duration of treatment.

#### **If you have accidentally used an overdose**

Pay attention not to apply too much gel. Applying an excessive amount or more frequently will not help the pimples to disappear faster and may cause skin irritation. If this occurs, use the gel less frequently or stop the treatment for several days and resume the treatment.

If someone has accidentally swallowed some of the medicine, he should immediately contact a doctor or go to a hospital emergency room and bring the medicine package with him. He may experience symptoms identical to those associated with oral intake of antibiotics (abdominal pain).

#### **If you have forgotten to apply the medicine.**

If you have forgotten to apply the medicine at the required time, do not apply a double dose. Use the next dose at the regular time and consult your doctor. Persist with the treatment as recommended by your doctor. Even if your health has improved, do not stop treatment with the medicine without consulting your doctor or pharmacist. **If you stop treatment with the medicine prematurely, against the doctor's advice,** your acne may return.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding the use of this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, use of TaroClindin Gel may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them. Stop the treatment and contact your doctor immediately if the following signs occur:

- Signs of allergic reaction (such as swelling of the face, eyes, lips or tongue, hives, breathing difficulties, collapse).
- Prolonged or severe diarrhea, abdominal cramps.
- Severe peeling, burning or itching.

Additional side effects:

Very frequent: local redness, peeling and dryness. These side effects are usually moderate.

Frequent: headaches. In the treatment area: burning, pain, sensitivity to sunlight.

Rare: Tingling (paresthesia), exacerbation of acne, red and itchy skin, rash (dermatitis, erythematous rash).

Unknown frequency: allergic reaction, intestinal inflammation, diarrhea including bloody diarrhea, abdominal pain. In the treatment area: skin effects, skin discoloration, raised and itchy rash.

**If any side effect is worsening or if you experience any side effect not mentioned in the leaflet, consult your doctor.**

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medication therapy" located on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for side effects reporting, or by entering the link:

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

#### **5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the external package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store TaroClindin Gel refrigerated (2°C-8°C). Do not freeze.
- After first opening: can be used for 60 days from the date of opening if the product is stored refrigerated (2°C-8°C).

#### **6. Additional information**

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

Glycerin, carbomer, silicone dioxide, poloxamer 182, sodium hydroxide, methylparaben, dimeticone, edetate disodium, disodium lauryl sulfosuccinate, purified water.

- What does the medicine look like and what is the content of the pack: white to white yellowish gel. Each pack contains one multiple-use tube. The tube contains: 25 or 45 grams. Not all pack sizes may be marketed.
- Registration holder name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.
- Manufacturer name and address: Taro Pharmaceuticals Inc., Ontario, Canada.
- Revised in April 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:160-25-34826-00