

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

This medicine is dispensed with a doctor's prescription only

Pliaglis

Cream

Active ingredients and quantity:

Each 1 gram of cream contains:

lidocaine 70 mg

tetracaine 70 mg

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. 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 this medicine intended for?

Pliaglis is intended for use in adults to produce local dermal anaesthesia on intact skin prior to dermatological procedures.

Therapeutic group:

Lidocaine and tetracaine are local anaesthetics of the amide group.

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to any of the active ingredients, to another local anaesthetic of the amide group or to any of the other ingredients in this medicine (see section 6).
- If you are sensitive (allergic) to PABA (para-aminobenzoic acid), a breakdown product of tetracaine, methyl parahydroxybenzoate (E218) or propyl parahydroxybenzoate (E216).
- On broken or irritated skin.
- On mucous membranes such as your mouth.

Special warnings about using this medicine

Before treatment with Pliaglis, tell your doctor if:

- You have known liver, kidney or heart problems.
 - You are very ill or physically weak as you may be more sensitive to the effect of Pliaglis.
- Contact of Pliaglis with the eyes should be avoided. If Pliaglis comes into contact with your eyes, immediately rinse with water or salt solution and protect your eyes until feeling returns.
 - Do not leave the cream on the skin for a longer time than recommended. See section 3.
 - Once Pliaglis has been removed, your skin in the treated area will feel numb. Take care not to scratch or rub the anaesthetised area or touch very hot or cold surfaces until feeling returns as you could accidentally damage the skin.

Children and adolescents

Pliaglis is not intended for use in children and adolescents aged up to 18 years because there is no information about the safety and efficacy of using this medicine in this age group.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

The risk of side effects increases if Pliaglis is used at the same time as other medicines such as:

- some medicines for treatment of heart disease such as quinidine, disopyramide, tocainide, mexiletine and amiodarone.
- medicines known to induce methemoglobinemia such as fonamides, naphthalene, nitrates and nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, and quinine.
- other medicines containing lidocaine and/or tetracaine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

Pregnancy

There are no data or a limited amount of data on the use of Pliaglis during pregnancy. Use Pliaglis with caution in pregnant women.

Breast-feeding

Lidocaine and tetracaine are excreted into breast milk, but the recommended dose of Pliaglis is not expected to have an effect on the child. Therefore, breastfeeding can continue while using Pliaglis as long as you do not apply the cream on the chest area.

Fertility

There is no information on fertility when using lidocaine and tetracaine in humans.

Driving and using machines

Pliaglis has no or negligible influence on your ability to drive and use machines.

Important information about some of this medicine's ingredients

Pliaglis contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause an allergic reaction (possibly delayed).

3. How to use this medicine?

Always use according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually approximately 1.3 grams of cream per 10 sq. cm.

Do not exceed the recommended dose.

Pliaglis is intended for personal use only for the patient to whom the medicine was prescribed.

Pliaglis should only be applied to dry, intact skin.

Do not apply Pliaglis on your face yourself. Use of Pliaglis on your face should only be done by your physician.

Pliaglis has to be spread evenly and thinly (approximately 1 mm thickness) across the area to be treated (as determined by your doctor) using a flat-surfaced tool such as a metal spatula or tongue depressor.

Pliaglis should not be applied with fingers.

Do not touch the cream with your fingers.

Do not cover the treated area with an occlusive dressing.

Take care to avoid contact with the eyes. If Pliaglis comes into contact with your eye, immediately rinse your eye with water or salt solution and protect your eye until feeling returns.

The cream should be left to dry for 30 to 60 minutes depending on the procedure, as determined by your doctor. After waiting for the required time, the dried cream will have formed a soft peel on your skin. Pliaglis can be removed by grasping a free-edge of the peel and pulling it away from the skin.

The peel should be carefully disposed of immediately after removal (see section 5 for more information on how to dispose of the peel).

Wipe with a compress (such as tissue or cotton wool) any remaining peel residue from the area.

Hands should be washed immediately after removing and disposal of the peel.

Do not swallow. For external use only.

If you have accidentally used a higher dose

The maximum application area should not exceed 400 sq. cm (no more than two 30-gram tubes should be used).

If you used too much Pliaglis, tell your doctor or pharmacist immediately.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you think you used too little Pliaglis, tell your doctor immediately.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, ask your doctor or pharmacist.

4. Side effects

As with any medicine, using Pliaglis may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. Most side effects are limited to the application area, only last for a short time and usually go away completely after the end of treatment.

The two medicines that make up Pliaglis (lidocaine and tetracaine) may cause allergic (anaphylactoid) reactions. Remove the cream from your skin and seek medical assistance immediately if you develop any of the following signs: skin rash, swelling and breathing difficulties.

Very common side effects: may affect more than 1 in 10 people:

- Redness of the skin
- Skin discolouration

Common side effects: may affect 1-10 in 100 people:

- Swelling of the skin

Uncommon side effects: may affect 1-10 in 1,000 people:

- Itchy skin
- Pain or pain of skin

Rare side effects: may affect 1-10 in 10,000 people:

- Pallor of the skin
- Skin burning sensation
- Swelling of the face
- Peeling of the skin
- Skin irritation
- Tingling feeling
- Swelling of the eyelid

Side effects of unknown frequency:

- Urticaria

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this 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 your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store the medicine under refrigeration (2°C – 8°C), even after opening.
- Do not freeze.
- Once opened, it should be used within 3 months and remain under refrigeration. It is recommended that the date of opening is noted in the designated space on the packaging.
- Do not use Pliaglis if you notice that the packaging is damaged.
- Dispose of waste peel with care, since the waste peel contains concentrated quantities of the ingredients.
- To help protect the environment, do not flush waste peel down the toilet.
- Waste peel should be put in a closed container, such as a plastic bag.
- Do not throw away any medicines via wastewater.
- Ask the pharmacist how to dispose of medicines you no longer use.

6. Additional information

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

calcium hydrogen phosphate anhydrous, purified water, polyvinyl alcohol, paraffin white soft, sorbitan monopalmitate, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216).

What the medicine looks like and contents of the pack:

White to off-white cream.

Comes in a 15- or 30-gram tube.

Not all pack sizes may be marketed.

Registration holder's name and address:

Taro International Ltd., 14 Hakitor Street, Haifa Bay 2624761.

Manufacturer's name and address:

Crescita Therapeutics, Inc. 2805, Place Louis-R-Renaud, Laval Québec H7V 0A3, Canada

This leaflet was checked and approved by the Ministry of Health in January 2025

Registration number of the medicine in the Ministry of Health's National Drug Registry: 178-34-37581-99

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<https://israeldrugs.health.gov.il/#!/medDetails/178%2034%2037581%2099>

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