

PRESCRIBING INFORMATION

Pr **Odan-Cyclopentolate**

Cyclopentolate Hydrochloride Ophthalmic Solution, USP

0.5% w/v and 1% w/v

Sterile

Anticholinergic

Odan Laboratories Ltd.
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^{PR} **Odan-Cyclopentolate**

Cyclopentolate Hydrochloride Ophthalmic Solution, USP

HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Topical ophthalmic	Ophthalmic solution/ 0.5% w/v and 1% w/v	Purified Water, Boric Acid, Potassium Chloride, Edetate Disodium, Sodium Carbonate, Sodium Chloride, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH), Benzalkonium Chloride 0.01% as preservative.

INDICATIONS AND CLINICAL USE

Odan-Cyclopentolate (cyclopentolate hydrochloride ophthalmic solution, USP) is used to produce mydriasis and cycloplegia.

Geriatrics (> 65 years of age):

Evidence from clinical studies and experience suggests that use in the geriatric population may be associated with differences in safety or effectiveness (see **WARNINGS AND PRECAUTIONS, Special Populations, Geriatrics**).

Pediatrics (< 6 years of age):

Odan-Cyclopentolate should not be used in pediatric patients < 6 years of age due to the risk of serious side effects.

Pediatrics (≥ 6 years of age):

Evidence from clinical studies and experience suggests that use in certain subgroups of the pediatric population is associated with differences in safety or effectiveness (see **WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics (≥ 6 years of age)** and **DOSAGE AND ADMINISTRATION**).

CONTRAINDICATIONS

Odan-Cyclopentolate is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Prescribing Information.
- Patients with known or suspected angle-closure glaucoma.
- Pediatric patients < 6 years of age.

WARNINGS AND PRECAUTIONS

General

Odan-Cyclopentolate is for topical use only and is not for injection.

Odan-Cyclopentolate should be used with caution in patients, especially children, who have previously had a severe systemic reaction to atropine.

Because of the risk of provoking hyperthermia, **Odan-Cyclopentolate** should be used with caution in patients, especially children, who may be exposed to elevated environmental temperatures or who are febrile.

Ophthalmologic

Odan-Cyclopentolate may cause increased intraocular pressure (IOP). In the elderly and others where increased IOP may be encountered, mydriatics and cycloplegics should be used cautiously. To avoid inducing angle closure glaucoma, IOP and an estimation of the depth of the angle of the anterior chamber should be made prior to initiation of therapy.

Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation.

Cyclopentolate may cause drowsiness, blurred vision and sensitivity to light. Patients should be advised not to drive or engage in other hazardous activities unless vision is clear.

Odan-Cyclopentolate contains the preservative benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses (see **DOSAGE AND ADMINISTRATION**).

Psychiatric

Cyclopentolate-induced psychotic reactions and behavioural disturbances and other central nervous system (CNS) disturbances may occur in patients with increased susceptibility to anticholinergic drugs (see **WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics (≥ 6 years of age) and Geriatrics (> 65 years of age)).**

Sexual Function/Reproduction

Studies have not been performed to evaluate the effects of topical ocular administration of cyclopentolate on fertility.

Special Populations

Pregnant Women: There is little or no data from the use of cyclopentolate in pregnant women. **Odan-Cyclopentolate** should only be used during pregnancy if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Women: It is not known whether cyclopentolate or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, precaution should be exercised.

Pediatrics (< 6 years of age): **Odan-Cyclopentolate** should not be used in pediatric patients <6 years of age (see **CONTRAINDICATIONS**).

Serious adverse reactions may occur with the use of this product in young children (see **ADVERSE REACTIONS**). **Odan-Cyclopentolate** is contraindicated in children less than 6 years of age (see **CONTRAINDICATIONS**).

Pediatrics (≥ 6 years of age): **Odan-Cyclopentolate** should be used with extreme caution, if at all, in children with Down syndrome, spastic paralysis or brain damage.

Young patients and children with Down syndrome, spastic paralysis or brain damage are particularly susceptible to central nervous system disturbances, cardiopulmonary and gastrointestinal toxicity from systemic absorption of cyclopentolate.

Seizures and acute psychosis induced by cyclopentolate are especially prominent in children. **Odan-Cyclopentolate** should be used with caution in children, with known epilepsy.

Fair-skinned children with blue eyes may exhibit an increased response and/or increased susceptibility to adverse reactions.

Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration.

Geriatrics (> 65 years of age): Elderly patients may be at a higher risk of having undiagnosed glaucoma and developing cyclopentolate-induced psychotic reactions and behavioural disturbances and other CNS disturbances.

ADVERSE REACTIONS

Odan-Cyclopentolate produces reactions similar to those of other anticholinergic drugs. Central nervous system manifestations, such as ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people, are possible. Other toxic manifestations of anticholinergic drugs are skin rash, abdominal distension, feeding intolerance and necrotizing enterocolitis in infants, unusual drowsiness, tachycardia,

hyperpyrexia, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchii and nasal passages. Severe manifestations of toxicity include coma, medullary paralysis, death, and hypotension with rapid progressive respiratory depression (see OVERDOSAGE).

Use of cyclopentolate has been associated with psychotic reactions and behavioural disturbances in children. Central nervous system reactions manifest similar to those listed above. Seizures and acute psychosis induced by cyclopentolate are especially prominent in children.

A local or generalized allergic-type response to cyclopentolate consisting of an urticarial rash has been described in children.

Additional adverse reactions observed following the use of **Odan-Cyclopentolate** include the following:

Eye disorders: drug effect prolonged (mydriasis), hyperemia, eye irritation, eye pain, increased intraocular pressure, conjunctivitis, punctate keratitis, photophobia, vision blurred;

Gastrointestinal disorders: dry mouth, nausea, vomiting;

General disorders and administration site conditions: fatigue, gait disturbance, pyrexia;

Immune system disorders: hypersensitivity;

Nervous system disorders: dizziness, headache, incoherent retrograde amnesia, somnolence;

Psychiatric disorders: agitation, confusional state, disorientation, hallucination, restlessness;

Skin and subcutaneous tissue disorders: erythema.

DRUG INTERACTIONS

The effects of **Odan-Cyclopentolate** may be enhanced by concomitant use of other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics and tricyclic antidepressants.

DOSAGE AND ADMINISTRATION

Patients must be instructed to remove contact lenses prior to application of **Odan-Cyclopentolate** and wait at least 15 minutes before re-insertion. **Odan-Cyclopentolate** contains the preservative benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses.

Dosing Considerations

Individuals with heavily pigmented irides may require larger doses.

Recommended Dose

Adults: One drop in the eye(s), followed by a second drop in 5 minutes, if necessary. Complete recovery usually occurs in 24 hours.

Pediatrics (≥6 years of age): One drop in the eye(s), followed by a second drop 5 minutes later, if necessary. Pretreatment with **Odan-Cyclopentolate** on the day prior to examination is usually not necessary.

Pediatrics (<6 years of age): **Odan-Cyclopentolate** should not be used in pediatric patients <6 years of age (see **CONTRAINDICATIONS**).

Administration

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decreased in systemic adverse reactions.

OVERDOSAGE

Systemic toxicity may occur following topical use, particularly in children. It is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, convulsions and hallucinations and the loss of neuromuscular coordination. Severe intoxication is characterized by CNS depression, coma, circulatory and respiratory failure and death.

The onset of cyclopentolate toxicity occurs within 20 to 30 minutes of drug instillation, and although usually transient (subsiding in 4 to 6 hours), the symptoms can last up to 12 to 24 hours.

Patients exhibiting signs of overdose should receive supportive care and monitoring.

In case of accidental use/overdose in infants and small children, the body surface must be kept moist.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Odan-Cyclopentolate blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing pupillary dilation (mydriasis) and paralysis of accommodation (cycloplegia). Cyclopentolate acts rapidly, but has a shorter duration of action than atropine.

STORAGE AND STABILITY

Store at 15°C – 30°C. Keep container tightly closed. Keep out of the reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Odan-Cyclopentolate is an anticholinergic prepared as a sterile borate buffered topical ophthalmic solution.

Each mL contains:

Active: Cyclopentolate Hydrochloride 0.5% w/v or 1% w/v.

Preservative: Benzalkonium Chloride 0.01% w/v.

Inactives: Purified Water, Boric Acid, Potassium Chloride, Edetate Disodium, Sodium Carbonate Sodium Chloride, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH).

Odan-Cyclopentolate is available in 10 mL multiple-dose plastic dropper bottles.

Tamper evidence is provided by a closure with an extended skirt that locks to the bottle finish on application and breaks away from the closure on opening. After cap is removed: if tamper evident snap collar is loose, remove before using product.

REFERENCES

Prescribing Information - CYCLOGYL™ (Cyclopentolate Hydrochloride Ophthalmic Solution, USP) 1% w/v, Alcon Canada Inc. Submission No. 242648; Date of Revision: September 11, 2020.

CONSUMER INFORMATION

Odan-Cyclopentolate
Cyclopentolate Hydrochloride Ophthalmic Solution, USP

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Odan-Cyclopentolate. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Odan-Cyclopentolate is used to dilate the pupil of your eye(s). This allows for closer examination of the eye(s).

What it does:

Odan-Cyclopentolate acts on your eyes by:

- Dilating the pupils of your eye(s). This is known as mydriasis.
- Freezing the ciliary muscles of your eye(s). This is known as cycloplegia.

When it should not be used:

Odan-Cyclopentolate should not be used in patients who:

- Are allergic to cyclopentolate hydrochloride or to any other ingredients in **Odan-Cyclopentolate** (see What the important nonmedicinal ingredients are).
- Have or may have narrow-angle glaucoma.
- Are under 6 years old.

What the medicinal ingredient is:

Cyclopentolate hydrochloride

What the important nonmedicinal ingredients are:

Benzalkonium chloride (preservative), boric acid, edetate disodium, potassium chloride, sodium bicarbonate sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH), purified water

What dosage forms it comes in:

Drops: 0.5% w/v or 1% w/v

WARNINGS AND PRECAUTIONS

BEFORE you use Odan-Cyclopentolate talk to your doctor or pharmacist if you or your child:

- Have or have had an allergic reaction to atropine.
- Have a fever or are exposed to hot climates. This may increase your chances of developing a high body temperature (*hyperthermia*).
- May have glaucoma. **Odan-Cyclopentolate** may cause an increase in your eye pressure (*intraocular pressure*).

BEFORE you use Odan-Cyclopentolate for your child talk to your doctor or pharmacist if you child has:

- Down syndrome.
- Spastic paralysis.
- Brain damage.
- A history of epilepsy.
- Fair skin and blue eyes.

Your child may be at a higher risk of developing serious side effects. Do not get **Odan-Cyclopentolate** in your child's mouth or cheeks. Wash your hands and your child's hands, mouth and cheeks after using **Odan-Cyclopentolate**.

While using Odan-Cyclopentolate

Talk to your doctor or pharmacist if you notice any changes in your behaviour. Some people may develop psychotic reactions and other behavioural disturbances while using **Odan-Cyclopentolate**.

Eye care and contact lens wear: Your eyes may become more sensitive to light when using **Odan-Cyclopentolate**. Protect your eyes in bright light.

Do not wear contact lenses while applying **Odan-Cyclopentolate**. **Odan-Cyclopentolate** contains a preservative (*benzalkonium chloride*), which may irritate your eyes and can discolour soft contact lenses. Remove your contact lenses before using **Odan-Cyclopentolate** and wait at least 15 minutes before you put your lenses back in.

Driving and using machinery: **Odan-Cyclopentolate** may:

- Cause you to become sleepy.
- Make your eyes sensitive to light.
- Make your vision become blurry.

If any of these effects happen to you, wait until they pass before driving or using machines.

Pregnant and Breastfeeding Women: If you are or may be pregnant or are breastfeeding or planning to breastfeed, talk to your doctor or pharmacist before using **Odan-Cyclopentolate**.

INTERACTIONS WITH THIS MEDICATION

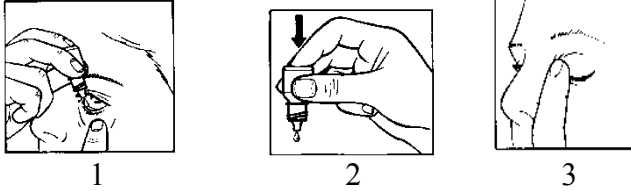
Drugs that may interact with Odan-Cyclopentolate include:

- Amantadine (a medicine used to treat Parkinson's disease and certain influenza infections).
- Medicines used to treat allergy symptoms (anti-histamines).
- Medicines used to treat schizophrenia and bipolar disorder (anti-psychotics).
- Medicines used to treat depression (anti-depressants).

Tell your doctor or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

PROPER USE OF THIS MEDICATION**Usual adult and child (6 years and older) dose:**

Apply 1 drop to the eye(s). **If necessary**, apply a second drop 5 minutes later.

How to use:**Before you start:**

- Get the **Odan-Cyclopentolate** bottle and a mirror.
- Wash your hands.
- Twist off the bottle cap.
- After cap is removed: if security snap collar is loose, remove before using product.

Applying a drop:

- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a clean finger until there is a 'pocket' between your eyelid and your eye. The drop will go in here (**picture 1**).
- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently press on the base of the bottle to release one drop of **Odan-Cyclopentolate** at a time.
- **Do not squeeze the bottle.** It is designed so that a gentle press on the bottom of the bottle is all that it needs (**picture 2**).
- After a drop has been put into the eye, press a finger into the corner of your eye by the nose (**picture 3**). This helps to keep the drop in the eye.
- If you use drops in both eyes, repeat the steps for your other eye.
- If a drop misses your eye, try again.

After use:

- Close the bottle cap firmly immediately after use.
- Wash your hands (and your child's hands, mouth and cheeks).

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you use more **Odan-Cyclopentolate** than you should, rinse your eye(s) with warm water. **Do not** put any more drops in.

Symptoms of an overdose may include:

- Flushing and dryness of the skin
- A rash in children
- Blurred vision
- Rapid and irregular pulse
- Fever
- Shaking (*convulsions*)
- Hallucinations
- Loss of coordination

SIDE EFFECTS AND WHAT TO DO ABOUT THEM**Related to the eye(s):**

- Blurred vision
- Increased pressure in the eye
- Inflammation
- Irritation
- Prolonged increase in pupil size
- Pain
- Redness
- Sensitivity to light
- Swelling

General effects:

- Agitation
- Confusion
- Decreased intestinal motility
- Decreased secretion in saliva, sweating, throat, breathing and nasal passages
- Difficulty urinating
- Difficulty walking
- Disorientation
- Dizziness
- Drowsiness
- Dry mouth
- Headache
- Increase in heart rate
- Lack of coordination
- Nausea
- Recent memory loss
- Restlessness
- Skin redness
- Tiredness (*fatigue*)
- vomiting

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN

Symptom / effect

Unknown

A
b1

L

MORE INFORMATION

This document plus the full Prescribing Information, prepared for health professionals can be found by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or by contacting the sponsor, Odan Laboratories Ltd., at: 1-888-666-6326.

This leaflet was prepared by Odan Laboratories Ltd.
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This is not a complete list of side effects. For any unexpected effects while taking Odan-Cyclopentolate contact your doctor or pharmacist.

HOW TO STORE IT

Store at 15°C to 30°C. Keep bottle tightly closed. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to: Canada Vigilance Program
Health Canada, Postal Locator
0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.