

PRESCRIBING INFORMATION

NITROSTAT[®]
Nitroglycerin Sublingual Tablets USP
0.3 mg, 0.6 mg

VASODILATOR

BGP Pharma ULC
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Etobicoke, Ontario
M8Z 2S6

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PRESCRIBING INFORMATION

NAME OF DRUG

NITROSTAT[®]

Nitroglycerin Sublingual Tablets USP

0.3 mg and 0.6 mg

PHARMACOLOGICAL CLASSIFICATION

Vasodilator

ACTIONS AND CLINICAL PHARMACOLOGY

The principal pharmacological action of nitroglycerin is relaxation of vascular smooth muscle. Although venous effects predominate, nitroglycerin produces, in a dose-related manner, dilation of both arterial and venous beds. Dilation of postcapillary vessels, including large veins, promotes peripheral pooling of blood, decreases venous return to the heart, and reduces left ventricular end-diastolic pressure (preload). Nitroglycerin also produces arteriolar relaxation, thereby reducing peripheral vascular resistance and arterial pressure (afterload), and dilates large epicardial coronary arteries; however, the extent to which this latter effect contributes to the relief of exertional angina is unclear.

Therapeutic doses of nitroglycerin may reduce systolic, diastolic, and mean arterial blood pressure. Effective coronary perfusion pressure is usually maintained, but can be compromised if blood pressure falls excessively or increased heart rate decreases diastolic filling time.

Elevated central venous and pulmonary capillary wedge pressures, and pulmonary and systemic vascular resistance are also reduced by nitroglycerin therapy. Heart rate is usually slightly increased, presumably due to a compensatory response to the fall in blood pressure. Cardiac index may be increased, decreased, or unchanged. Myocardial oxygen consumption or demand (as measured by the pressure-rate product, tension-time index, and stroke-work index) is decreased and a more favorable supply-demand ratio can be achieved. Patients with elevated left ventricular filling pressures and increased systemic vascular resistance in association with a depressed cardiac index are likely to experience an improvement in cardiac index. In contrast, when filling pressures and cardiac index are normal, cardiac index may be slightly reduced following nitroglycerin administration.

Mechanism of Action: Nitroglycerin forms free radical nitric oxide (NO) which activates guanylate cyclase, resulting in an increase of guanosine 3'5' monophosphate (cyclic GMP) in

smooth muscle and other tissues. These events lead to dephosphorylation of myosin light chains, which regulate the contractile state in smooth muscle, and result in vasodilatation.

Pharmacodynamics: Consistent with the symptomatic relief of angina, digital plethysmography indicates that onset of the vasodilatory effect occurs approximately 1 to 3 minutes after sublingual nitroglycerin administration and reaches a maximum by 5 minutes postdose. Effects persist for at least 25 minutes following NITROSTAT administration.

Pharmacokinetics and Drug Metabolism

Absorption: Nitroglycerin is rapidly absorbed following sublingual administration of NITROSTAT (nitroglycerin sublingual tablets). Mean peak nitroglycerin plasma concentrations occur at a mean time of approximately 6 to 7 minutes postdose (Table 1). Maximum plasma nitroglycerin concentrations (C_{max}) and area under the plasma concentration-time curves (AUC) increase dose-proportionally following 0.3 to 0.6 mg NITROSTAT. The absolute bioavailability of nitroglycerin from NITROSTAT tablets is approximately 40% but tends to be variable due to factors influencing drug absorption such as sublingual hydration and mucosal metabolism.

Table 1

Parameter	Mean Nitroglycerin (SD) Values	
	2 x 0.3 mg NITROSTAT Tablets	1 x 0.6 mg NITROSTAT Tablets
C _{max} , ng/mL	2.3 (1.7)	2.1 (1.5)
t _{max} , min	6.4 (2.5)	7.2 (3.2)
AUC(0-∞), ng/mL•min	14.9 (8.2)	14.9 (11.4)
t _{1/2} , min	2.8 (1.1)	2.6 (0.6)

Distribution: The volume of distribution (V_{Area}) of nitroglycerin following intravenous administration is 3.3 L/kg. At plasma concentrations between 50 and 500 ng/mL, the binding of nitroglycerin to plasma proteins is approximately 60%, while that of 1,2- and 1,3-dinitroglycerin is 60% and 30%, respectively.

Metabolism: A liver reductase enzyme is of primary importance in the metabolism of nitroglycerin to glycerol di- and mononitrate metabolites and ultimately to glycerol and organic nitrate. Known sites of extrahepatic metabolism include red blood cells and vascular walls. In addition to nitroglycerin, 2 major metabolites 1,2- and 1,3-dinitroglycerin, are found in plasma. Mean peak 1,2- and 1,3-dinitroglycerin plasma concentrations occur at approximately 15 minutes postdose. The elimination half-life of 1,2- and 1,3-dinitroglycerin is 36 and 32 minutes, respectively. The 1,2- and 1,3-dinitroglycerin metabolites have been reported to possess approximately 2% and 10% of the pharmacological activity of nitroglycerin. Higher plasma concentrations of the dinitro

metabolites, along with their nearly 10-fold longer elimination half-lives, may contribute significantly to the duration of pharmacologic effect. Glycerol mononitrate metabolites of nitroglycerin are biologically inactive.

Elimination: Nitroglycerin plasma concentrations decrease rapidly with a mean elimination half-life of 2 to 3 minutes. Half-life values range from 1.5 to 7.5 minutes. Clearance (13.6 L/min) greatly exceeds hepatic blood flow. Metabolism is the primary route of drug elimination.

INDICATIONS AND CLINICAL USE

NITROSTAT (nitroglycerin sublingual tablets) are indicated for the acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease.

CONTRAINDICATIONS

Sublingual nitroglycerin therapy is contraindicated in patients with early myocardial infarction, severe anemia, increased intracranial pressure, and those with a known sensitivity or hypersensitivity to nitroglycerin or its ingredients, or other nitrates or nitrites.

Concomitant use of NITROSTAT (nitroglycerin sublingual tablets) either regularly and/or intermittently, with phosphodiesterase type 5 (PDE5) inhibitors such as sildenafil citrate (VIAGRA) is absolutely contraindicated since sildenafil citrate has been shown to potentiate the hypotensive effects of nitrates.

Do not use NITROSTAT in patients who are taking a soluble guanylate cyclase (GC) stimulator, such as riociguat. Concomitant use may potentiate the hypotensive effects of GC stimulators.

WARNINGS

The benefits of sublingual nitroglycerin in patients with acute myocardial infarction or congestive heart failure have not been established. If one elects to use nitroglycerin in these conditions, careful clinical or hemodynamic monitoring must be used because of the possibility of hypotension and tachycardia.

PRECAUTIONS

General: Only the smallest dose required for effective relief of the acute anginal attack should be used. Excessive use may lead to the development of tolerance. NITROSTAT (nitroglycerin sublingual tablets) are intended for sublingual or buccal administration and should not be swallowed.

Severe hypotension, particularly with upright posture, may occur with small doses of nitroglycerin. This drug should therefore be used with caution in patients who may be volume-depleted or who, for whatever reason, are already hypotensive. Hypotension induced by nitroglycerin may be accompanied by paradoxical bradycardia and increased angina pectoris.

Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

As tolerance to other forms of nitroglycerin develops, the effects of sublingual nitroglycerin on exercise tolerance, although still observable, is blunted.

In industrial workers who have had long-term exposure to unknown (presumably high) doses of organic nitrates, tolerance rarely occurs. Chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitrates from these workers, demonstrating the existence of true physical dependence.

Several clinical trials of nitroglycerin patches or infusions in patients with angina pectoris have evaluated regimens which incorporated a 10 to 12 hour nitrate free interval. In some of these trials, an increase in the frequency of anginal attacks during the nitrate free interval was observed in a small number of patients. In one trial, patients had decreased exercise tolerance at the end of the nitrate interval. Hemodynamic rebound has been observed only rarely; on the other hand, few studies were so designed that rebound, if it had occurred, would have been detected.

Nitrate tolerance as a result of sublingual nitroglycerin administration is probably possible, but only in patients who maintain high continuous nitrate levels for more than 10 or 12 hours daily. Such use of sublingual nitroglycerin would entail administration of scores of tablets daily and is not recommended.

The drug should be discontinued if blurring of vision or drying of the mouth occurs. Excessive dosage of nitroglycerin may produce severe headaches.

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Nitroglycerin should be given to a pregnant woman only if clearly needed.

Lactation

It is not known whether nitroglycerin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nitroglycerin is administered to a nursing woman.

Use in Children

Safety and effectiveness of nitroglycerin in children have not been established.

Use in the Elderly

Clinical studies of NITROSTAT did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Drug Interactions

Hypotensive Agents: Patients receiving antihypertensive drugs, beta-adrenergic blockers, phenothiazines, or other drugs known to cause hypotension with nitrates should be observed for possible additive hypotensive effects. Marked orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used concomitantly.

Alcohol: Concomitant use of nitrates and alcohol may cause hypotension.

Aspirin: The vasodilatory and hemodynamic effects of nitroglycerin may be enhanced by concomitant administration of aspirin.

Alteplase: Intravenous administration of nitroglycerin decreases the thrombolytic effect of alteplase. Therefore, caution should be observed in patients receiving sublingual nitroglycerin during alteplase therapy.

Heparin: Intravenous nitroglycerin reduces the anticoagulant effect of heparin and activated partial thromboplastin times (APTT) should be monitored in patients receiving heparin and intravenous nitroglycerin. It is not known if this effect occurs following single sublingual nitroglycerin doses.

Anticholinergic Agents: Tricyclic antidepressants (amitriptyline, desipramine, doxepin, others) and anticholinergic drugs may cause dry mouth and diminished salivary secretions. This may make dissolution of sublingual nitroglycerin difficult. Increasing salivation with chewing gum or artificial saliva products may prove useful in aiding dissolution of sublingual nitroglycerin.

Ergot Alkaloids: Oral administration of nitroglycerin markedly decreases the first-pass metabolism of dihydroergotamine and subsequently increases its oral bioavailability. Ergotamine is known to precipitate angina pectoris. Therefore, patients receiving sublingual nitroglycerin should avoid ergotamine and related drugs or be monitored for symptoms of ergotism if this is not possible.

Nitrates: A decrease in therapeutic effect of sublingual nitroglycerin may result from use of long-acting nitrates.

Phosphodiesterase Type 5 (PDE5) Inhibitors: Concomitant use of NITROSTAT (nitroglycerin) and phosphodiesterase type 5 (PDE5) inhibitors such as sildenafil citrate (VIAGRA) has been shown to potentiate the hypotensive effect of NITROSTAT (nitroglycerin). This could result in life-threatening hypotension with syncope or myocardial infarction and death. Therefore, VIAGRA (sildenafil citrate) should not be given to patients receiving NITROSTAT (nitroglycerin).

Soluble guanylate cyclase (GC) stimulators: See CONTRAINDICATIONS.

Drug/Laboratory Test Interactions

Nitrates may interfere with the Zlatkis-Zak colour reaction causing a false report of decreased serum cholesterol.

ADVERSE REACTIONS

Headache, which may be severe and persistent may occur immediately after use. Vertigo, dizziness, weakness, palpitation, and other manifestations of postural hypotension may develop occasionally, particularly in erect, immobile patients. Marked sensitivity to the hypotensive effects of nitrates (manifested by nausea, vomiting, weakness, diaphoresis, pallor and collapse) may occur at therapeutic doses. Syncope due to nitrate vasodilation has been reported. Flushing, drug rash, exfoliative dermatitis, and urticaria have been reported in patients receiving nitrate therapy. Paradoxical bradycardia and increased angina pectoris may accompany nitroglycerin-induced hypotension. (See PRECAUTIONS)

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Hemodynamic Effects: The effects of nitroglycerin overdose are generally the results of nitroglycerin's capacity to induce vasodilatation, venous pooling, reduced cardiac output, and hypotension. These hemodynamic changes may have protean manifestations, including increased intracranial pressure, with any or all of persistent throbbing headache, confusion, and moderate fever; vertigo; palpitations; tachycardia; visual disturbances; nausea and vomiting (possibly with colic and even bloody diarrhea); syncope (especially in the upright posture); dyspnea, later followed by reduced ventilatory effort, diaphoresis, with the skin either flushed or cold and clammy; heart block and bradycardia; paralysis; coma; seizures; and death.

No specific antagonist to the vasodilator effects of nitroglycerin is known, and no intervention has been subject to controlled study as a therapy of nitroglycerin overdose. Because the hypotension associated with nitroglycerin overdose is the result of venodilatation and arterial hypovolemia, prudent therapy in this situation should be directed toward increase in central fluid volume. Passive elevation of the patient's legs may be sufficient, but intravenous infusion of normal saline or similar fluid may also be necessary.

The use of epinephrine or other arterial vasoconstrictors in this setting is likely to do more harm than good.

In patients with renal disease or congestive heart failure, therapy resulting in central volume expansion is not without hazard. Treatment of nitroglycerin overdose in these patients may be subtle and difficult, and invasive monitoring may be required.

Methemoglobinemia: Methemoglobinemia has been rarely reported in association with organic nitrates. The diagnosis should be suspected in patients who exhibit signs of impaired oxygen delivery despite adequate cardiac output and adequate arterial PO₂. Classically, methemoglobinemic blood is described as chocolate brown, without color change on exposure to air.

If methemoglobinemia is present, intravenous administration of methylene blue, 1 to 2 mg/kg of body weight, may be required.

DOSAGE AND ADMINISTRATION

Usual adult dosage ranges from 0.3 to 0.6 mg.

One tablet should be dissolved under the tongue or in the buccal pouch at the first sign of an acute anginal attack. The dose may be repeated approximately every five minutes, until relief is obtained. If the pain persists after a total of 3 tablets in a 15-minute period, prompt medical attention is recommended. NITROSTAT (nitroglycerin sublingual tablets) may be used prophylactically five to ten minutes prior to engaging in activities which might precipitate an acute attack.

During administration for an acute angina attack, the patient should rest, preferably in the sitting position.

No dosage adjustment is required in patients with renal failure.

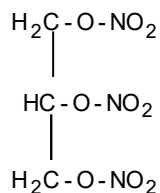
PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: Nitroglycerin

Chemical Name: 1,2,3-propanetriol trinitrate

Chemical Structure:



Molecular Formula: $\text{C}_3\text{H}_5\text{N}_3\text{O}_9$

Molecular Weight: 227.09

Description: Nitroglycerin is an organic nitrate. It is a pale yellow oily liquid which is soluble in water, ethanol and methanol.

Composition

Each sublingual tablet contains: nitroglycerin 0.3 or 0.6 mg. Non-medicinal ingredients: calcium stearate, glyceryl monostearate, lactose monohydrate, pregelatinized starch, silicon dioxide. Gluten-, paraben-, sodium-, sulfite- and tartrazine-free. Bottles of 100.

NITROSTAT is a stabilized sublingual compressed nitroglycerin tablet. This compressed tablet formulation is more stable and more uniform than conventional moulded tablets.

Stability and Storage Recommendations

Store at controlled room temperature, 15-30°C.

AVAILABILITY OF DOSAGE FORMS

NITROSTAT (nitroglycerin sublingual tablets) are available as small, round, white sublingual tablets in amber glass bottles of 100. Each tablet contains 0.3 or 0.6 mg nitroglycerin. The 0.3 mg tablet is marked with “N” on one side and the number “3” on the other side. The 0.6 mg tablet is marked with “N” on one side and the number “6” on the other side.

TOXICOLOGY

Carcinogenesis/Mutagenesis: Animal carcinogenesis studies with sublingually administered nitroglycerin have not been performed.

Carcinogenicity potential of nitroglycerin was evaluated in rats receiving up to 434 mg/kg/day of dietary nitroglycerin for 2 years. Rats developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes. At high dose, the incidence of hepatocellular carcinomas in males was 48% and in females was 33% compared to 0% in untreated controls. Incidences of testicular tumors were 52% vs 8% in controls. Lifetime dietary administration up to 1058 mg/kg/day of nitroglycerin was not tumorigenic in mice.

Nitroglycerin was weakly mutagenic in Ames tests performed in 2 different laboratories. Nevertheless, there was no evidence of mutagenicity in an *in vivo* dominant lethal assay with male rats treated with doses up to about 363 mg/kg/day, PO, or in *ex vivo* cytogenetic tests in rat and dog tissues.

Reproductive toxicity

Impairment of Fertility: In a 3-generation reproduction study, rats received dietary nitroglycerin at doses up to about 434 mg/kg/day for 6 months prior to mating of the F₀ generation with treatment continuing through successive F₁ and F₂ generations. The high dose was associated with decreased feed intake and body weight gain in both sexes at all matings. No specific effect on the fertility of the F₀ generation was seen. Infertility noted in subsequent generations, however, was attributed to increased interstitial cell tissue and aspermatogenesis in the high-dose males.

Teratogenicity: Animal reproduction and teratogenicity studies have not been conducted with nitroglycerin sublingual tablets. Teratology studies in rats and rabbits, however, were conducted with topically applied nitroglycerin ointment at doses up to 80 mg/kg/day and 240 mg/kg/day, respectively. No toxic effects on dams or fetuses were seen at any dose tested. In this 3-generation study there was no clear evidence of teratogenicity.

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PART III: CONSUMER INFORMATION**NITROSTAT®
(nitroglycerin sublingual tablets USP)**

This leaflet is part III of a three-part "Product Monograph" published when NITROSTAT (nitroglycerin sublingual tablets) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NITROSTAT. Contact your doctor or pharmacist if you have any questions about the drug.

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

NITROSTAT is used for acute relief of a type of chest pain called angina. Angina is a pain or discomfort that keeps coming back when part of your heart does not get enough blood. Angina feels like a pressing or squeezing pain, usually in your chest under the breastbone. Sometimes you can feel it in your shoulders, arms, neck, jaws, or back. NITROSTAT can relieve this pain.

What it does:

NITROSTAT works by relaxing blood vessels and increasing the supply of blood and oxygen to the heart.

When it should not be used:

Do not use NITROSTAT if you are allergic to organic nitrates (such as the active ingredient in NITROSTAT) or any of its non-medicinal ingredients.

You should not take NITROSTAT if you have the following conditions:

- very recent heart attack
- severe anemia (low number of red blood cells)
- increased pressure in the head

Do not take NITROSTAT with drugs for erectile dysfunction, like Viagra (sildenafil citrate), Cialis (tadalafil), or Levitra (vardenafil) as this may lead to extreme lowering of your blood pressure.

Do not take NITROSTAT with drugs for pulmonary hypertension, like Adempas (riociguat), as this may lead to lowering of your blood pressure.

What the medicinal ingredient is:

Nitroglycerin

What the nonmedicinal ingredients are:

calcium stearate, glyceryl monostearate, lactose monohydrate, pregelatinized starch, silicon dioxide.

What dosage forms it comes in:

sublingual tablets, 0.3 mg and 0.6 mg.

WARNINGS AND PRECAUTIONS**BEFORE you use NITROSTAT talk to your doctor or pharmacist if you:**

- have hypotension (low blood pressure).
- are pregnant, think you may be pregnant, or are planning to become pregnant.
- are breast-feeding.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food store without a prescription.

Before using NITROSTAT, tell your doctor if you are taking:

- medicines that are used to treat angina, heart failure, or an irregular heartbeat.
- medicines that reduce blood pressure.
- diuretics (water pills).
- medicines to treat depression or psychiatric illness.
- ergotamine or similar drugs for migraine headaches.

- aspirin.
- blood thinner medicine heparin.
- medicines for erectile dysfunction.
- medicines for pulmonary hypertension

PROPER USE OF THIS MEDICATION

Usual adult dose: Dissolve one tablet underneath the tongue (sublingual use) or in the mouth at the first sign of chest pain.

- You should sit down when taking NITROSTAT tablets and be careful when you stand up. This eliminates the possibility of falling due to light headedness or dizziness.
- The dose may be repeated approximately every 5 minutes, until the chest pain is relieved.
- If the pain persists after a total of 3 tablets in a 15-minute period, or is different than you typically experience, seek emergency medical help.
- NITROSTAT may be used 5 to 10 minutes prior to activities that might cause chest pain.
- You may feel a burning or tingling sensation in your mouth when you take NITROSTAT.
- Always take the tablets exactly as your doctor tells you to. Do not change the dose or stop taking NITROSTAT without talking to your doctor.
- Do not chew, crush, or swallow NITROSTAT tablets.
- Do not consume alcohol while taking NITROSTAT as this can lower your blood pressure.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, NITROSTAT can cause some side effects. For most patients, these side effects are likely to be minor and temporary. However, some may be serious. Consult your doctor or pharmacist as soon as you can, if you do not feel well while taking NITROSTAT.

NITROSTAT may cause the following side effects: low blood pressure upon rising from a seated position, sweating, paleness, other skin reactions that may be severe.

NITROSTAT may cause a false test result of decreased serum cholesterol.

NITROSTAT may cause dizziness, vertigo, or fainting. Avoid driving or operating machinery until you are sure that NITROSTAT does not affect your ability to perform these activities.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Allergic reaction involving swelling of the face, lips and/or tongue accompanied by difficulty breathing			✓
	Dizziness, vertigo (a major symptom of balance disorder)	✓		
	Weakness	✓		
	Nausea, vomiting	✓		
	Flushing (warm or red condition of your skin)	✓		
	Syncope: Fainting or unusually rapid heart beat		✓	
	Hypotension: low blood pressure upon rising from a seated position		✓	
	Headache	✓		
	Skin reactions: rash, blistering, or peeling of the skin		✓	

This is not a complete list of side effects. For any unexpected effects while taking NITROSTAT, contact your doctor or pharmacist.

HOW TO STORE IT

NITROSTAT should be kept in the original glass container and tightly capped after each use. Store NITROSTAT tablets at room temperature between 15-30° C. Keep out of the sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
- Fax toll-free to 1-866-678-6789,

or

- Mail to:
Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.viatris.ca> or by contacting the sponsor, BGP Pharma ULC, at: 1-844-596-9526

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