

Indikacije za primjenu propafenona sukladno postojećim smjernicama Europskog kardiološkog društva i drugim preporukama

Indications for Propafenone in the Latest ESC Guidelines and Beyond

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SAŽETAK: Brzina razvoja novih antiaritmjskih lijekova znatno je opala tijekom posljednjih desetljeća, što je dovelo do potreba za širom i preciznijom primjenom trenutno dostupnih lijekova. Stoga se ističe važnost temeljitog razumijevanja antiaritmjskih lijekova koji se upotrebljavaju u kliničkoj praksi. U ovom se preglednom radu razmatra uloga propafenona u liječenju fibrilacije atrijske, supraventrikularnih tahikardija i određenih ventrikularnih aritmija, s posebnim naglaskom na postojeće smjernice Europskoga kardiološkog društva (ESC) i druge klinički relevantne preporuke.

SUMMARY: The development of novel antiarrhythmic agents has decelerated considerably in recent decades, necessitating broader and more specific use of currently available medications. This underscores the importance of a thorough understanding of antiarrhythmic drugs used in clinical practice. In this summary, we discuss the role of propafenone in the management of atrial fibrillation, supraventricular tachycardias, and selected ventricular arrhythmias, with particular emphasis on current European Society of Cardiology (ESC) guideline recommendations and further clinically relevant applications.

KLJUČNE RIJEČI: antiaritmici, propafenon, aritmije, sigurnost.

KEYWORDS: antiarrhythmic drugs, propafenone, arrhythmias, safety.

CITATION: *Cardiol Croat.* 2026;21(5-6):130-5. | <https://doi.org/10.15836/ccar2026.130>

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TO CITE THIS ARTICLE: Kassa K, Vámos M. Indications for Propafenone in the Latest ESC Guidelines and Beyond. *Cardiol Croat.* 2026;21(5-6):130-5. | <https://doi.org/10.15836/ccar2026.130>

TO LINK TO THIS ARTICLE: <https://doi.org/10.15836/ccar2026.130>

Uvod

U posljednjih je nekoliko desetljeća u kliničku praksu uveden samo ograničen broj novih antiaritmjskih lijekova. Povećani regulatorni zahtjevi, relativno male ciljane populacije te smanjen interes farmaceutske industrije pridonijeli su usporavanju razvoja novih antiaritmika¹. Posljedično tomu, optimalna primjena i dobro poznavanje postojećih lijekova postaju sve važniji². Svrha je ovoga preglednog rada olakšati donošenje kliničkih odluka prikazom indikacija za primjenu propafenona te raspravom o njihovoj primjeni u određenim kliničkim situacijama kada ta primjena nije isključivo utemeljena na smjernicama.

Introduction

Over the past decades, only a limited number of novel antiarrhythmic drugs have reached clinical practice. Increasing regulatory requirements, relatively small target populations, and reduced industrial interest have contributed to the slowdown in antiarrhythmic drug development¹. Consequently, comprehensive knowledge and optimal utilization of existing agents have become increasingly important². This short review aims to support clinical decision-making by presenting the indications of propafenone and discussing selected clinical scenarios extending beyond guideline-based administration.

RECEIVED:
February 24, 2026

ACCEPTED:
February 25, 2026



First published in *Cardiologia Hungarica*. 2025;55:295-99.

<https://doi.org/10.26430/CHUNGARICA.2025.55.4.295> and reproduced with permission.

Propafenon je antiaritmik klase IC³. Njegov osnovni mehanizam djelovanja uključuje blokadu srčanih natrijevih kanala, što dovodi do usporivanja depolarizacije faze 0. To uzrokuje produljenje refraktarnosti u atrijskom, atrioventrikularnom nodalnom i ventrikularnom tkivu, kao i u dodatnim provodnim putevima kod Wolff-Parkinson-Whiteova (WPW) sindroma. Osim toga, propafenon blokira i β -adrenergičke receptore i kalijeve kanale⁴ te blago blokira kalcijeve kanale. Poluvijek lijeka kreće se između 2 i 10 sati, pri čemu jetreni metabolizam ima ključnu ulogu.

1. Fibrilacija atrijsa

Prema smjernicama Europskoga kardiološkog društva (ESC) iz 2024. godine⁵, propafenon ima dvije glavne indikacije u liječenju fibrilacije atrijsa (AF):

- farmakološka kardioverzija
- dugotrajno održavanje sinusnog ritma.

Propafenon se preporučuje za farmakološku kardioverziju u bolesnika bez teške hipertrofije lijeve klijetke, oštećene sistoličke funkcije lijeve klijetke (srčano zatajivanje sa sniženom ejekcijskom frakcijom, HFrEF) ili koronarne bolesti srca⁵. Preporučena oralna doza za akutnu kardioverziju iznosi 450 – 600 mg, dok se intravenska primjena preporučuje u dozi od 1,5 do 2,0 mg/kg tijekom 10 minuta (**Slika 1, Tablice 1 i 2**). Pristup „tableta u džepu“ specifičan je oblik samostalne primjene farmakološke kardioverzije koji se nakon pažljive procjene može uzeti u obzir u bolesnika s rijetkim epizodama paroksizmalne AF. Takvom se strategijom u pojedinim slučajevima može izbjeći hospitalizacija ili potreba za dolaskom u hitnu službu.

Propafenon se također preporučuje za terapiju kontrole ritma srca u bolesnika s AF-om bez strukturne bolesti srca. Iako

Propafenone is a class IC antiarrhythmic drug³. Its principal mechanism of action involves the blockade of cardiac sodium channels, resulting in slowing of phase 0 depolarization. This leads to prolongation of refractoriness in atrial, atrioventricular nodal, and ventricular tissue, as well as accessory pathways in Wolff-Parkinson-White (WPW) syndrome. In addition, propafenone exhibits β -adrenergic receptor-blocking properties, potassium channel-blocking effects⁴, and mild calcium channel-blocking activity. The substance's half-life ranges between 2 and 10 hours, with hepatic metabolism playing a main role.

1. Atrial fibrillation

According to the 2024 ESC guidelines⁵, propafenone has two principal indications in the management of atrial fibrillation (AF):

- Pharmacological cardioversion
- Long-term maintenance of sinus rhythm

Propafenone is recommended for pharmacological cardioversion in patients without severe left ventricular hypertrophy, impaired left ventricular systolic function (heart failure with reduced ejection fraction, HFrEF), or coronary artery disease⁵. The recommended oral dose for acute cardioversion is 450–600 mg, while intravenous administration is recommended at 1.5–2 mg/kg over 10 minutes (**Figure 1, Tables 1 and 2**). The “pill-in-the-pocket” approach represents a specific form of self-administered pharmacological cardioversion that may be considered in patients with infrequent paroxysmal AF following careful evaluation. This strategy can avoid emergency department presentation or hospitalization in selected cases.

Propafenone is also recommended for rhythm control therapy in patients with AF without structural heart disease.

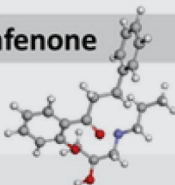
Propafenone	Administration	Safety
		
Pharmacological features Class I.C AAD Starting dose • 1.5-2 mg/kg (i.v.) • 450-600 mg (oral) Maintenance treatment • 450-900 mg (oral) • 2-3 times a day Half life: 2-10 hours Metabolism: liver Frequent side effects Bradycardia, headache, dizziness, dysgeusia	Main indications Atrial fibrillation • Pharmacological CV • Maintenance of SR Supraventricular tachycardia • Focal atrial tachycardia • WPW-syndrome Further potential usage Premature ventricular complexes Ventricular tachycardia	Contraindications and Precautions • Severe LV hypertrophy • Structural heart disease (HFrEF CAD, prior MI) • Brugada-syndrome • Severe kidney or liver disease • Severe sinus bradycardia, conduction disease, wide QRS duration, bundle branch block • Not for CV of atrial flutter • Recovered tachycardia-induced cardiomyopathy (proarrhythmic risk may be increased)

FIGURE 1. Indications and safety of propafenone use.

TABLE 1. Indications of propafenone based on recent ESC guidelines.

Indication	Class of indication	Level of evidence
Rhythm control for atrial fibrillation (ESC 2024)⁵		
Intravenous flecainide or propafenone is recommended when pharmacological cardioversion of recent-onset AF is desired, excluding patients with severe left ventricular hypertrophy, HFrEF, or coronary artery disease	I	A
Flecainide or propafenone is recommended in patients with AF requiring long-term rhythm control to prevent recurrence and progression of AF, excluding those with impaired left ventricular systolic function, severe left ventricular hypertrophy, or coronary artery disease.	I	A
A single self-administered oral dose of flecainide or propafenone (pill-in-the-pocket) should be considered for patient-led cardioversion in selected patients with infrequent paroxysmal AF, after efficacy and safety assessment and excluding those with severe left ventricular hypertrophy, HFrEF, or coronary artery disease	IIa	B
Concomitant use of a beta-blocker, diltiazem, or verapamil should be considered in AF patients treated with flecainide or propafenone, to prevent 1:1 conduction if their rhythm is transformed to atrial flutter.	IIa	C
Flecainide or propafenone may be considered for longer-term rhythm control in pregnancy, if rate controlling drugs are ineffective or not tolerated, to reduce symptoms and improve maternal and fetal outcomes	IIb	C
Focal atrial tachycardia (ESC 2019)¹⁰		
For acute therapy in hemodynamically stable patients, if agents such as adenosine, beta-blockers, verapamil, or diltiazem are ineffective, intravenous ibutilide, flecainide, propafenone, or amiodarone may be considered.	IIb	C
Beta-blockers or non-dihydropyridine calcium channel blockers (verapamil or diltiazem in the absence of HFrEF), or propafenone or flecainide in the absence of structural or ischemic heart disease, should be considered if ablation is not desirable or feasible.	IIa	C
Accessory pathway-mediated reentry tachycardia (ESC 2019)¹⁰		
Propafenone or flecainide may be considered in patients with AVRT and without ischemic or structural heart disease, if ablation is not desirable or feasible	IIb	B
Flecainide or propafenone should be considered for prevention of SVT in patients with WPW syndrome, and without ischemic or structural heart disease.	IIa	C
Flecainide or propafenone (i.v.) may be considered in hemodynamically stable patients with pre-excited atrial fibrillation.	IIb	B
In pregnant women, flecainide or propafenone should be considered for prevention of SVT in patients with WPW syndrome and without ischemic or structural heart disease.	IIa	C

AVRT = atrioventricular re-entry tachycardia; ESC = European Society of Cardiology; HFrEF = heart failure with reduced ejection fraction; AF = atrial fibrillation; SVT = supraventricular tachycardia; WPW = Wolff-Parkinson-White

TABLE 2. Intravenous and oral dosing of propafenone for specific indications.

Administration	Starting dose	Maintenance dose	Indications	Contraindication
Oral	450-600 mg	450-900 mg	cardioversion of AF, maintenance of SR	• Severe LV hypertrophy • Structural heart disease • Brugada-syndrome
		(2-3 times daily)	PVC, VT	• Severe kidney or liver disease • Severe sinus bradycardia, conduction disease, wide QRS duration • Not for CV of atrial flutter
Intravenous	1.5-2 mg/kg – in 10 minutes	-	cardioversion of AF	• Recovered tachycardia-induced cardiomyopathy (proarrhythmic risk may be increased)

AF = atrial fibrillation, SR = sinus rhythm; PVC = premature ventricular complex, VT = ventricular tachycardia

je tehnika kateterske ablacije napredovala te se sve češće primjenjuje kao terapija prve linije za kontrolu srčanog ritma u mnogih bolesnika^{6,7}, antiaritmici i dalje imaju važnu ulogu u određenim kliničkim situacijama, kao što su bolesnici koji čekaju ablaciju, oni u kojih je zahvat odgođen zbog komorbiditeta, oni koji odbijaju invazivno liječenje, te bolesnici s ponovnim pojavljivanjem bolesti nakon ablacije^{5,8}. U takvih je bolesnika propafenon i dalje osobito koristan jer dugotrajna terapija amiodaronom može biti ograničena kumulativnom toksičnošću⁹, a alternativni lijekovi preporučeni smjernicama (dronedaron i flekainid) nisu dostupni u nekim europskim zdravstvenim sustavima.

ESC-ove smjernice dotiču se i AF-a tijekom trudnoće, pri čemu je navedeno da se propafenon može razmotriti za dugotrajnu kontrolu srčanog ritma radi smanjenja simptoma i poboljšanja ishoda za majku i fetus kada se lijekovi za kontrolu frekvencije srca ne pokažu učinkoviti ili ih se loše podnosi.

2. Supraventrikularna tahikardija

ESC-ove smjernice za supraventrikularnu tahikardiju iz 2019. godine sadržavaju detaljne preporuke o primjeni propafenona za niz različitih uzroka aritmija¹⁰. U akutnim slučajevima, intravenska primjena propafenona može se razmotriti u sljedećim stanjima:

- fokalna atrijska tahikardija u hemodinamski stabilnih bolesnika kada su adenozin, β -blokatori ili blokatori kalcijskih kanala neučinkoviti
- atrioventrikularna kružna tahikardija (AVRT) u bolesnika s WPW sindromom bez strukturne ili ishemijske bolesti srca kada kateterska ablacija nije izvediva
- fibrilacija atrijske u bolesnika s preekcitacijom pri kojoj su blokatori AV čvora kontraindicirani.

Primjena propafenona za dugoročnu kontrolu srčanog ritma može se uzeti u obzir kod fokalne atrijske tahikardije kada ablacija nije izvediva ili nije poželjna te kada ne postoji strukturna ili ishemijska bolest srca. Propafenon također može smanjiti aritmijske epizode u bolesnika s WPW sindromom (bez strukturne bolesti srca), kada ablacija nije poželjna. Tijekom trudnoće slične indikacije vrijede i za prevenciju epizoda supraventrikularne tahikardije u žena s WPW sindromom.

3. Ventrikularne aritmije

Primjena antiaritmjskih lijekova za ventrikularne aritmije – osobito u prisutnosti strukturne bolesti srca – zahtijeva oprez zbog njihova potencijalnog proaritmjskog učinka i povećanog rizika od iznenadne srčane smrti¹¹. Iako ESC-ove smjernice za ventrikularne aritmije iz 2022. godine ne sadržavaju izravnu preporuku uporabe propafenona za njihovo liječenje, srodni lijek klase IC, flekainid, preporučuje se za više indikacija, uključujući česte idiopatske ventrikularne ekstrasistole ili ventrikularnu tahikardiju koja potječe iz lijeve ili desne klijetke (preporuka razreda IIa)¹². Nekoliko je istraživanja potkrijepilo učinkovitost i sigurnost propafenona u sličnim kliničkim situacijama^{13,14}, a nisu uočene klinički značajne razlike između propafenona i flekainida u smanjenju opterećenja ektopijama ili u poboljšanju kardiomiopatije inducirane ektopijama¹⁵. Smjernice također uzimaju u obzir primjenu flekainida u rijetkim nasljednim aritmijskim sindromima, uključujući katekolaminergičku polimorfnu vent-

Although catheter ablation has evolved, and is increasingly considered as the first-line rhythm control strategy in many patients^{6,7}, antiarrhythmic drugs continue to play an important role in several clinical scenarios, including patients awaiting ablation, those in whom the procedure is postponed due to comorbidities, patients declining invasive treatment, and those experiencing post-ablation recurrences^{5,8}. In such situations, propafenone remains particularly relevant, as long-term amiodarone therapy might be limited by cumulative toxicity⁹, while alternative agents recommended by guidelines (dronedarone and flecainide) may not be available in certain European healthcare systems.

The ESC guidelines also address AF during pregnancy, noting that propafenone may be considered for long-term rhythm control to reduce symptoms and improve maternal and fetal outcomes when rate-control drugs are ineffective or not tolerated.

2. Supraventricular tachycardias

The 2019 ESC supraventricular tachycardia guidelines provide detailed recommendations regarding propafenone use across multiple arrhythmia mechanisms¹⁰. In acute settings, intravenous propafenone may be considered for:

- Focal atrial tachycardia in hemodynamically stable patients when adenosine, β -blockers, or calcium channel blockers are ineffective;
- Atrioventricular re-entry tachycardia (AVRT) in patients with WPW syndrome without structural or ischemic heart disease when catheter ablation is not feasible;
- Pre-excited atrial fibrillation, where AV nodal blocking agents are contraindicated.

For long-term rhythm control, propafenone may be considered in focal atrial tachycardia when ablation is not feasible or not preferred and no structural or ischemic heart disease is present. Similarly, the drug may reduce arrhythmic events in patients with WPW syndrome (without structural heart disease) when ablation is not desired. Comparable indications apply during pregnancy for prevention of supraventricular tachycardia episodes in women with WPW syndrome.

3. Ventricular arrhythmias

The use of antiarrhythmic drugs in ventricular arrhythmias – particularly in the presence of structural heart disease – requires appropriate consideration due to potential proarrhythmic effects and increased risk of sudden cardiac death¹¹. Although the 2022 ESC ventricular arrhythmia guidelines do not directly recommend propafenone, the closely related class IC agent flecainide is recommended for several indications, including frequent idiopathic premature ventricular complexes or ventricular tachycardia originating from either ventricle (Class IIa recommendation)¹². Several studies support the efficacy and safety of propafenone in similar clinical scenarios^{13,14}, and no clinically meaningful differences between propafenone and flecainide have been observed regarding reduction of ectopic burden or improvement of ectopy-induced cardiomyopathy¹⁵. The guidelines also discuss flecainide use in rare inherited arrhythmia syndromes, including catecholaminergic polymorphic ventricular tachycardia (CPVT) and Andersen–Tawil syndrome (ATS). While available evidence

rikularnu tahikardiju (CPVT) i Andersen-Tawilov sindrom (ATS). Iako dostupni podatci upućuju na to da bi učinkovitost propafenona mogla biti usporediva s flekainidom za CPVT^{16,17}, prikazi bolesnika upućuju na ograničenu učinkovitost propafenona za ATS, u kojemu je, čini se, flekainid učinkovitiji^{18,19}.

Osobito je zahtjevna klinička situacija terapijski rezistentna maligna ventrikularna tahikardija u bolesnika sa strukturnom bolesti srca koji već imaju implantabilni kardioverterski defibrilator te primaju amiodaron i već su bili podvrgnuti pokušajima kateterske ablacije. U takvim se slučajevima može razmotriti eskalacija antiaritmijske terapije – čak i izvan odobrenih indikacija. Iako za primjenu meksiletina u ovom kontekstu postoji više dokaza^{2,20-22}, propafenon se može uzeti u obzir u odabranih bolesnika kada druge terapijske mogućnosti nisu dostupne²³.

4. Kontraindikacije i stanja koje zahtijevaju poseban oprez

Najčešće nuspojave propafenona uključuju bradikardiju, glavobolju, poremećaj okusa i omaglicu. Također se mogu pojaviti palpitacije, bol u prsima, umor, mučnina i povraćanje. Rjeđe nuspojave uključuju sinkopu, tremor, parestezije, bol u trbuhu i konstipaciju. Kao nuspojave propafenona spominju se i agranulocitoza, oštećenje jetre, sindrom sličan lupusu te bronhospazam. Sveukupno gledano, bolesnici općenito dobro podnose propafenon. Klinički značajne interakcije s drugim lijekovima uključuju istodobnu primjenu s apiksabanom (povećan rizik od krvarenja) i metoprololom (rizik od hipotenzije i bradikardije). Najvažnije kontraindikacije za primjenu propafenona uključuju koronarnu bolest srca, HFrEF, tešku hipertrofiju lijeve klijetke, Brugada sindrom i znatne poremećaje provođenja impulsa. Propafenon se ne smije primjenjivati za farmakološku kardioverziju undulacije atrijske⁵. Bolesnici s anamnestičkim podatcima o kardiomiopatiji induciranoj tahikardijom mogu imati povećan rizik od proaritmijских učinaka propafenona. Nakon započinjanja terapije propafenonom – često u kombinaciji s β -blokatorom – preporučuje se kontrolni EKG unutar 1 – 2 tjedna. Liječenje treba prekinuti ako se trajanje QRS kompleksa poveća za više od 25 % ili prelazi 130 ms, odnosno ako se razvije novi blok grane snopa ili drugi poremećaji provođenja impulsa (vidjeti sliku 12 u izvornim ESC-ovim smjernicama¹²). Također treba razmotriti istodobnu primjenu β -blokatora (ili alternativno diltiazema ili verapamila), jer propafenon pokatkad može AF pretvoriti u udulaciju atrijske, što paradoksalno može povećati ventrikularnu frekvenciju zbog poboljšanog atrioventrikularnog provođenja impulsa⁵.

5. Zaključci

Propafenon je široko primjenjiv i lako dostupan antiaritmik s brojnim klinički relevantnim indikacijama. Uz pažljivo razmatranje kontraindikacija i odgovarajući odabir bolesnika propafenon može znatno pridonijeti individualiziranim strategijama kontrole srčanog ritma u bolesnika s AF-om, fokalnom atrijskom tahikardijom, WPW sindromom i određenim ventrikularnim aritmijama.

Sukob interesa

Autori izjavljuju da ne postoje financijski ni drugi sukobi interesa povezani s ovim rukopisom koji bi mogli utjecati na prikazane rezultate, donesene zaključke ili njihovu interpretaciju.

suggests that propafenone may have comparable efficacy to flecainide in CPVT^{16,17}, case reports indicate limited effectiveness in ATS, where flecainide appears to be more efficient^{18,19}.

A particularly challenging clinical scenario involves therapy-refractory malignant ventricular tachycardia in patients with structural heart disease and implantable cardioverter-defibrillator (ICD) therapy, amiodarone treatment, and catheter ablation attempts. In such cases, escalation of antiarrhythmic therapy - even off-label - may be considered. Although more evidence exists for mexiletine in this context^{2,20-22}, propafenone may be considered in selected patients when alternative options are unavailable²³.

4. Contraindications and situations requiring particular caution

The most common adverse effects of propafenone include bradycardia, headache, dysgeusia, and dizziness. Palpitations, chest pain, fatigue, nausea, and vomiting may also occur. Less frequent adverse events include syncope, tremor, paraesthesia, abdominal pain, and constipation. Agranulocytosis, hepatic injury, lupus-like syndrome, and bronchospasm have also been reported. Overall, propafenone is generally well tolerated by patients. Clinically relevant drug interactions include concomitant use with apixaban (increased bleeding risk) and metoprolol (risk of hypotension and bradycardia). The most important contraindications include coronary artery disease, heart failure with reduced ejection fraction, severe left ventricular hypertrophy, Brugada syndrome, and significant conduction disturbances. Propafenone should not be used for pharmacological cardioversion of atrial flutter⁵. Patients with a history of tachycardia-induced cardiomyopathy may be at an increased risk of proarrhythmic effects. After initiation of propafenone therapy - often combined with a β -blocker - follow-up ECG assessment is recommended within 1-2 weeks. Treatment should be discontinued if QRS duration increases by more than 25% or exceeds 130 ms, or if new bundle branch block or conduction abnormalities develop (see also Figure 12 in the original ESC guidelines¹²). Concomitant administration of a β -blocker (or alternatively diltiazem or verapamil) should also be considered because propafenone may occasionally convert AF to atrial flutter, which paradoxically may increase ventricular rate through improved atrioventricular conduction⁵.

Conclusions

Propafenone is a widely applicable and readily available antiarrhythmic agent with multiple clinically relevant indications. When contraindications are carefully considered and patient selection is appropriate, propafenone may contribute substantially to personalized rhythm management strategies in patients with atrial fibrillation, focal atrial tachycardia, WPW syndrome, and selected ventricular arrhythmias.

Conflict of interest

The authors declare no financial or other conflicts of interest related to this manuscript that could have influenced the results presented, the conclusions drawn, or their interpretation.

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