

Nicardipine Hydrochloride: A Potent Drug for Calcium Channel Blocker

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Abstract:

Nicardipine hydrochloride (HCl) is a second-generation dihydropyridine calcium channel blocker primarily used to manage hypertension and angina pectoris. By selectively inhibiting L-type calcium channels in vascular smooth muscle, Nicardipine induces vasodilation, resulting in reduced peripheral resistance and improved blood flow without significant negative inotropic effects. Its pharmacokinetic profile includes rapid absorption and extensive first-pass metabolism, with a relatively short half-life that necessitates frequent dosing or use in controlled-release formulations.

Nicardipine is available in both oral and intravenous forms, with the IV formulation is often utilized in acute care settings for hypertensive emergencies, especially when rapid blood pressure control is necessary. Clinical studies have demonstrated its efficacy in lowering blood pressure and improving outcomes in various cardiovascular conditions, including subarachnoid hemorrhage-induced vasospasm and perioperative hypertension. The drug is generally well-tolerated, with common adverse effects including headache, flushing, dizziness, and tachycardia. It has minimal interaction with cardiac conduction or contractility, making it a preferred option in patients with contraindications to other antihypertensives. Recent research also explores its potential neuroprotective effects and utility in critical care environments. Despite its efficacy, careful monitoring is required in patients with hepatic or renal impairment. Ongoing developments in drug delivery systems aim to optimize its therapeutic profile and minimize dosing frequency. Overall, Nicardipine HCl remains a valuable agent in the pharmacologic arsenal against cardiovascular diseases, particularly where precision and rapid blood pressure control are vital.

Discovery of History

Nicardipine Hydrochloride (HCl) is a pharmacologically significant compound belonging to the class of dihydropyridine calcium channel blockers (CCBs). It plays a key role in managing various cardiovascular disorders, particularly hypertension and angina pectoris. Its discovery and subsequent development mark a notable milestone in cardiovascular pharmacotherapy, emerging during a time when there was a growing need for safer, more selective, and effective antihypertensive medications. This historical overview highlights the scientific, clinical, and regulatory journey of Nicardipine from its discovery to its present-day clinical applications.

The Scientific Context: A Need for Better Antihypertensives

By the 1970s, the medical community had already recognized the importance of calcium ion regulation in cardiovascular physiology. Calcium ions are essential for the contraction of vascular smooth muscle and cardiac muscle.

This led researchers to investigate calcium channel blockers as a potential therapeutic class for cardiovascular diseases. Early CCBs such as verapamil and diltiazem had proven effective but had notable cardiac depressant effects, limiting their use in patients with compromised cardiac function.

At the same time, there was a growing interest in developing dihydropyridine- based calcium channel blockers, which were structurally distinct and more selective for vascular smooth muscle than for cardiac muscle. These compounds showed the potential to lower blood pressure through vasodilation with a reduced risk of affecting heart rate or myocardial contractility. It was in this scientific climate that Nicardipine was born.

Discovery and Initial Development (1970s)

Nicardipine was synthesized in the 1970s by researchers at Tanabe Seiyaku Co., Ltd., a Japanese pharmaceutical company. The researchers aimed to create a dihydropyridine compound with improved potency, selectivity, and

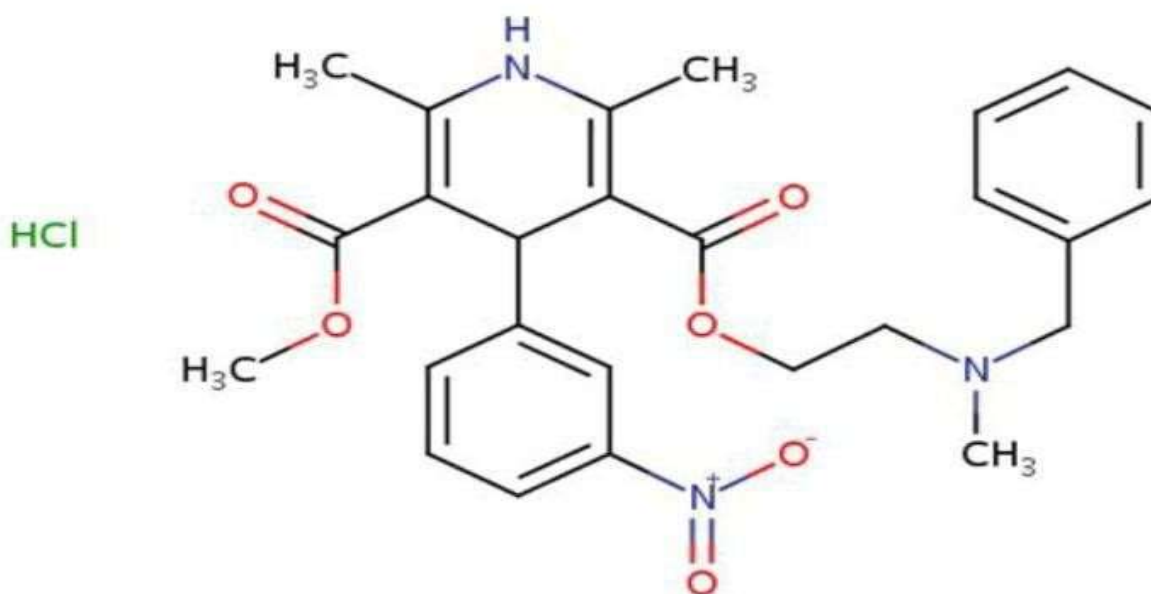
tolerability compared to existing agents like nifedipine. Through structure-activity relationship (SAR) studies, they identified Nicardipine as a compound with a unique chemical structure capable of selectively inhibiting L-type calcium channels in arterial smooth muscle.

Nicardipine showed strong vasodilatory effects in animal models, particularly in reducing systemic vascular resistance and arterial blood pressure. It was also Less likely to cause negative inotropic or chronotropic effects, which means that it could be safely used in patients without significantly impacting heart function. These characteristics made it an ideal candidate for clinical

development as both an antihypertensive and anti-anginal agent. Early Clinical Trials and Approvals (1980s)

Encouraged by preclinical success, Tanabe Seiyaku moved forward with clinical trials in Japan in the early 1980s. The trials confirmed Nicardipine's ability to lower blood pressure effectively while being generally well tolerated. Adverse effects were consistent with the expected pharmacologic profile of

vasodilators—namely, headache, dizziness, flushing, and peripheral edema. Importantly, these side effects were manageable and dose-dependent.



Pharmacokinetic Properties

Here are the physicochemical properties of Nicardipine Hydrochloride (HCl):

1. **Chemical Name:** (±)-2-[benzyl(methyl)amino]ethyl methyl 1,4-dihydro- 2,6-dimethyl-4-(3-nitrophenyl)-3,5-pyridinedicarboxylate monohydrochloride.
2. **Molecular Formula:** C₂₆H₂₉N₃O₆·HCl
3. **Molecular Weight:** 515.99 g/mol (including the HCl salt)
4. **Appearance:** Yellow to pale yellow crystalline powder
5. **Solubility:**

Soluble in water, methanol, and ethanol

Practically insoluble in ether and chloroform

1. **Melting Point:** Approximately 169–174°C (for the HCl salt form)
2. **pKa:** Approximately 8.3 (basic amine group)
3. **Log P (Partition Coefficient):** Around 3.8 (indicating lipophilicity)
4. **Stability:**

Stable under normal storage conditions

Light-sensitive; should be protected from light Decomposes at high temperatures

1. **Ionization:** Forms a hydrochloride salt to enhance solubility in aqueous solutions
2. **Polymorphism:** May exist in multiple polymorphic forms which can affect solubility and stability

These properties influence its formulation and pharmacokinetic profile, particularly its moderate bioavailability and the need for specialized delivery systems in IV formulations.

Physiochemical Properties

Parameter	Oral (immediate release)	Oral (Sustained release)	Intravenous (IV)
BCS Classification	Class II (Low solubility, high permeability)	Same as IR	Not applicable
Cmax	-45-70 ng/ml. (20 mg dose)	Lower than IR, prolonged over time	Rapid rise depending on dose/ infusion rate
Tmax	0.5 - 2 hours	2-6 hours	Immediate (end of infusion)
T1/2	-8.6 hours	8.6-11 hours	2-4 hours (terminal half- life)
Absorption	Rapid extensive first-pass metabolism	Slower, more sustained	Immediate
Distribution	Highly Protein-bound (~95%). Large Vd (~3-8 L/kg)	Same as IR	Same as Oral
Metabolism	Hepatic {CYP3A4}	Same	Same

Excretion	Mainly via urine (60%), feces (-35%)	Same	Same
Bioavailability	35% (due to first-pass metabolism)	Slightly increased vs IR	100% (direct administration)

Mechanism of Working

Mechanism of Action of Nicardipine Hydrochloride

Nicardipine Hydrochloride is a calcium channel blocker (CCB) of the dihydropyridine class, primarily used to manage hypertension and angina. Its therapeutic effect arises from its ability to inhibit the influx of calcium ions through L-type calcium channels in vascular smooth muscle and, to a lesser extent, in cardiac muscle.

Calcium ions play a critical role in the contraction of smooth muscle cells. Under normal conditions, depolarization of the cell membrane opens voltage--dependent L-type calcium channels, allowing calcium to enter the cells, leading to muscle contraction. Nicardipine binds to and blocks these channels, reducing intracellular calcium levels.

This blockade results in the relaxation of arterial smooth muscle, producing vasodilation, particularly in the peripheral arterioles and coronary arteries. This reduces systemic vascular resistance and lowers blood pressure. In coronary arteries, nicardipine improves oxygen delivery to the myocardium, making it useful in angina management.

Unlike non-dihydropyridine calcium channel blockers (e.g., verapamil or diltiazem), nicardipine has minimal direct effect on cardiac conduction or contractility at therapeutic doses. However, reflex tachycardia may occur due to baroreceptor-mediated responses to vasodilation.

Overall, nicardipine's mechanism of action involves:

Selective inhibition of L-type calcium channels

Arterial vasodilation, leading to reduced blood pressure and Increased coronary blood flow, beneficial in angina

Due to its potent vasodilatory effects and rapid onset (especially via IV),

Nicardipine is also widely used in emergency settings for acute blood pressure control, such as in hypertensive crises and stroke management.

Method of Synthesis

General Method of Synthesis:

Nicardipine is synthesized through the Hantzsch reaction, which is a common method to create 1,4-dihydropyridine (DHP) derivatives. The process involves a multi-component condensation of three types of compounds:

Step-by-Step Overview:

1. Starting Materials:

Methyl acetoacetate (a β -keto ester)

3-nitrobenzaldehyde (an aromatic aldehyde with a nitro group) Methyl 2-(methylamino)ethylamine (an amine source)

1. Formation of Dihydropyridine Ring:

The components undergo a Hantzsch condensation reaction in the presence of a catalyst (like acetic acid or ammonia). This leads to the formation of a 1,4-dihydropyridine ring, which is the core structure of Nicardipine.

1. Esterification/Substitution:

Side chains like 3-nitrophenyl and 2-(methylanino)ethyl ester are introduced at specific positions on the ring for activity.

1. Formation of Hydrochloride Salt:

Finally, the free base is reacted with hydrochloric acid to form Nicardipine. Hydrochloride, which improves its stability and solubility for pharmaceutical use.

In Summary:

Nicardipine is made by a Hantzsch-type condensation of methyl acetoacetate, an aldehyde, and an amine to build the dihydropyridine ring, followed by functionalization and salt formation to yield Nicardipine Hydrochloride.

Medicinal Uses

Nicardipine hydrochloride is a calcium channel blocker (CCB) that primarily works by inhibiting the influx of calcium ions into vascular smooth muscle and cardiac muscle. This results in vasodilation, especially in arterial vessels, which helps to reduce blood pressure and improve blood flow. It is commonly used in the following medicinal contexts:

1. Hypertension (High Blood Pressure) Oral Nicardipine:

Nicardipine is used to manage chronic hypertension (high blood pressure). By relaxing the blood vessels, it reduces the workload on the heart and helps lower blood pressure. It is often used in combination with other antihypertensive medications. Intravenous Nicardipine:

In acute or emergencies where rapid blood pressure reduction is required, nicardipine can be administered intravenously in a hospital setting for hypertensive crises or severe hypertension.

1. Angina Pectoris (Chest Pain) Stable Angina:

Nicardipine is used in the treatment of stable angina, a condition where the heart's demand for oxygen exceeds supply, causing chest pain. By relaxing the coronary arteries, nicardipine improves blood flow to the heart muscle, thus reducing angina episodes.

Unstable Angina:

In patients with unstable angina, nicardipine can help reduce the frequency of angina attacks and improve myocardial oxygen supply.

1. Hypertensive Emergencies (Intravenous Use) Emergency Hypertension Management:

Intravenous nicardipine is a preferred agent for the rapid and controlled reduction of blood pressure in hypertensive emergencies, where immediate and sustained blood pressure control is necessary to prevent organ damage. (e.g., in cases of hypertensive encephalopathy, aortic dissection, or preeclampsia).

Post-Operative Hypertension:

It is also used in post-operative patients who develop sudden increases in blood pressure to help manage these episodes.

1. Cerebral Vasospasm (Secondary Use in Neurology) Subarachnoid Hemorrhage (SAH):

Nicardipine has been used in the management of cerebral vasospasm following subarachnoid hemorrhage. By dilating blood vessels in the brain, it can reduce the risk of ischemia and improve cerebral blood flow during the critical post-hemorrhage period.

1. Pre-eclampsia and Eclampsia (Severe Pregnancy-Related Hypertension) Blood Pressure Control:

Nicardipine is used intravenously to manage severe hypertension in pregnant women with pre-eclampsia or eclampsia. Its

ability to lower blood pressure helps prevent complications like stroke or organ damage during these conditions.

1. Coronary Artery Spasm Spasm-Induced Angina:

Nicardipine is effective in treating angina caused by coronary artery spasms, such as Prinzmetal's angina. It works by relaxing the smooth muscle of the coronary arteries and preventing spasms that constrict blood flow.

1. Heart Failure (Adjunctive Use) Chronic Heart Failure:

In some cases, nicardipine may be used as part of the treatment for chronic heart failure to reduce afterload and improve cardiac output by dilating blood vessels. However, its use in heart failure is less common than other agents, such as ACE inhibitors or beta-blockers.

1. Arrhythmias (As an Adjunct Therapy) Atrial Arrhythmias:

As a calcium channel blocker, nicardipine may sometimes be used in the management of certain types of arrhythmias, particularly atrial fibrillation or atrial flutter, where it helps slow the conduction of electrical impulses in the heart and stabilize the rhythm.

1. Other Potential Uses

Vasodilator for Various Conditions:

As a potent vasodilator, nicardipine may be used off

Adverse Effects

Nicardipine hydrochloride is a calcium channel blocker used primarily for hypertension and angina. It works by relaxing blood vessels, making it easier for the heart to pump blood.

Specific Adverse Effects (Long-Term Use)

- Peripheral Edema:** One of the more common long-term effects of nicardipine use is swelling, particularly in the lower limbs. This occurs because the medication can cause dilation of blood vessels, which might lead to fluid leakage into surrounding tissues.
- Tachycardia:** Prolonged use of nicardipine may increase heart rate, as the body compensates for the lowered blood pressure. This effect can be particularly significant in patients with pre-existing heart conditions.
- Hypotension:** Chronic use of nicardipine may lead to persistent low blood pressure, especially if the dose is not carefully managed. This can cause dizziness, fainting, or lightheadedness, particularly when standing up quickly.
- Gingival Hyperplasia:** Although more common with other calcium channel blockers, long-term use can sometimes lead to overgrowth of the gums, which may require dental treatment.
- Liver Dysfunction:** Extended use may lead to mild elevations in liver enzymes, indicating possible liver stress. Monitoring liver function during long-term treatment is recommended.
- Heart Failure Exacerbation:** In patients with pre-existing heart failure, nicardipine can worsen symptoms, as it may reduce the heart's ability to pump efficiently over time.
- Flushing:** A common side effect with long-term use of nicardipine is facial flushing due to the vasodilation effect, though this is generally not harmful.
- Skin Rash:** Some individuals may experience a rash as a reaction to prolonged therapy, which could indicate an allergic response or sensitivity to the drug.
- Dysrhythmias:** Although uncommon, the prolonged use of nicardipine can lead to arrhythmias or irregular heartbeats, which may be serious in some cases.

These specific adverse effects highlight the importance of monitoring during long-term use of nicardipine, particularly for patients with underlying health conditions. Regular check-ups and dose adjustments are necessary to minimize potential risks.

Treatment of overdose

Nicardipine hydrochloride is a calcium channel blocker used to treat hypertension and angina. In case of overdose, prompt medical attention is crucial. The general treatment sequence for nicardipine overdose typically involves:

1. Initial Assessment:

Vital Signs: Monitor blood pressure, heart rate, and oxygen saturation.

Signs of Overdose: Symptoms can include hypotension, tachycardia, bradycardia, dizziness, nausea, and potentially cardiac arrest.

1. Discontinuation of Nicardipine:

Stop administering nicardipine immediately upon suspicion of overdose.

1. Symptomatic Management: Hypotension:

Fluid Resuscitation: Administer IV fluids (e.g., normal saline) to counteract low blood pressure.

Vasopressors: If hypotension persists, medications like norepinephrine or dopamine may be used to support blood pressure.

Bradycardia:

Atropine: If bradycardia (slow heart rate) is observed, atropine can be administered to increase heart rate.

Tachycardia: If the overdose causes reflex tachycardia, beta-blockers may be used carefully.

1. Activated Charcoal (if within 1 hour):

Gastrointestinal Decontamination: If the overdose was recent (within 1 hour), activated charcoal may be administered to limit further absorption of nicardipine.

1. Advanced Treatments:

Calcium: Calcium salts (such as calcium gluconate) may be administered as they may help reverse the effects of calcium channel blockers like nicardipine.

Cardiac Monitoring: Continuous ECG monitoring is essential, especially if the patient develops arrhythmias or signs of cardiac distress.

1. Alternative Routes (if necessary):

IV or Intramuscular (IM) Administration: In severe cases where oral administration is not feasible (e.g., vomiting or unconsciousness), intravenous (IV) or intramuscular (IM) routes may be utilized for drug administration.

Hemodialysis: This is generally not effective for nicardipine overdose due to its high protein binding but might be considered in extreme cases of poisoning.

1. Supportive Care:

Close Monitoring: Continue to monitor the patient's vital signs, ECG, and neurological status until they stabilize. Always seek emergency medical care if an overdose of nicardipine or any other medication is suspected.

Contradictions

Nicardipine hydrochloride is a calcium channel blocker, and like all medications, it has certain contraindications. Here's a breakdown of the key

contraindications and considerations regarding its use in various disease states: Key Contraindications:

- **Hypersensitivity:**
 - Known hypersensitivity to nicardipine or any of the formulation's ingredients.
- **Advanced Aortic Stenosis:**
 - Nicardipine can reduce diastolic pressure, which may worsen myocardial oxygen balance in patients with advanced aortic stenosis. Disease-Related Considerations:
- **Hepatic Impairment:**
 - Nicardipine is extensively metabolized by the liver. Therefore, caution is advised in patients with hepatic impairment or reduced hepatic blood flow. Lower dosages may be required.
- **Renal Impairment:**
 - Caution is also advised in patients with renal impairment. Dose adjustments may be necessary.
- **Congestive Heart Failure (CHF) and Left Ventricular Dysfunction:**
 - Nicardipine can have negative inotropic effects, so caution is warranted, especially when used in combination with beta-blockers.
- **Hypotension:**
 - Nicardipine can cause symptomatic hypotension. Therefore, it should be used with caution in patients who are already hypotensive or at risk of hypotension.
- **Acute Cerebral Infarction or Hemorrhage:**
 - Careful titration is necessary to avoid systemic hypotension in patients with acute cerebral infarction or hemorrhage.
- **Pheochromocytoma and Portal Hypertension:**
 - Use with caution in hypertension associated with these conditions.
- **Drug Interactions:**
 - Many drug interactions are important to be aware of. For example, there are contraindications with drugs that are affected by the CYP3A4 enzyme. It's crucial to consult the prescribing information and a healthcare professional for specific guidance based on individual patient circumstances.

Interaction

Nicardipine hydrochloride can interact with a variety of other drugs and substances. Here's a summary of key interactions: Key Drug Interactions:

- **Beta-Blockers:**

- Concomitant use can lead to increased cardiovascular adverse effects, such as hypotension. Careful monitoring is advised.

- **Cimetidine:**

- Cimetidine can increase nicardipine plasma levels, potentially leading to increased effects and side effects. Monitoring is recommended.

- **Digoxin:**

- Nicardipine may increase digoxin serum concentrations. Therefore, serum digoxin levels should be monitored, and the digoxin dose adjusted if necessary.

- **Cyclosporine and Tacrolimus:**

- Nicardipine can increase plasma levels of these Immunosuppressant drugs by inhibiting CYP3A4. Close monitoring of cyclosporine or tacrolimus levels is essential, and dosage adjustments may be required.

- **Fentanyl Anesthesia:**

- Severe hypotension has been reported with the combined use of fentanyl anesthesia, beta-blockers, and calcium channel blockers (including nicardipine). Increased fluid volume may be necessary.

- **Rifampin:**

- Rifampin can decrease the effectiveness of nicardipine. Therefore concurrent use should be avoided.

- **CYP3A4 Inhibitors/Inducers:**

- Nicardipine is metabolized by CYP3A4. Drugs that inhibit or induce this enzyme can significantly affect nicardipine levels. Therefore, careful consideration must be taken when prescribing nicardipine with other medications that affect the CYP3A4 enzyme system.

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Conventional Marketed Formulation

Nicardipine hydrochloride is a calcium channel blocker used to treat hypertension and angina. Here's a breakdown of its conventional marketed formulations, brand names, dosages, and price information: Compound Name:

- Nicardipine hydrochloride Types and Brand Names:

- Oral Capsules:

- Generic Nicardipine HCl

- Cardene (brand name, though primarily generics are used now)

- Intravenous (IV) Solution:

- Generic Nicardipine HCl IV Dosage:

- Oral Capsules:

- Dosage varies depending on the individual and the condition being treated. Typical starting doses are 20

mg or 30 mg, taken three times daily.

- Dosage adjustments are made based on the patient's response.
- IV Solution:
 - Used in hospital settings for acute hypertension.
 - Dosage is individualized and administered as a continuous infusion.
 - Initial infusion rates typically start at 5 mg/hour and are adjusted as needed. Price: It's important to note that medication prices can vary significantly based on:
 - Pharmacy location
 - Dosage and quantity
 - Insurance coverage
 - Whether it's a generic or brand-name medication Here's a general overview of price information:
 - Oral Capsules:
 - Sources like GoodRx indicate that the price of generic nicardipine capsules varies. Using discount coupons can greatly reduce the price. For example, GoodRx provides price ranges for 90 capsules of 20mg and 30mg.
 - Sites like [costplusdrugs.com](https://www.costplusdrugs.com) also provide pricing, and show the breakdown of the drug cost.
 - IV Solution:
 - The cost of IV nicardipine also varies. [Drugs.com](https://www.drugs.com) provides some price ranges for various strengths of the IV solution.
 - Information from sources such as [bambangpharma.com](https://www.bambangpharma.com) provides pricing for ampules of nicardipine hydrochloride solution for IV infusion.
 - It is very important to consult with your local pharmacy for the most accurate and up-to-date pricing. Important Considerations:
 - This information is for general knowledge and should not be considered medical advice.
 - Always consult with a healthcare professional before starting or changing any medication.
 - Dosage and administration should be determined by a doctor based on individual patient needs.
 - Pricing can change frequently.

Novel marketed Formulation

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Patent

Patent of nicardipine HCL.

1. ep0162705B1:- injection of nicardipine hydrochloride and production These European patents focus on the method of

production of an injectable formulation of nicardipine hydrochloride, aiming to enhance its stability and efficacy.

2. US5198226A:- long-acting nicardipine hydrochloride formulation:- this US patent describes a sustained release formulation of nicardipine HCL, designed to provide prolonged therapeutic effects, thereby reducing dosing frequency.

3. US4940556A:- method of preparation long-acting formulation:- this patent outlines a method of preparation of long-acting formulation of nicardipine hydrochloride, focusing on achieving consistent and extended drug release.

4. EP0231026B1:- sustained release dihydropyridine formulation:- this European patent pertains to sustained-release formulation of dihydropyridine compounds, including nicardipine, aiming to maintain therapeutic levels over extended periods.

5. US5209933A:- long-acting calcium channel blockers composition:- this patent describes the composition of long-acting calcium channel blockers, such as nicardipine HCL, formulated to enhance patent compliance.

6. EP0324982A1:- inclusion complex of nicardipine or its hydrochloride with beta cyclodextrin:- this patent describes the formulation of inclusion complexes between nicardipine hydrochloride and beta-cyclodextrin to improve its solubility and bioavailability of drugs.

Conclusion

Nicardipine hydrochloride is a calcium channel blocker widely used for the management of hypertension and angina. Its rapid onset of action, especially in intravenous form, makes it effective in emergency settings such as hypertensive crises. While it is generally well-tolerated, careful monitoring is essential due to potential side effects like hypotension and reflex tachycardia. Continued research and clinical monitoring are important to optimize its therapeutic use and minimize risks.

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