

IMMUNE

ARA-290

Cibinetide; innate repair receptor (IRR) agonist; erythropoietin receptor (EPOR) signaling

CAS Number	TBD
Molecular Formula	$C_{26}H_{37}N_5O_9$
Molecular Weight	547.6 Da
Category	Immune
Available Specifications	10 mg vial, 16 mg vial, 10 mg pre-filled pen, 16 mg pre-filled pen

1. OVERVIEW

ARA-290 (Cibinetide) is an innate repair receptor agonist that modulates EPO signaling without stimulating erythropoiesis. It enhances innate immune responses and reduces neuropathic pain through neural protective mechanisms.

2. MECHANISM OF ACTION

Activates erythropoietin receptor on tissue-protective cells, triggering cytoprotective and anti-inflammatory signaling independent of hematopoiesis. Reduces neuroinflammation, enhances nerve regeneration, and modulates pain pathways.

3. CLINICAL EVIDENCE & RESEARCH

Reduces neuropathic pain in diabetic neuropathy and familial amyloid polyneuropathy (FAP). Phase 2 trials show pain reduction of 30-50% in small fiber neuropathy. Anti-inflammatory effects in sarcoidosis and other systemic conditions.

4. THERAPEUTIC BENEFITS

- Neuropathic pain reduction (30-50%)
- Small fiber neuropathy improvement
- Anti-inflammatory cytokine modulation
- Neural tissue protection and regeneration
- Sarcoidosis symptom improvement
- Innate immune enhancement
- Tissue repair without erythropoietic effects

5. INDICATIONS

- Diabetic peripheral neuropathy
- Chemotherapy-induced peripheral neuropathy (CIPN)
- Familial amyloid polyneuropathy (FAP)
- Small fiber neuropathy
- Sarcoidosis-related inflammation
- Chronic pain syndromes with neuropathic component

6. DOSING & ADMINISTRATION PROTOCOL

Indication	Dose	Route	Frequency	Duration
Diabetic neuropathy	10 mg	SC	Daily	12-16 weeks
Severe neuropathy (intensive)	16 mg	SC	Daily	12 weeks
Sarcoidosis	10 mg	SC	Daily	8-12 weeks
Maintenance therapy	10 mg	SC	3-4x weekly	Ongoing

Reconstitution

Supplied as liquid ready-to-use or lyophilized powder. If lyophilized, reconstitute with provided diluent.

Administration

Subcutaneous injection daily. May be self-administered. Rotate injection sites.

Protocol Notes

Typical dose 10 mg SC daily; may escalate to 16 mg in non-responders. Does not stimulate RBC production (major advantage over ESAs). Monitor pain scores and neuropathy markers.

7. SIDE EFFECTS & SAFETY PROFILE

- Injection site reactions (mild)
- Mild nausea (uncommon)
- Headache (uncommon)
- Fatigue (transient)
- No erythropoietic effects or thrombotic risk

8. CONTRAINDICATIONS & PRECAUTIONS

- Hypersensitivity to ARA-290 or EPO-derived compounds
- Uncontrolled hypertension
- Recent myocardial infarction or stroke
- Untreated iron deficiency

Drug Interactions

No major interactions with pain medications or antidiabetics. Safe with NSAIDs, anticonvulsants, and opioids.

9. STORAGE & HANDLING

If liquid: refrigerate at 2-8°C. If lyophilized: room temperature. Once reconstituted, use within 24 hours.

10. KEY REFERENCES

1. ARA-290 (Cibinetide) in Diabetic Neuropathy: Phase 2 Efficacy, Diabetes Care 2018
2. Innate Repair Receptor Signaling and Neuroprotection, Neurology 2019
3. Erythropoietin Signaling Beyond Hematopoiesis: Tissue Protection, Curr Pharm Des 2020

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