

Spesolimab Therapeutic Cheat Sheet

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TRADE NAME

- > Spevigo

MECHANISM OF ACTION

- > A human IgG1 monoclonal antibody, spesolimab binds to the interleukin-36 receptor (IL-36R) and inhibits IL-36 signaling, leading to decreased downstream pro-inflammatory and pro-fibrotic pathways.

FDA APPROVED FOR³

- > Treating generalized pustular psoriasis (GPP) flares in ages 12 years and older, with minimum weight of 40 kg
- > Treating GPP without flaring in ages 12 years and older, with minimum weight of 40 kg

OFF-LABEL DERMATOLOGIC USES

- > Pyoderma gangrenosum^{4,5}
- > Acrodermatitis continua of Hallopeau⁶

DOSING

- > Intravenous Dosage for Acute Flare
 - > Single 900 mg dose infused over 90 minutes
 - > If symptoms persist, additional single 900 mg dose 1 week after initial dose
- > Subcutaneous Dosage for Maintenance Regimen
 - > If already received IV spesolimab: 4 weeks after the last IV dose, 300 mg every 4 weeks
 - > If no previous IV spesolimab: loading dose of 600 mg once, followed by 300 mg every 4 week

ADMINISTRATION CONSIDERATIONS³

- > Sterile, low protein binding in-line filter with a pore size of 0.2 micron should be used for infusion
- > If rate of infusion is slowed, the maximum total infusion time should be 180 minutes.
- > Subcutaneous 600 mg loading dose should be administered by a healthcare professional. Subsequent 300 mg doses can be self-administered.

SIDE EFFECTS

- > Fatigue, nausea, vomiting, headache, drug-induced hypersensitivity syndrome,
- > and infections were the most frequently reported in clinical trials.^{7,8}
- > Symptoms of DIHS, or drug reaction with eosinophilia and systemic symptoms (DRESS), were reported with RegiSCAR scores of 1 (no DRESS) and 3 (possible DRESS).⁸
- > The infections included upper respiratory tract infection, urinary tract infection, cellulitis, bacteremia, herpes dermatitis, vulvovaginal candidiasis, and otitis externa, but were overall deemed mild to moderate.⁸
- > Limited cases of Guillain-Barre syndrome during clinical development³

DRUG INTERACTIONS

- > Live vaccines should be avoided.³

CONTRAINDICATIONS

- > History of anaphylaxis or hypersensitivity to spesolimab³

PREGNANCY & BREASTFEEDING

- > Limited data of spesolimab use in pregnant or breastfeeding women. No reproductive toxicity shown in murine studies.³
- > Human IgG does cross placental barrier and is likely present in human breast milk.

MONITORING¹

- > Baseline Labs:
 - > Screen for tuberculosis infection with QuantiFERON-TB Gold+
- > Periodic monitoring:
 - > Annual QuantiFERON-TB Gold+

REFERENCES

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