# VANCOUVER GENERAL HOSPITAL
# CSU PHARMACEUTICAL SCIENCES
# NON-FORMULARY DRUG DATA SHEET

**DRUG NAME**
Vedolizumab

**ALTERNATE NAME**
ENTYVIO

**MANUFACTURER**
Takeda Canada

**STRENGTH**
300 mg/5 mL (60 mg/mL)

**DOSAGE FORM**
injectable

**INDICATIONS**
Treatment of moderate to severely active Crohn's disease or ulcerative colitis

**DOSAGE**
300 mg at 0, 2 and 6 weeks, then every 8 weeks thereafter

**PREPARATION (See product monograph for complete instructions)**
Each vial is single use only. Allow vial to warm to room temperature.
Reconstitute with 4.8 mL of sterile water for injection at room temperature.
Gently swirl for 15 seconds (DO NOT SHAKE or invert).
Let vial sit for 20 minutes at room temperature to allow for reconstitution and for foam to settle.
If drug is not fully dissolved, let vial sit additional 10 minutes. Do not use if drug not dissolved in 30 minutes.
Once dissolved, gently invert vial 3 times and withdraw 5 mL (300 mg) of reconstituted solution.
Add to 250 mL of sodium chloride 0.9% (NS) and gently mix the infusion bag.

**ADMINISTRATION (See product monograph for complete instructions)**
Infuse over 30 minutes (do not administer as IV push or bolus)
Do not administer with any other medications or solutions
Administer the infusion solution as soon as possible after reconstitution
Flush line with 30mL of sodium chloride 0.9% for injection (NS) post infusion

**STORAGE (See product monograph for complete instructions)**

Store reconstituted solution in vial for up to 8 hours in refrigerator.
Store diluted solution for up to 12 hours at room temperature or up to 24 hours in refrigerator.

**KNOWN SIDE EFFECTS***
- Hypersensitivity: urticaria, flushing, rash, dyspnea, bronchospasm, tachycardia, hypertension
- Infusion-related: nausea/vomiting, headache, pruritus, dizziness, fatigue, fever/chills, urticaria
- Most common: headache, arthralgia, nasopharyngitis, nausea, fever, fatigue, cough, URTI.
- Increased risk of serious infections
- Elevations of AST, ALT and/or bilirubin
- Theoretical risk of progressive multifocal leukoencephalopathy (PML)

**SPECIAL PRECAUTIONS**
- Contraindicated in patients with a history of hypersensitivity to any ingredient in this product
- Monitor baseline and post-infusion vital signs (BP, HR, RR and temperature). More frequent monitoring may be warranted in patients with a history of hypersensitivity or infusion-related reactions.
- Monitor patients for hypersensitivity and infusion-related reactions:
    - If severe reaction occurs – STOP infusion immediately and start appropriate treatment (eg. antihistamines, steroids, epinephrine)
    - If mild-moderate reaction – SLOW or STOP the infusion and start appropriate treatment. May consider pre-treatment one hour prior to next infusion
- Stop treatment in patients with jaundice or other evidence of severe hepatic impairment (eg. fatigue, anorexia, dark urine or right upper abdominal discomfort)

- Prior to first dose, screen for latent TB, hepatitis B or signs and symptoms of active infection
- All patients should be up to date with vaccinations preferably 4 weeks prior to vedolizumab

**Knowledge of its side effects is incomplete and may involve risks that are unknown and currently unforeseen.**

***REPORT ANY ADVERSE DRUG REACTIONS TO THE PHYSICIAN***

APR2020 (AD/CA/RT/JD)