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Tocilizumab (Actemra) Clinical Guideline for Home Intravenous Therapy

Section: Clinical Guideline

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I. BACKGROUND

Tocilizumab (Actemra) is a recombinant humanized anti-human interleukin 6 (IL-6) receptor monoclonal antibody of the immunoglobulin IgG1 κ (gamma 1, kappa) subclass with a typical H2L2 polypeptide structure. Tocilizumab binds specifically to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R) and has been shown to inhibit IL-6-mediated signaling through these receptors. IL-6 is a pleiotropic pro-inflammatory cytokine produced by a variety of cell types including T- and B-cells, lymphocytes, monocytes and fibroblasts. IL-6 has been shown to be involved in diverse physiological processes such as T-cell activation, induction of immunoglobulin secretion, initiation of hepatic acute phase protein synthesis, and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is also produced by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis.

Biosimilars: A biosimilar product is highly similar and has no clinically meaningful differences in safety, purity, and potency (safety and effectiveness) from an existing FDA-approved reference product. The manufacturer of a proposed biosimilar product generates data comparing the proposed product to the FDA-approved reference product to demonstrate biosimilarity. A manufacturer that shows its proposed biosimilar product is highly similar may rely in part on FDA's previous determination of safety and effectiveness for the reference product for approval. This generally means that biosimilar manufacturers do not need to conduct as many expensive and lengthy clinical trials, potentially leading to faster access to these products, additional therapeutic options, and reduced costs for patients. Biosimilar products may have different inactive or excipient ingredients than the reference product.

Multiple biosimilars for tocilizumab (Actemra) are available in the United States including Tofidence (tocilizumab-bavi), Avtozma (tocilizumab-anoh), and Tyenne (tocilizumab-aazg). When dispensing biosimilar products, the four-letter suffix (ex: tocilizumab- **bavi**) must be present after the generic drug name to distinguish which biosimilar product is dispensed.

The following outlines clinical guidelines for servicing patients in need of outpatient intravenous tocilizumab.

II. PATIENT ACCEPTANCE CRITERIA

- A. All candidates for home care service must be evaluated by the clinician(s) and deemed appropriate to receive home care based upon dispensing pharmacy's admission criteria.
- B. The decision to administer a first dose in the home by a nurse will be determined on a case-by-case basis and reviewed by nursing and pharmacy management. These criteria will be evaluated:

1. Prescriber preference
2. Allergy profile
3. Age
4. Other relevant social and/or medical history

C. Prescriber orders for tocilizumab shall include:

1. Patient weight
2. Drug and dose (including weight-based dosing)
3. Route of administration
4. Frequency of administration
5. Emergency medications per protocol
6. Orders for pre-medications
7. Line care protocol
8. Routine lab monitoring, if applicable

D. Baseline labs:

1. Patients must have documentation of tuberculosis (TB) screening and be free from active TB infection
2. Evidence of baseline bloodwork including CBC with differential (with ANC and platelets), AST/ALT, total bilirubin, and lipid panel.
3. Prior to starting therapy, patients should be free from any active infections.

E. Patient should be up to date on recommended vaccinations prior to therapy initiation.

F. Dispensing pharmacy treatment protocol for anaphylaxis will be instituted unless a more comprehensive patient-specific orders are provided by the physician. See Appendix A (Nursing CarepathRx policy on *Management of Allergic/Anaphylactic Reactions*).

III. PHARMACOLOGIC OVERVIEW

Refer to manufacturer's full Prescribing Information for most up to date information

A. Indications:

1. Rheumatoid Arthritis (RA): Adult patients with moderately to severe active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.
2. Giant Cell Arteritis (GCA): In adult patients. GCA is an inflammation of the arteries typically in the temple and head.
3. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Slows the rate of decline in pulmonary function in adult patients.
4. Polyarticular Juvenile Idiopathic Arthritis (PJIA): Patients 2 years of age and older with active disease.

5. Systemic Juvenile Idiopathic Arthritis (SJIA): Patients 2 years of age and older with active disease.
6. Cytokine release syndrome (CRS): Patients 2 years and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.
7. Corona virus 19 (COVID-19): Adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

B. Dose (IV administration):

**Subcutaneous dosing and administration will not be discussed in the scope of this guideline*

1. Rheumatoid Arthritis: 4 mg/kg IV once every 4 weeks; may be increased to 8 mg/kg IV once every 4 weeks based on clinical response (maximum dose: 800 mg)
2. Giant Cell Arteritis: 6 mg/kg IV once every 4 weeks
3. Polyarticular Juvenile Idiopathic Arthritis
 - a. Patients < 30 kg: 10 mg/kg IV every 4 weeks
 - b. Patients $\geq$ 30 kg: 8 mg/kg IV every 4 weeks
4. Systemic Juvenile Idiopathic Arthritis
 - a. Patients < 30 kg: 12 mg/kg IV every 4 weeks
 - b. Patients $\geq$ 30 kg: 8 mg/kg IV every 4 weeks
5. Cytokine release syndrome:
 - a. Patients < 30 kg: 12mg/kg IV one time dose
 - b. Patients $\geq$ 30 kg: 8 mg/kg IV one time dose
6. COVID-19: 8mg/kg IV one time dose

*Dosing is based off actual body weight. Tocilizumab has not been studied in extremes of body weights.

C. Dose adjustments:

1. No renal dose adjustments
2. Tocilizumab treatment is not recommended in patients with active hepatic disease or hepatic impairment, including patients with positive HBV and HCV serology.
3. Liver enzyme abnormalities in RA, SSc-ILD, and GCA

Lab Value	Recommendation for RA and SSc-ILD	Recommendation for GCA
Greater than 1 to 3x upper limit of normal (ULN)	Dose modify concomitant DMARDs if appropriate For persistent increases in this range: For patients receiving IV tocilizumab, reduce the dose to 4 mg/kg or hold until AST or ALT have normalized	Dose modify immunomodulatory agents if appropriate. For persistent increases in this range: For patients receiving IV tocilizumab, hold treatment until AST or ALT have normalized
Greater than 3-5x ULN (confirmed by repeat testing)	Hold tocilizumab dosing until less than 3x ULN and follow recommendations above for greater than 1-3x ULN. For persistent increases greater than 3x ULN, discontinue tocilizumab.	Hold tocilizumab dosing until less than 3x ULN and follow recommendations above for greater than 1-3x ULN. For persistent increases greater than 3x ULN, discontinue tocilizumab.
Greater than 5x ULN	Discontinue tocilizumab	Discontinue tocilizumab

4. Low absolute neutrophil count (ANC) in RA, SSc-ILD, and GCA

Lab Value	Recommendation for RA and SSc-ILD	Recommendation for GCA
ANC greater than 1,000	Maintain dose	Maintain dose
ANC 500-1,000	Hold tocilizumab dosing. When ANC greater than 1,000 cells per mm ³ : For patients receiving IV tocilizumab, resume at 4mg/kg and increase to 8mg/kg as clinically appropriate.	Hold tocilizumab dosing. When ANC greater than 1,000 cells per mm ³ : For patients receiving IV tocilizumab, resume at 6mg/kg
ANC less than 500	Discontinue tocilizumab	Discontinue tocilizumab

5. Low platelet count in RA, SSc-ILD, and GCA

Lab Value (cells per mm ³)	Recommendation for RA and SSc-ILD	Recommendations for GCA
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50,000-100,000	Hold tocilizumab dosing. When platelet count is greater than 100,000 cells per mm ³ : For patients receiving IV tocilizumab, resume at 4mg/kg and increase to 8 mg/kg as clinically appropriate.	Hold tocilizumab dosing. When platelet count is greater than 100,000 cells per mm ³ : For patients receiving IV tocilizumab, resume at 6mg/kg.
Less than 50,000	Discontinue tocilizumab	Discontinue tocilizumab

6. Dose adjustments in PJIA and SJIA: dose reduction of tocilizumab has not been studied in these two populations. Dose interruptions of tocilizumab are recommended for liver enzyme abnormalities, low neutrophil counts, and low platelet counts in patients with PJIA and SJIA at levels similar to what is outlined for patients with RA and GCA. Dose modify or stop concomitant methotrexate and/or other medications and hold tocilizumab until the clinical situation has been evaluated.

D. Duration: Duration of therapy is dependent on patient response and adverse reactions

E. Contradictions: Tocilizumab is contraindicated in patients with a known hypersensitivity.

F. Warnings and Precautions:

1. **Serious Infections:** Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, protozoal, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents including tocilizumab. Tocilizumab should not be administered in patients with an active infection, including localized infections. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with tocilizumab, as signs and symptoms of acute inflammation may be lessened due to suppression of the acute phase reactants. Tocilizumab should be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis.
 - a. COVID-19: In patients with COVID-19, monitor for signs/symptoms of new infections during and after treatment with tocilizumab. There is limited information with the use of tocilizumab in patients with COVID-19 and concomitant active serious infections.
 - b. Tuberculosis (TB): Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating tocilizumab. Patients with a history of past active or latent TB should be considered for TB treatment prior to initiating tocilizumab.
 - c. Viral Reactivation: Viral reactivation has been reported with immunosuppressive biologic therapies and cases of herpes zoster exacerbation were observed in clinical studies with tocilizumab. No cases of hepatitis B reactivation were observed in clinical trials; however, patients who screened positive for hepatitis were excluded.
2. **Gastrointestinal perforations:** Events of gastrointestinal perforation have been reported in clinical trials, primarily as complications of diverticulitis. Tocilizumab should be used with caution in patients who may be at increased risk for gastrointestinal perforation. Patients

presenting with new onset abdominal symptoms should be evaluated promptly for early identification of gastrointestinal perforation.

3. **Hepatotoxicity:** Serious cases of hepatic injury have been observed in patients taking tocilizumab. Some of these cases have resulted in liver transplant or death. Time to onset for cases ranged from months to years after treatment initiation with tocilizumab. While most cases presented with marked elevations of transaminases (> 5 times ULN), some cases presented with signs or symptoms of liver dysfunction and only mildly elevated transaminases. During randomized controlled studies, treatment with tocilizumab was associated with a higher incidence of transaminase elevations. Increased frequency and magnitude of these elevations was observed when potentially hepatotoxic drugs (ex: methotrexate) were used in combination with tocilizumab.
4. **Changes in laboratory parameters:**
 - a. **Neutropenia:** Treatment with tocilizumab was associated with a higher incidence of neutropenia. It is not recommended to initiate tocilizumab treatment in patients with a low neutrophil count. In patients who develop an ANC < 500 per mm^3 treatment is not recommended. It is not recommended to initiate tocilizumab in COVID-19 patients with an ANC $< 1,000$ per mm^3 . Monitor neutrophils 4-8 weeks after the start of therapy and every 3 months thereafter.
 - b. **Thrombocytopenia:** Treatment with tocilizumab was associated with a reduction in platelet counts. It is not recommended to initiate tocilizumab treatment in patients with a platelet count below 100,000 per mm^3 . Treatment is not recommended in patients with a platelet count of $< 50,000$ per mm^3 . Monitor platelets 4-8 weeks after the start of therapy and every 3 months thereafter.
 - c. **Elevated liver enzymes:** Treatment with tocilizumab was associated with a higher incidence of transaminase elevations, especially when used with other hepatotoxic drugs. It is not recommended to initiate tocilizumab treatment in patients with elevated transaminases ALT or AST $> 1.5\times$ ULN.
 - d. **Lipid abnormalities:** Treatment with tocilizumab was associated with increases in lipid parameters such as total cholesterol, triglycerides, LDL cholesterol, and/or HDL cholesterol. Assess lipid parameters 4-8 weeks following the initiation of tocilizumab.
5. **Immunosuppression:** The impact of treatment with tocilizumab on the development of malignancy is not known but malignancies were observed in clinical studies. Tocilizumab is an immunosuppressant, and treatment with immunosuppressants may result in an increased risk of malignancies.
6. **Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been reported in association with infusion of tocilizumab. Appropriate medical treatment should be available for immediate use in the event of anaphylactic reaction during administration of tocilizumab. In clinical trials, hypersensitivity reactions were reported in 0.1-0.2% of patients.
7. **Demyelinating Disorders:** The impact of treatment with tocilizumab on demyelinating disorders is not known, but multiple sclerosis and chronic inflammatory demyelinating polyneuropathy were reported rarely in clinical studies. Patients should be closely monitored

for signs and symptoms potentially indicative of demyelinating disorders. Prescribers should exercise caution in considering the use of tocilizumab in patients with preexisting or recent onset demyelinating disorders.

8. **Active hepatic disease and hepatic impairment:** Treatment with tocilizumab is not recommended in patients with active hepatic disease or hepatic impairment.
9. **Vaccinations:** Live vaccines should not be given concurrently with tocilizumab as clinical safety has not been established. Because IL-6 inhibition may interfere with the normal immune response to new antigens, patients should be brought up to date on all recommended vaccinations prior to therapy initiation.
10. **Pregnancy and Lactation:** Monoclonal antibodies, such as tocilizumab, are transported across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. In animal reproduction studies, intravenous administration of tocilizumab to Cynomolgus monkeys during organogenesis caused abortion/embryo-fetal death at doses 1.25 times and higher than the maximum recommended human dose by the intravenous route of 8 mg/ kg every 2 to 4 weeks. The literature in animals suggests that inhibition of IL-6 signaling may interfere with cervical ripening and dilatation and myometrial contractile activity leading to potential delays of parturition. Based on the animal data, there may be a potential risk to the fetus. No information is available on the presence of tocilizumab in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.

G. Pharmacokinetics (IV)

1. Volume of distribution: 4.01-4.08 L in PJIA and SJIA; 6.4-8.75 L in RA, COVID-19, and SSc-ILD.
2. Half-life of 11-13 days in RA; 16-17 days in PJIA and SJIA. Due to the dependence of total clearance on tocilizumab serum concentrations, the half-life of tocilizumab is also concentration-dependent and varies depending on the serum concentration level.
3. Excretion: 17.6-35.4 mL/hr, eliminated by a combination of linear clearance and nonlinear elimination.

H. Adverse Reactions

1. Cardiovascular: hypertension (4-7%), septic shock (COVID-19, 6%)
2. Gastrointestinal: Constipation (COVID-19, 6-13%), diarrhea (COVID-19, 4-6%), nausea (COVID-19, 3-4%), upper abdominal pain (2-3%)
3. Hematologic: neutropenia (1.8-15.4%), thrombocytopenia (up to 4%)
4. Hepatic: elevated ALT (0.7-48%), elevated AST (0.1-41%)
5. Immunologic: anaphylaxis, hypersensitivity reaction (up to 0.9%)
6. Neurologic: dizziness (2-3%), headache (3-7%), insomnia (COVID-19, 4-5%)
7. Psychiatric: anxiety (COVID-19, 3-6%)
8. Respiratory: nasopharyngitis (4-7%), upper respiratory infection (6-8%)
9. Other: infusion reaction (7-20.2%)

I. Drug Interactions

1. Concomitant immunosuppressants due to additive effects

2. CYP 450 substrates: increased metabolism of drugs that are CYP450 substrates when co-administered with tocilizumab.
3. Drug-drug interactions may exist. Consult interaction database for patient specific assessment.

IV. ADMINISTRATION GUIDELINES

- A. IV infusions should be given immediately after reconstitution and dilution. Begin infusion within 4 hours of preparation per current USP Immediate-Use Guidelines.
- B. Tocilizumab should not be infused concomitantly in the same intravenous line with other drugs.
 1. The infusion must be administered with an infusion set. Do not administer as an intravenous push or bolus.

V. NURSING PROCEDURE

- A. Supplies may include but are not limited to:

1. Alcohol Swabs
2. Gloves
3. Tape
4. IV access supplies as applicable
 - a. Peripheral IV access supplies for patients requiring peripheral IV access
 - 1) IV start Kit
 - 2) Peripheral IV catheter (ex. 22 Gauge x 1" and 24 Gauge x 3/4")
 - 3) Extension set 8" with needless connector
 - b. Port access supplies for patients with a port
 - 1) Port needle (ex. 22 Gauge x 3/4 to 1" safe step)
 - 2) Needless connector
 - 3) Central line dressing change kit
5. IV pole
6. IV administration set (flow regulator or gravity tubing)
7. Supplies if utilizing a pole mounted ambulatory infusion pump:
 - a. Ambulatory pump tubing
 - b. Pole mounted ambulatory pump
 - c. Batteries for ambulatory pump (Ex: 9 Volt Duracell battery or 4 Double A batteries)
 - d. Battery change procedure teaching sheet
 - e. Continuous delivery mode teaching sheet
 - f. Pump return box
8. Syringes (20-60 mL) with needles (20 G x 1")
9. Sharps container

- B. Prescription items:

1. Tocilizumab vials
2. 50 mL or 100 mL bag of sodium chloride 0.9% for dilution
3. Standard flushes per protocol

4. Anaphylaxis kit per protocol
- C. How Supplied (for IV infusion):
Tocilizumab is supplied as a sterile, preservative-free solution for intravenous (IV) infusion at a concentration of 20 mg/mL. Tocilizumab is a colorless to pale yellow liquid, with a pH of about 6.5. Single-use vials are available containing 80 mg/4 mL, 200 mg/10 mL, or 400 mg/20 mL of tocilizumab.
- D. Storage and Handling:
Do not use beyond expiration date on the container. Tocilizumab must be refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Protect the vials from light by storage in the original package until time of use.
- E. Compatibility
1. Fully diluted tocilizumab solutions are compatible with polypropylene, polyethylene and polyvinyl chloride infusion bags and polypropylene, polyethylene and glass infusion bottles.
 2. Stable in 0.9% sodium chloride and 0.45% sodium chloride
- F. Procedures
- :
1. Explain the reasoning for visit and use of tocilizumab
 2. Don gloves.
 3. Assess for signs and symptoms of infection prior to establishing venous access and preparing medication. Notify ordering physician and pharmacist if signs or symptoms are present.
 4. Establish venous access prior to preparation of drug.
 5. Counsel the patient on warnings, precautions, and potential adverse effects including but not limited to: constipation, hypertension, elevated AST/ALT, diarrhea, insomnia, nausea, hematologic effects, infusion related reactions, and hypersensitivity reactions.
 6. Prepare product:
 - a. For pediatric patients <30 kg, utilize 50mL 0.9% sodium chloride bag; for patients ≥ 30 kg, utilize 100mL 0.9% sodium chloride bag. For adult patients at or above 30 kg, utilize 100mL 0.9% sodium chloride bag.
 - b. From a 50 mL or 100 mL 0.9% sodium chloride infusion bag, withdraw a volume of 0.9% sodium chloride equal to the volume of the tocilizumab solution required for the patient's dose and discard.
 - c. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If particulates and discolorations are noted, the product should not be used.
 - d. Slowly withdraw tocilizumab volume from each vial and inject into the diluent infusion bag. To mix the solution, gently invert the bag to avoid foaming. Discard unused product left in vials.
 - e. Allow the fully diluted tocilizumab solution to reach room temperature prior to infusion.
 7. Infusion Rate: The infusion should be administered IV over 60 minutes.
 8. Monitor patient and vital signs periodically during the infusion and 30 minutes after the infusion is complete per CarePathRx Nursing Best Practice Administration Guidelines.

VI. CLINICAL MONITORING

A. Prior to therapy:

1. Labs: Neutrophils, platelets, AST/ALT, alkaline phosphatase, total bilirubin, and lipid panel.
2. Patients must have documentation of TB screening and be free from active infection
3. Patients should be up to date on vaccinations prior to starting tocilizumab

B. During therapy:

1. Monitor neutrophils and platelets 4 to 8 weeks after starting therapy, and every 3 months thereafter
2. Monitor AST/ALT, alkaline phosphatase, and total bilirubin every 4 to 8 weeks after start of therapy for the first 6 months, and every 3 months thereafter
3. Monitor lipid panel 4 to 8 weeks following initiation of therapy, then subsequently according to current guidelines.
4. Monitor patients for signs and symptoms of infection and other adverse effects including new onset abdominal pain, nausea, constipation, diarrhea, hypertension, infusion related reactions, and hypersensitivity reactions.
5. Monitor therapy efficacy including quality of life, activities of daily living (ADLs), joint pain, stiffness, myalgia, fevers, and rash.

Please refer to the package insert for the most up to date guidance on this medication.

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APPENDIX A: ANAPHYLAXIS KIT INSTRUCTIONS

Emergency Medication After Your Infusion

Please call your pharmacy if you have any questions or concerns. In the event of an emergency, always call 911.

Your nurse will tell you when you need to use Emergency Medications.

The epinephrine dose will be noted on the Anaphylaxis Protocol included with your kit.

Start with a clean work surface and clean hands.

Open the supply bag labeled Anaphylaxis Kit Contents.

You will need:

1. Bag containing Pills (2 Acetaminophen and 2 Diphenhydramine)
2. Bag containing Alcohol Prep Pads
3. Bag labeled IM Epinephrine

All other contents will not be needed.

Open the IM Epinephrine Bag

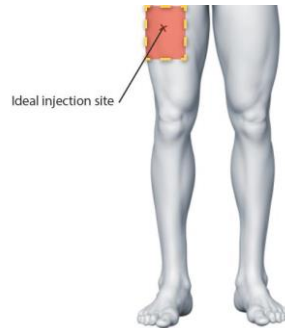
1. Remove 1 of each item
 - a. 1 -syringe
 - b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampule use only**
 - c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1’')
 - d. 1 ampule of epinephrine

Prepare IM (intramuscular) injection of Epinephrine:

1. **Attach the brown filtered needle to syringe**
 - a. Be careful not to touch the tip of the syringe or the needle.
2. Using an **alcohol swab, wipe the neck of the epinephrine ampule.**
3. Holding the ampule upright, **swirl and flick the ampule until all fluid flows to the bottom chamber** (the top chamber should be empty).
4. Using a new alcohol wipe, grasp the neck of the ampule and with your other hand grasp the bottom chamber of the ampule. **Quickly snap the top of the ampule off, directing the snap way from you.**
5. **Place the tip of the brown filter needle inside the ampule.** Tilting the ampule, **withdraw dose of medication into the syringe** by gently pulling back on the plunger. Be careful not to pull the plunger out of the syringe.
6. Remove the needle from the ampule and **hold the syringe upright** with the needle pointing upward. **Gently tap the side of the syringe to bring any air to the top of the syringe.**
7. **Push the air out of the syringe by gently pushing on the plunger.**

8. Replace the cap on the brown filter needle. Discard remainder in ampule.
9. **Remove the brown filter needle and place the black safety needle onto the syringe.**

Give your IM Epinephrine injection



1. **Grasp your leg muscle at the outer mid-thigh** and **cleanse the area** with a new alcohol wipe.
2. **Push the needle into your leg muscle straight** in at a 90-degree angle.
3. **Inject the medication** by depressing the plunger in a slow and steady motion.
4. **Remove the needle** and wipe the site with the alcohol wipe.
5. May repeat dose every 5 minutes (**maximum 3 doses**) if ordered per protocol.

Take the pills by mouth.

- a. 2 – Acetaminophen
- b. 2 – Diphenhydramine

Place all trash in the bag the pills came in and take with you when you seek medical care. **Give the bag to the nurse or EMT**, so your doctor will know what medication you already took. They will properly dispose of the syringe and needles.

Call 911 or have someone drive you to the emergency department.