

## DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

**POLICY:** Topical Diclofenac Duration Limit

**DATE REVIEWED:** 07/28/2020

**DRUGS AFFECTED:**

- diclofenac sodium 2% solution (Pennsaid® - Horizon Pharma, Inc.)
- diclofenac sodium 3% gel (Solaraze – Fougera Pharmaceuticals, Inc., generics)
- diclofenac sodium 1.5% liquid (generics)
- diclofenac sodium 1% gel (Voltaren – Endo Pharmaceuticals, Inc., generics)

**Table 1. Quantity Level Limits**

<i>Medication Name and Strength</i>	<i>Per Days Quantity Level Limit</i>
Diclofenac liquid 1.5% – 150 ml bottle	1 bottle (150 ml) per 28 days
Pennsaid 2% solution – 112 gram bottle	1 bottle (112 grams) per 28 days
Solaraze 3% gel – 100 gram tube	1 tube (100 grams) per 28 days
Voltaren 1% gel – 100 gram tube	5 tubes (500 grams) per 28 days

### OVERVIEW

The initial quantity limit supplies a sufficient quantity for each of the four topical diclofenac products to treat minimum number of affected areas according to prescribing information. For patients treating multiple joints or actinic keratosis lesions, additional quantities of each are available through coverage review. The objective of this program is to prevent stockpiling, misuse and/or overuse.

Diclofenac sodium is a nonsteroidal anti-inflammatory drug that inhibits cyclooxygenase (COX) which results in the reduced formation of prostaglandins, thromboxanes, and prostacyclin. Diclofenac sodium has anti-inflammatory, anti-nociception, and antipyretic effects.

Voltaren® Gel (diclofenac sodium topical gel 1%), and Pennsaid® (diclofenac sodium topical solution 1.5% and 2%), Klofenaid II (diclofenac sodium topical solution 1.5%) and Solaraze (diclofenac sodium topical gel 3%) are topical NSAIDs. Voltaren Gel is indicated for the relief of osteoarthritis (OA) pain of joints amenable to topical treatment (knees, ankles, feet, elbows, wrists, and hands). Pennsaid and Klofenaid II are indicated for the treatment of signs and symptoms of OA of the knees. Solaraze is indicated for the topical treatment of actinic keratoses. Topically delivered drugs have the advantage of producing a local effect without systemic activity, potentially decreasing adverse effects (AEs) and drug-drug interactions.<sup>10</sup> The recent recognition of both the cardiovascular (CV) and gastrointestinal (GI) risk associated with NSAIDs (selective and nonselective) also brings interest to topical agents.

#### *Diclofenac liquid 1.5% (generics)*

The dose of diclofenac liquid is up to 40 drops on each painful knee, four times a day. According to the prescribing information of topical 1.5% diclofenac products there are 40 drops per 1.2 ml of liquid. If treating both knees, a quantity of 268.8 ml will be needed every 28 days. Apply diclofenac to clean, dry skin. To avoid spillage, dispense diclofenac 10 drops at a time either directly onto the knee or first into the hand and then onto the knee. Spread diclofenac evenly around front, back and sides of the knee. Repeat this procedure until 40 drops have been applied and the knee is completely covered with solution. To treat the other knee, if symptomatic, repeat the procedure. Application of diclofenac in an amount exceeding or less than the recommended dose has not been studied and is therefore not recommended.

### ***Pennsaid 2% Solution***

The recommended dose of Pennsaid solution is 40 mg (2 pump actuations) on each painful knee, 2 times a day. The pump must be primed before first use. Instruct patients to fully depress the pump mechanism (actuation) 4 times while holding the bottle in an upright position. This portion should be discarded to ensure proper priming of the pump. No further priming of the bottle should be required. After the priming procedure, Pennsaid solution is properly dispensed by completely depressing the pump 2 times to achieve the prescribed dosage for one knee. Deliver the product directly into the palm of the hand and then apply evenly around front, back, and sides of the knee. Apply Pennsaid to clean, dry skin. Application of Pennsaid in an amount exceeding or less than the recommended dose has not been studied and is therefore not recommended.

### ***Solaraze (generic)***

Solaraze Gel is applied to lesion areas twice daily. It is to be smoothed onto the affected skin gently. The amount needed depends upon the size of the lesion site. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

### ***Voltaren (generic)***

The proper amount of VOLTAREN® GEL should be measured using the dosing card supplied in the drug product carton. The dosing card is made of clear polypropylene. The dosing card should be used for each application of drug product. The gel should be applied within the oblong area of the dosing card up to the 2 gram or 4 gram line (2 g for each elbow, wrist, or hand, and 4 g for each knee, ankle, or foot). The 2 g line is 2.25 inches long. The 4 g line is 4.5 inches long. The dosing card containing VOLTAREN® GEL can be used to apply the gel. The hands should then be used to gently rub the gel into the skin. After using the dosing card, hold with fingertips, rinse, and dry. If treatment site is the hands, patients should wait at least one (1) hour to wash their hands.

#### Lower extremities, including the knees, ankles, and feet

Apply the gel (4 g) to the affected foot or knee or ankle, 4 times daily. The gel should be gently massaged into the skin ensuring application to the entire affected foot or knee or ankle. The entire foot includes the sole, top of the foot and the toes. Do not apply more than 16 g daily to any single joint of the lower extremities.

#### Upper extremities including the elbows, wrists and hands

Apply the gel (2 g) to the affected hand or elbow or wrist, 4 times daily. The gel should be gently massaged into the skin ensuring application to the entire affected hand or elbow or wrist. The entire hand includes the palm, back of the hands, and the fingers. Do not apply more than 8 g daily to any single joint of the upper extremities. Total dose should not exceed 32 g per day, over all affected joints.

### **CRITERIA**

All approvals are provided for 12 months in duration unless otherwise noted below.

### ***Diclofenac liquid 1.5% (generics)***

1. For patients treating both knees, an override of up to a total of two bottles (300 ml) can be allowed per 28 days.

### ***Pennsaid Solution 2%***

1. For patients treating both knees, an override of up to a total of two bottles (224 grams) can be allowed per 28 days.

***Solaraze Gel (generic)***

1. For patients treating greater than three 5 x 5 cm actinic keratosis lesions, an override of 100 grams per 28 days can be allowed for each additional three 5 x 5 sites being treated.

***Voltaren 1% gel (generic)***

1. For patients treating multiple joints requiring greater than 16 grams per day, an override of up to 10 tubes (1000 grams) per 28 days.

**EXCLUSIONS**

1. No overrides are recommended for use in compounded formulations.
2. No overrides are recommended for any other indications not listed in the prescribing information.

**REFERENCES**

1. Pennsaid® 2% solution [prescribing information]. Deerfield, IL: Horizon Pharma USA, Inc. December 2019.
2. Diclofenac 1.5% solution [prescribing information]. Hawthorne, NY; Taro Pharmaceuticlas U.S.A., July 2019
3. [omitted]
4. Solaraze® 3% gel [prescribing information]. Melville, NY: Fougera Pharmaceuticals, Inc. May 2016.
5. Voltaren® 1% gel [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc. February 2018.