

**Plaquverazon®**  
Calcipotriol 50 microgram + betamethasone 0.5mg  
Topical Ointment

**Composition:**

Each one gram contains:

**Active Ingredients:**

\_Calcipotriol as hydrate 52.2 mcg equivalent to 50 mcg calcipotriol.  
Betamethasone dipropionate 0.643 mg equivalent to 0.05 % (0.5mg  
betamethasone.)

**Inactive Ingredients:**

White bees wax, hard paraffin, cetostearyl alcohol, propylene glycol, white soft paraffin.

**Pharmacological Action:**

Plaquverazon® ointment contains **calcipotriol** (a substance like Vitamin D) and **betamethasone** (a steroid). Calcipotriol helps to bring the rate of skin cell growth back to normal. Betamethasone is a corticosteroid, which acts to reduce inflammation.

Plaquverazon® ointment is used on the skin to treat a certain type of psoriasis called **plaque psoriasis** (psoriasis vulgaris.) Psoriasis is caused by skin cells being produced too quickly. This causes redness, scaling and thickness of skin. Plaquverazon® treats the symptoms of psoriasis and helps bring the rate at which skin cells are produced back to normal.

**Pharmacokinetics:**

The systemic absorption of calcipotriol and betamethasone from Plaquverazon® is less than 1% of the dose (2.5 g) when applied to normal skin for 12 hours. Application to psoriasis plaques increases the absorption of topical corticosteroids. Absorption through damaged skin is approx 24%. Protein binding is approx 64%. The formation of a depot in the skin elimination after dermal application is in order of days. Betamethasone is metabolised especially in the liver, but also in the kidneys to glucuronide and sulphate esters. Excretion takes place by urine and faeces.

**Indications:**

Plaquverazon® is indicated for the topical treatment of psoriasis vulgaris.

**Dosage:**

Use the ointment **once a day**. It may be more convenient to use the ointment in the evening.

The normal initial treatment period is **4** weeks but the doctor may decide on a different treatment period.

**Administration:**

- Use only on your psoriasis and do not use on skin which is not affected by psoriasis.
- Squeeze the ointment onto a clean finger.
- Rub **gently** into your skin to cover the area affected by psoriasis until most of the ointment has disappeared into the skin.
  - Do not worry if some ointment accidentally gets on normal skin near psoriasis, but wipe it off if it spreads too far.
- Wash your hands immediately after use (unless you are using the ointment to treat your hands); this will avoid accidentally spreading ointment to other parts of your body (especially the face, mouth and eyes).

**Warnings:**

Do not use more than 15 grams in one day or 100 grams in one week or on more

than 30% of your body.

### **Precautions:**

- Avoid concurrent treatment with other medicines that contain corticosteroids as you may get side-effects.
- Diabetes mellitus, blood sugar/glucose level may be affected by the steroids. If the skin becomes infected, stop treatment.
- Do not use on large areas of damaged skin or skin folds (groin, armpits, under breasts) as it increases the absorption of the steroid.
- Do not use on the face or genitals (sex organs) as they are very sensitive to steroids. If there is a risk your psoriasis will get worse or 'flare up' when steroids are stopped suddenly, please contact your doctor if you have used this medicine for a long time and plan to stop.
- Avoid excessive exposure to sun light and sun lamps.
- If used with UV treatment, apply at least 2 hours before UV exposure.

### **Contraindications:**

- **Plaquverazon®** is contraindicated in those patients with a history of hypersensitivity to any of the components in the preparation.
- They should be avoided by those with calcium metabolism disorder.
- Used with caution in generalized pustular or erythrodermic exfoliative psoriasis (enhanced risk of hypercalcemia).

### **Pregnancy & Lactation:**

**Do not use Plaquverazon®** if you are pregnant (or might be pregnant) or you are breast-feeding, **unless you have discussed it with your doctor first.** If your doctor has agreed that you can breast-feed, take care and do not apply Plaquverazon® to the breast.

### **Side Effects:**

Like all medicines, Plaquverazon® can cause side effects, but not everybody gets them. Photosensitivity and rarely facial or perioral dermatitis and skin atrophy may occur. Local skin reactions (itching, erythma, burning, parasthesia, dermatitis) are not uncommon.

### **Storage:**

**Keep out of reach of children.**

**Store at a temperature not exceeding 30°C.**

### **Package:**

Carton box containing 15 or 30 gm in an aluminum tube.

### **Information for Patients:**

Patients using topical corticosteroids should review the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only.
2. Patients should report to their physician any signs of local adverse reactions.
3. This medication should not be used on the face, eyes, underarms or groin areas, unless directed by the physician.
4. Other corticosteroid-containing products should not be used with plaquverazon® ointment without first consulting with the physician.

Produced by Medizen Pharmaceutical Industries