

# BEZONE OINTMENT 0.1% W/W

Betamethasone 0.1% w/w

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## What Bezone Ointment 0.1% w/w is used for

Bezone Ointment 0.1% w/w contains the active ingredient betamethasone valerate, which is a type of medicine called a topical corticosteroid.

Betamethasone Valerate is a potent corticosteroid that can be applied topically to treat eczema including atopic, infantile, and discoid eczemas. It is also used for Prurigo nodularis, Psoriasis (excluding widespread plaque psoriasis) and Neurodermatoses including lichen simplex, lichen planus and Seborrhoeic dermatitis. Other indication includes contact sensitivity reactions, Discoid lupus erythematosus, an adjunct to systemic steroid therapy in generalised erythroderma, insect bite reactions and prickly heat.

## How Bezone Ointment 0.1% w/w works

Betamethasone Valerate is a corticosteroids and is used for its anti-inflammatory, antipruritic (relieve itching) and vasoconstrictive (constriction of blood vessel) actions on the skin.

## Before you use Bezone Ointment 0.1% w/w

### - When you must not use it

- ◆ If you are allergic (hypersensitive) to betamethasone valerate or any of

the other ingredients of Bezone Ointment 0.1% w/w.

- ◆ If you have primary skin infection, skin atrophy, pre-existing acne vulgaris, perioral dermatitis
- ◆ If you have primary cutaneous viral infection (e.g Herpes simplex, chicken pox)
- ◆ If you have tuberculosis of the skin, vaccinia, varicella and rosacea.

### - Before you start to use it

You must tell your doctor or pharmacist if:

- ◆ You are treating a child or infant, as long term use in children and infant is not recommended.
- ◆ You are applying the ointment on the face.
- ◆ You are applying the ointment on eyes, in the ano-genital region and on broken or infected skin including cold sores, acne and athlete's foot.
- ◆ You are applying the ointment on large areas of the body for a long period of time.
- ◆ You are pregnant or plan to become pregnant or breast-feeding.

### - Taking other medicines

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

### Pregnancy and Breast-feeding

- ◆ Safe use during pregnancy has not been established. Topical corticosteroids should only be used when the potential benefits justify the possible risks to the fetus.
- ◆ Used with caution in nursing women.

## How to use Bezone Ointment 0.1% w/w

Gently rub the correct amount of ointment into the skin until it has all disappeared. Your doctor will decide the right amount of Bezone Ointment 0.1% w/w for you to use and will tell you how long to use your medicine. Follow your doctor's instructions exactly.

### - How much to use it

*Adults, elderly and children over 1 year*

The ointment is applied to the affected area once or twice daily.

### *Children*

Betamethasone valerate is contraindicated in children less than one year of age.

### - When to use it

Use as directed by your doctor or pharmacist

### - How long to use it

Duration of therapy varies and depends upon the extent and location of the disease.

### - If you forget to use it

If you forget to use your ointment, apply the ointment as soon as possible as you remember, unless it is nearly time to apply the next dose.

### - If you use too much (Overdose)

Seek emergency medical attention if you think you have used too much of this medicine, or if anyone has accidentally swallow it. An overdose of betamethasone valerate topical may cause adrenal atrophy and show signs of Cushing's syndrome, with moon face, striae, acne and buffalo hump. Symptomatic treatment should be given and the drug should be slowly withdrawn where possible.

**While you are using Bezone Ointment 0.1% w/w**

**- Things you must do**

If you do become pregnant whilst using Bezone Ointment 0.1% w/w, tell your doctor.

The medicine should be applied thinly and evenly to the affected area(s) as directed by your pharmacist.

**- Things you must not do**

- ◆ Do not give Bezone Ointment 0.1% w/w to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Bezone Ointment 0.1% w/w for you and your condition.
- ◆ Do not apply this ointment to the face, or to areas around the genitals unless instructed by the doctor.
- ◆ Do not apply this ointment to broken or infected skin.

**- Things to be careful of**

- ◆ The ointment is for external use only.
- ◆ Avoid getting the ointment in the eyes, or in contact with the inside of the mouth or nose. Rinse with cold water if accidental contact occurs.
- ◆ Wash your hands thoroughly after applying this ointment, unless the hands are the area being treated.

**Side Effects**

Like all medicines, Bezone Ointment 0.1% w/w can have side effects, although not everybody gets them.

Stop using Bezone Ointment and contact your doctor at once if skin irritation or contact dermatitis occurs.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Local side effects includes burning, irritation, dryness, folliculitis (infection in the hair follicles), hypertrichosis (excessive hair growth over the body), hypopigmentation (loss of skin color), increased hair growth, thinning of skin and perioral dermatitis (facial rash around the mouth) in young women.
- Maceration of the skin (softening and breaking down of skin),

secondary infection, striae (linear mark) and miliria (itchy rashes) may occur more frequently with occlusive dressings.

- Systemic side effects associated with steroid use such as hyperglycemia (excess sugar in blood), glycosuria (excess sugar in urine), features of hypercorticism (excessive production of adrenal cortical hormones in the body) and hypothalamic-pituitary-adrenal (HPA) axis suppression may occur.
- Treatment of psoriasis (skin disease marked by red and itchy patches) may provoke pustular form of the diseases (uncommon form of the disease with appearance of pus-filled lesions).

If you feel unwell or have any unusual discomfort you do not understand, contact your doctor as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→Reporting)

**Storage and Disposal of Bezone Ointment 0.1% w/w**

**- Storage**

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package and in a dry place.

Protect from light.

Do not use Bezone Ointment 0.1% w/w if you notice visible signs of deterioration.

**Keep out of the reach and sight of children.**

**- Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

**- What it looks like**

A semi-transparent, unctuous, off-white ointment.

It is supplied in 15g collapsible aluminium tubes.

**- Ingredients**

- Active ingredient

Each gram contains Betamethasone Valerate equivalent to 1.0mg Betamethasone

- Inactive ingredients

The other ingredients are Propylene Glycol, Mineral Oil Heavy and White Petrolatum.

**- MAL number:**

**Manufacturer and Product Registration Holder**

Malaysian Pharmaceutical Industries Sdn. Bhd.

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Penang, Malaysia.

**Date of Revision**

09/08/2016