1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PERSIVATE OINTMENT 5 mg/5 g

betamethasone valerate

PERSIVATE 5 mg/5 g cream

betamethasone valerate

Read all of this leaflet carefully before you start using PERSIVATE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PERSIVATE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PERSIVATE is and what it is used for
2. What you need to know before you use PERSIVATE
3. How to use PERSIVATE
4. Possible side effects
5. How to store PERSIVATE
6. Contents of the pack and other information

1. What PERSIVATE is and what it is used for

PERSIVATE belongs to a group of medicines called steroids that reduce swelling and irritation.

PERSIVATE is used to help reduce the redness and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis.

2. What you need to know before you use PERSIVATE

Do not use PERSIVATE:

- If you are hypersensitive (allergic) to betamethasone or any of the other ingredients of PERSIVATE (listed in section 6),
- if you have a virus that causes contagious sores, most often around the mouth or on the genitals (herpes simplex, vaccinia or varicella),
- if you have a skin infection caused by fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo),
- if you suffer from tuberculosis (TB) of the skin or varicose ulcers that form on the skin near varicose veins,
- if you are pregnant,
- on children below 1 year of age,
- long term use of PERSIVATE is not recommended if you have diabetes (high blood sugar) or tuberculosis (TB).

You should not use PERSIVATE to treat any of the following skin problems, it could make them worse:

- infected skin (unless the infection is being treated with an anti-infective medicine at the same time),
- severe flushing of skin on and around your nose (rosacea),

- acne (acne vulgaris),
- itchy skin which is not inflamed (pruritus without inflammation),
- itching around your back passage or private parts (perianal and genital pruritus),
- spotty red rash around your mouth (perioral dermatitis),
- infection of the skin caused by a type of bacteria called tuberculosis,
- leg ulcers.

Warnings and precautions

Take special care with PERSIVATE:

- If you have previously had an allergic reaction with another steroid type cream or ointment,
- if you use PERSIVATE for long periods of time or apply it to large areas you may develop hypercortisolism, a condition where the body produces too much cortisol called Cushing's syndrome, this is more severe in children,
- if you are applying the cream under an airtight dressing, these dressings make it easier for the active ingredient to pass through the skin, it is possible to accidentally end up using too much,
- if you are applying PERSIVATE to the face,
- if you have psoriasis, it could aggravate it so your doctor will need to see you more often,
- if you are applying the cream or ointment on broken skin or within the skin folds,
- if you are applying PERSIVATE near your eyes or on your eyelids, as cataracts or glaucoma may result if PERSIVATE repeatedly enters the eye,
- if you have an infection of the skin as this will need to be treated,
- if you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts,

- if you use PERSIVATE for a long time this can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). Symptoms may include intense redness, stinging and burning that can spread beyond the initial treatment area.

Children

There is no experience with PERSIVATE in infants and young children.

Duration of use should be limited to five days in children under 12 years of age.

Other medicines and PERSIVATE

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Ritonavir, medicines used to treat human immunodeficiency virus (HIV) infection,
- Itraconazole, medicines used to treat fungal infections.

Pregnancy, breastfeeding and fertility

You should not use PERSIVATE if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Driving and using machines

PERSIVATE can cause blurred vision which is likely to affect your ability to drive or use machines.

It is not always possible to predict to what extent PERSIVATE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PERSIVATE affects you (see section 4).

PERSIVATE contains chlorocresol

Chlorocresol can cause allergic reactions. PERSIVATE should be discontinued if this occurs.

3. How to use PERSIVATE

Do not share medicines prescribed for you with any other person.

Always use PERSIVATE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of PERSIVATE is:

FOR EXTERNAL USE ONLY.

PERSIVATE OINTMENT: Apply to the affected areas 2 or 3 times daily by gentle rubbing or use with occlusive dressings.

PERSIVATE cream: Apply to the affected areas 2 to 3 times daily by gently rubbing.

PERSIVATE should not be used on infants and young children.

Your doctor will tell you how long your treatment with PERSIVATE will last. Do not stop treatment early or abruptly as abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (a condition where your body does not produce adequate

cortisol). If you have the impression that the effect of PERSIVATE is too strong or too weak, tell your doctor or pharmacist.

If you use more PERSIVATE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use PERSIVATE

Do not apply a double dose to make up for forgotten individual doses.

If you have missed a dose of PERSIVATE, apply the dose that you have missed as soon as you remember. However, if it is nearly time for the next application, skip the missed application. If you have forgotten to apply several applications, contact your doctor without delay.

If you stop using PERSIVATE

Long term continuous or inappropriate use of PERSIVATE can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). Symptoms may include intense redness, stinging and burning that can spread beyond the initial treatment area.

4. Possible side effects

PERSIVATE can have side effects.

Not all side effects reported for PERSIVATE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using PERSIVATE, please consult your healthcare provider for advice.

If any of the following happens, stop using PERSIVATE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PERSIVATE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you have psoriasis and get raised bumps with pus under the skin, this can happen very rarely during or after treatment and is known as pustular psoriasis and urticaria,
- a build up of pressure around the brain (benign intracranial hypertension).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- A feeling of burning, pain, or itching where the PERSIVATE is applied (pruritus, local skin burning /skin pain).

Less frequent side effects:

- An increased risk of infection (opportunistic infection),

- an allergic skin reaction, skin irritation where the PERSIVATE is applied (hypersensitivity, application site irritation/pain, allergic contact dermatitis /dermatitis),
- rash, itchy bumpy skin or redness of the skin (generalised rash, erythema),
- a decrease in the level of the hormone cortisol in your blood (Hypothalamic-pituitary adrenal (HPA) axis suppression Cushingoid features),
- delayed weight gain/growth retardation in children,
- bones can become thin, weak and break easily (osteoporosis),
- increased pressure in eye (glaucoma),
- increased blood sugar levels or sugar in the urine (hyperglycaemia/glucosuria),
- cloudy lens in the eye (cataract),
- high blood pressure (hypertension),
- increased weight/obesity, rounding of the face,
- an increase or reduction in hair growth or hair loss (alopecia, trichorrhexis, hypertrichosis),
- thinning and dryness of your skin and it may also damage or wrinkle more easily (skin atrophy, skin wrinkling, skin dryness),
- stretch marks may develop (striae),
- dilated blood vessels under the surface of your skin may become more noticeable (telangiectasias),
- changes in skin colour (pigmentation, hypopigmentation).

Side effects with an unknown frequency:

- Blurred vision,
- steroid withdrawal reaction, if used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features:

redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of PERSIVATE.

5. How to store PERSIVATE

Store all medicines out of reach of children.

Store in an airtight container at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PERSIVATE contains

The active substance is 5 mg betamethasone valerate per 5 g cream/ointment.

PERSIVATE OINTMENT

The other ingredients are beeswax white, cholesterol, propylene glycol, stearyl alcohol, white soft paraffin.

PERSIVATE cream

The other ingredients are cetyl alcohol, chlorocresol, citric acid monohydrate (for pH adjustment), disodium hydrogen phosphate (for pH adjustment), emulsifying wax, liquid paraffin, propylene glycol, purified water.

Preservative:

Chlorocresol 1 % *m/m*

What PERSIVATE looks like and contents of the pack

PERSIVATE OINTMENT is a soft, smooth, translucent whitish ointment.

PERSIVATE cream is a soft, smooth, homogenous, white cream.

PERSIVATE OINTMENT:

15 g is packed in an aluminium collapsible tube, sealed with a white, self-piercing, high density polyethylene screw-cap, and placed in a unit cardboard carton together with a leaflet.

500 g is packed into a white round high density polyethylene jar sealed with a white, polypropylene screw-cap.

PERSIVATE cream:

15 g is packed in an aluminium collapsible tube, sealed with a white, self-piercing, high

density polyethylene screw-cap, and placed in a unit cardboard carton together with a leaflet.

500 g is packed into a white round high density polyethylene jar sealed with a white, polypropylene screw-cap.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

01 May 2024

Registration number

PERSIVATE OINTMENT: L/13.4.1/395

PERSIVATE cream: L/13.4.1/382

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana:	S2
PERSIVATE OINTMENT:	BOT0901496
PERSIVATE cream:	B9322635

Namibia:	NS2
PERSIVATE OINTMENT:	90/13.4.1/001108
PERSIVATE cream:	90/13.4.1/001109

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