

<p style="text-align: center;"><b>Patient Information</b></p> <p style="text-align: center;"><b>Betamethasone Dipropionate Ointment, USP (Augmented)</b></p> <p style="text-align: center;"><b>(bay'' ta meth' a sone dye proe' pee oh nate)</b></p>
<p><b>Important information: Betamethasone dipropionate ointment (augmented) is for use on skin only.</b> Do not use betamethasone dipropionate ointment (augmented) in your eyes, mouth, or vagina.</p>
<p><b>What is betamethasone dipropionate ointment (augmented)?</b></p> <p>Betamethasone dipropionate ointment (augmented) is a prescription corticosteroid medicine used on the skin (topical) for the relief of redness, swelling, heat, pain (inflammation) and itching, caused by certain skin problems in people 13 years of age and older.</p> <ul style="list-style-type: none"> <li>• Betamethasone dipropionate ointment (augmented) should not be used in children under 13 years of age.</li> </ul>
<p><b>Do not use betamethasone dipropionate ointment (augmented) if you</b> are allergic to betamethasone dipropionate or any of the ingredients in betamethasone dipropionate</p>

<p>ointment (augmented). See the end of this leaflet for a complete list of ingredients in betamethasone dipropionate ointment (augmented).</p> <p><b>Before using betamethasone dipropionate ointment (augmented), tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>• have had irritation or other skin reaction to a steroid medicine in the past.</li> <li>• have thinning of the skin (atrophy) at the treatment site.</li> <li>• have diabetes.</li> <li>• have adrenal gland problems.</li> <li>• have liver problems.</li> <li>• have cataracts or glaucoma.</li> <li>• are pregnant or plan to become pregnant. It is not known if betamethasone dipropionate ointment (augmented) will harm your unborn baby. If you use betamethasone dipropionate ointment (augmented) during pregnancy, use betamethasone dipropionate ointment (augmented) on the smallest area of the skin and for the shortest time needed.</li> <li>• are breastfeeding or plan to breastfeed. It is not known if betamethasone dipropionate ointment (augmented) passes into your breast milk. Breastfeeding women should use betamethasone dipropionate ointment (augmented) on the smallest area of skin and for the shortest time needed while breastfeeding. Do not apply betamethasone dipropionate ointment (augmented) directly to the nipple and areola to avoid contact with your baby.</li> </ul> <p><b>Tell your healthcare provider about all the medicines you take</b>, including prescription and over-the-counter medicines, vitamins, and herbal supplements.</p> <p><b>Especially</b> tell your healthcare provider if you take other corticosteroid medicines by mouth or injection or use other products on your skin or scalp that contain corticosteroids.</p> <p>Do not use other products containing a steroid medicine with betamethasone dipropionate ointment (augmented) without talking to your healthcare provider first.</p> <p><b>How should I use betamethasone dipropionate ointment (augmented)?</b></p> <ul style="list-style-type: none"> <li>• Use betamethasone dipropionate ointment (augmented) exactly as your healthcare provider tells you to use it.</li> <li>• Apply a thin layer (film) of betamethasone dipropionate ointment (augmented) to the affected skin area 1 or 2 times each day. Do not use more than 50 grams of betamethasone dipropionate ointment (augmented) in 1 week.</li> <li>• Do not use betamethasone dipropionate ointment (augmented) for longer than 2 weeks in a row unless your healthcare provider tells you to.</li> <li>• Tell your healthcare provider if the treated skin area does not get better after 2 weeks of treatment with betamethasone dipropionate ointment (augmented).</li> <li>• Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.</li> <li>• Betamethasone dipropionate ointment (augmented) should not be used to treat diaper rash or redness.</li> <li>• Avoid using betamethasone dipropionate ointment (augmented) on the face, groin, or underarms (armpits) or if thinning of the skin (atrophy) is present at the treatment site.</li> <li>• Wash your hands after applying betamethasone dipropionate ointment (augmented) unless you are using the medicine to treat your hands.</li> </ul> <p><b>What are the possible side effects of betamethasone dipropionate ointment (augmented)?</b>  <b>Betamethasone dipropionate ointment (augmented) may cause serious side effects, including:</b></p> <ul style="list-style-type: none"> <li>• <b>Betamethasone dipropionate ointment (augmented) can pass through your skin.</b> Too much betamethasone dipropionate ointment (augmented) passing through your skin can cause your adrenal glands to stop working properly. Your healthcare provider may do blood tests to check for adrenal gland problems.</li> <li>• <b>Cushing's syndrome</b>, a condition that happens when your body is exposed to too much of the hormone cortisol.</li> <li>• <b>High blood sugar</b> (hyperglycemia).</li> <li>• <b>Effects on growth and weight in children.</b></li> <li>• <b>Vision problems.</b> Topical corticosteroids including betamethasone dipropionate ointment (augmented) may increase your chance of developing cataract(s) and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with betamethasone dipropionate ointment (augmented).</li> <li>• <b>Skin problems.</b> Skin problems including, allergic reactions (contact dermatitis) may happen during treatment with betamethasone dipropionate ointment (augmented). Stop using betamethasone dipropionate ointment (augmented) and tell your healthcare provider if you develop any skin reactions or have problems with healing during treatment with betamethasone dipropionate ointment (augmented).</li> </ul> <p>Your healthcare provider may do certain blood tests to check for side effects.</p> <p><b>The most common side effects of betamethasone dipropionate ointment (augmented) include</b> redness of the skin, inflamed hair follicles, itching and blistering.</p> <p>These are not all of the possible side effects of betamethasone dipropionate ointment (augmented).</p> <p>Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p> <p><b>How should I store betamethasone dipropionate ointment (augmented)?</b></p> <ul style="list-style-type: none"> <li>• Store betamethasone dipropionate ointment (augmented) at room temperature between 68°F to 77°F (20°C to 25°C).</li> <li>• <b>Keep betamethasone dipropionate ointment (augmented) and all medicines out of the reach of children.</b></li> </ul> <p><b>General information about the safe and effective use of betamethasone dipropionate ointment (augmented).</b>  Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use betamethasone dipropionate ointment (augmented) for a condition for which it was not prescribed. Do not give betamethasone dipropionate ointment (augmented) to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about betamethasone dipropionate ointment (augmented) that is written for health professionals.</p> <p><b>What are the ingredients in betamethasone dipropionate ointment (augmented)?</b></p> <p><b>Active ingredient:</b> betamethasone dipropionate</p> <p><b>Inactive ingredients:</b> propylene glycol, propylene glycol monopalmitostearate, white petrolatum, and white wax.</p> <p>Manufactured for:  <b>Burel Pharmaceuticals, LLC</b>  Mason, OH 45040 USA</p> <p>Manufactured by:  <b>APL Health Care Limited, Unit-III</b>  SEZ, Mahabubnagar (Dt)-509302, India.</p> <p>M.L.No.: TS/MBR/2020-58039</p>
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This Patient Information has been approved by the U.S. Food and Drug Administration.

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