Betamethasone Valerate Foam, 0.12%

DESCRIPTION

Betamethasone Valerate Foam, 0.12% contains betamethasone valerate, USP (a synthetic corticosteroid), for topical dermatologic use. This corticosteroid constitutes a class of primary synthetic steroidal compounds used topically as anti-inflammatory agents. Betamethasone Valerate Foam, 0.12% is a foam that effectively delivers a range of corticosteroids to the skin. Betamethasone Valerate is a white to practically white, odorless crystalline powder, and is virtually insoluble in water, but soluble in alcohol and dimethyl sulfoxide.

PHARMACOTHERAPY

Betamethasone Valerate foam is a white, practically white, amorphous crystalline powder, and is virtually insoluble in water, but soluble in alcohol and dimethyl sulfoxide.

Betamethasone Valerate foam is a medium potency topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses of the scalp.

INDICATIONS AND USAGE

Betamethasone Valerate foam, 0.12% is a medium potency topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp.

SIDE EFFECTS

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary in the face that corticosteroids are absorbed following transdermal delivery. Phases of pharmacodynamic endpoints in relation to systemic corticosteroids are not currently under development.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids has caused reversible hypothalamic-pituitary-adrenal (HPA) axis suppression in the adult population. It is not known whether systemic absorption of topical corticosteroids also occurs in children.

Pregnancy: Topical corticosteroids are generally contraindicated during pregnancy unless the potential benefit justifies the potential risk to the fetus. Betamethasone Valerate foam should not be used on pregnant women except in special situations, such as congenital defects or scars.

General: Systemic absorption of topical corticosteroids has caused reversible hypothalamic-pituitary-adrenal (HPA) axis suppression in the adult population. It is not known whether systemic absorption of topical corticosteroids also occurs in children.

Pregnancy: Topical corticosteroids are generally contraindicated during pregnancy unless the potential benefit justifies the potential risk to the fetus. Betamethasone Valerate foam should not be used on pregnant women except in special situations, such as congenital defects or scars.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.

Pseudoephedrine, propylcycline, or pseudoephedrine are not to be used in children or infants.
• Do not use this medication for any condition other than the one for which it was prescribed.
• Betamethasone valerate foam, 0.12% is for external use only.
• Keep the foam away from your eyes, as it will sting. If the foam gets into your eyes, rinse well with cold water. If the stinging continues, contact your doctor immediately.

WHAT YOU SHOULD KNOW ABOUT BETAMETHASONE VALERATE FOAM, 0.12%:
• What to do if you miss an application
If you forget to apply betamethasone valerate foam, 0.12% at the scheduled time, use it as soon as you remember, and then go back to your regular schedule. If you remember at or about the time of your next daily application, apply the foam and continue with your normal application schedule. If you miss several doses, tell your doctor at your next appointment.

About side effects
As with all medications, there may be side effects.

The most frequent side effects associated with the use of betamethasone valerate foam, 0.12% include burning, stinging, or itching at the site of application. These side effects typically disappear after short application. Let your doctor know if you notice any of the following:
• Any unusual effects that you do not understand
• Affected areas that do not seem to be healing after several weeks of using the foam.

Important safety notes
• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hauppauge, NY 11788

Revised: September 2016 20740-0916-1 88

20740-0916-1 88

Important safety notes

• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hauppauge, NY 11788

Revised: September 2016 20740-0916-1 88

Important safety notes

• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hauppauge, NY 11788

Revised: September 2016 20740-0916-1 88

Important safety notes

• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hauppauge, NY 11788

Revised: September 2016 20740-0916-1 88

Important safety notes

• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hauppauge, NY 11788

Revised: September 2016 20740-0916-1 88

Important safety notes

• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.

Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel, 2624761
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hauppauge, NY 11788

Revised: September 2016 20740-0916-1 88

Important safety notes

• The treated areas should not be bandaged or covered unless directed by your doctor.
• Keep this and all medicines out of the reach of children.
• Store the can at controlled room temperature 68°F to 77°F (20°C to 25°C) and protect it from direct sunlight, as this is a preservative container.
• Keep away from and do not spray near fire, open flame, or direct heat—this product is flammable. Do not smoke while using or holding the can. Keep the can away from all sources of ignition. Do not pierce or burn the can, and never throw the can in a fire, even if empty.
• When you have finished your treatment, dispose of the can safely.
• Do not use the foam after the expiration date shown on the can.
• Do not give betamethasone valerate foam, 0.12% to anyone else. Your doctor has prescribed this medicine for your use only.