AQUAX-H- hydrocortisone butyrate cream
Pella Pharmaceuticals Co. ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Aquax-H

Composition

Each 1 g contains: Hydrocortisone 17-Butyrate 1 mg.
Excipients: Petrolatum, Cetearyl Alcohol, Mineral Oil, Ceteareth-20, Benzyl Alcohol, Citric Acid, Sodium Citrate, Propylparaben and Purified Water.

Properties

Aquax-H ® Cream contains a corticosteroid and quickly suppresses symptoms of certain skin conditions such as itching, redness and scaling. Corticosteroids don't generally remove the cause of the symptoms. The **Aquax-H ®** Cream base ensures that the skin condition becomes less moist.

Indications

Aquax-H ® Cream can be used for the treatment of superficial skin conditions where itching, redness and scaling are often present.

Contraindications

Do not use Aquax-H ® Cream

- If your skin condition is caused by infections with bacteria, viruses, fungi, yeasts or parasites as these could either be made worse or become unnoticeable.
- In acne even if the skin is red.
- For wounds or scaly skin (ichthyosis).
- If your skin condition is the result of earlier treatment with corticosteroids such as inflammation of the skin around the mouth or thin skin possibly with streaks and vulnerable blood vessels.
- For childhood rash on the foot sole.
- If you are hypersensitive to hydrocortisone 17-butyrate or to any of the excipients (uncommon).

Precautions

Aquax-H ®Cream contains certain excipients like Cetearyl Alcohol that in rare cases can cause hypersensitivity reactions (itching, red spots) of the skin.

Drug Interactions

Inform your doctor or pharmacist if you are using other medicines or have used them in the recent past. This also applies to medicines you have obtained without a prescription

Warnings

Be extra careful with **Aquax-H ®** Cream

- If you want to treat the facial skin, genital skin and skin folds as these areas of skin are particularly sensitive to corticosteroids.
- If you apply the cream under an occlusive bandage, to large areas of skin or are treating a child in which cases you should be under the control of your doctor.
- The **Aquax-H ®** Cream should not be introduced into the eye or applied to the eyelids.
- The application of corticosteroids for long periods in children should be avoided.
- Consult your doctor if any of the above warnings apply to you.

Pregnancy

Ask your doctor or pharmacist for advice before using a medical product. If you want to apply the cream during pregnancy then discuss this with your doctor.

Breast-feeding

Ask your doctor or pharmacist for advice before using a medical product. If you want to apply the **Aquax-H ®** during breast-feeding then discuss this with your doctor.

Driving and the use of machines

There is nothing known about **Aquax-H ®**Cream and the ability to drive or to use machines. However, no effects are to be expected.

Dosage and Administration

Apply **Aquax-H ®** Cream thinly to the affected skin area and massage lightly into the skin. Do not apply more often than 1-3 times daily unless your doctor has advised otherwise.
When your symptoms have receded, your doctor may decide that you can use the cream less often. In general, you should not use more than 1 to 2 tubes per week.
What you can expect when treatment has been stopped
The original symptoms can reappear if treatment is stopped prematurely.
Always consult you doctor or pharmacist before stopping treatment.

Overdosage

What you should do if you have used too much Aquax-H Cream
Contact you doctor or pharmacist if you have used too much **Aquax-H ®** Cream.
What you should do if you have forgotten to use Aquax-H Cream
If you have forgotten to apply it a single time just carry on as before. There is no need to compensate for a missed application.

Side Effects

Aquax-H ® Cream can cause side effects just like all medicines.
You could sometimes have a burning or prickly feeling at the site of application but this is mostly not serious and disappears on its own.
If you have used it for prolonged periods or under an occlusive bandage, you could get a rash, pimples or the formation of pus. The skin could become discolored or thin, sometimes with stripes.
Consult your doctor if you have any of these side effects.
Also consult your doctor or pharmacist if you either have any side effects not mentioned in this leaflet or any others that you think might be serious.

Storage

Store below 25 °C
Do not store in a refrigerator or freezer.

How Supplied

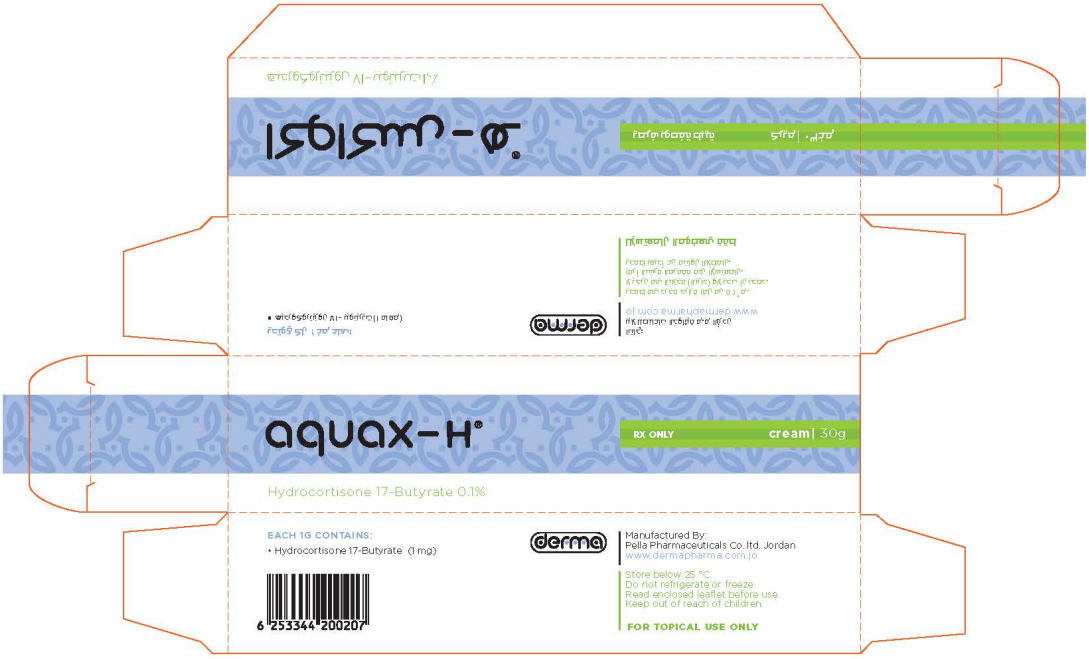
30 g packs

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children.

Primary Package

Secondary Package



AQUAX-H

hydrocortisone butyrate cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:82160-127
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE BUTYRATE (UNII: 05RMF7YPWN) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE BUTYRATE	30 mg in 30 g

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-127-01	1 in 1 CARTON	03/16/2015	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/16/2015	

Labeler - Pella Pharmaceuticals Co. ltd (562370925)

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