METAPHARMACEUTICAL

TECHNICAL DATA SHEET

1083-TDS-ENG-2025

HIDROCORTISONA ACETATO (EUR. PH.)		
DESCRIPTION DCI: HYDROCORTISONE ACETATE	DESCRIPTION DOE: HIDROCORTISONA ACETATO	
CAS Nº: 50-03-3	EC Nº: 200-004-4	AEMPS CODE: 54AC
MOL. WEIGHT: 404,50	MOL. FORMULA: C23H32O6	ARTICLE CODE: 1083

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Solubility	Practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride
Identification A	Complies
Identification B	Complies
Specific optical rotation	+158 / +167
Related substances	
Impurity C	=< 0.6 %
Impurity A	=< 0.5 %
Impurity B	=< 0.3 %
Impurity D	=< 0.3 %
Impurity E	=< 0.3 %
Impurity G	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total of impurities	=< 1.5 %
Loss on drying	=< 0.5 %
Assay	97.0 - 102.0 %

COMPLIES WITH

Euroepan Pharmacopoeia 11.0

STORAGE

Keep the containers in a cool and well-ventilated place.

REMARKS

Hydrocortisone Acetate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

HYDROCORTISONE is the main glucocorticoid secreted by the adrenal cortex, with anti-inflammatory, antiallergic and antipruritic activity. It is a corticoid with weak action (type IV). Orally, hydrocortisone acetate is transformed into

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869

HIDROCORTISONA ACETATO (EUR. PH.)		
DESCRIPTION DCI: HYDROCORTISONE ACETATE	DESCRIPTION DOE: HIDROCORTISONA ACETATO	
CAS Nº: 50-03-3	EC Nº: 200-004-4	AEMPS CODE: 54AC
MOL. WEIGHT: 404,50	MOL. FORMULA: C23H32O6	ARTICLE CODE: 1083

hydrocortisone base in the organism, thus presenting the same actions. The hydrocortisone base is used orally and in conditions of the oral cavity. Both hydrocortisone base and hydrocortisone acetate can be used topically.
HYDROCORTISONE ACETATE is used ophthalmicly. Like most corticosteroids, hydrocortisone is easily absorbed in the gastrointestinal tract and in local administration areas. The maximum plasma concentration is obtained after about 60 min. approximately. The half-life is around 1 h and 40 min. It is metabolized in the liver and other tissues to other molecules such as tetrahydrocortisone and tetrahydrocortisol. They are excreted in the urine, especially in the form of glucuronides. It is used orally in substitution treatment in acute or chronic adrenocortical insufficiency, in allergic states refractory to other therapies (such as allergic rhinitis, drug hypersensitivity, serum sickness, and asthma), in cases of congenital adrenal hyperplasia, hypercalcemia associated with cancer, thyroiditis, severe allergic and inflammatory ophthalmic conditions, respiratory disorders such as symptomatic sarcoidosis, berylliosis, aspiration pneumonitis and Loffer syndrome refractory to other treatments, in rheumatic disorders as an adjuvant in acute episodes of psoriatic arthritis, bursitis, gouty arthritis , etc ..., nephrotic syndrome, ulcerative colitis, and regional enteritis.
Topically they are used in the form of ointments, creams, lotions and ointments, in inflammatory or allergic skin diseases, such as contact dermatitis, atopic and seborrheic, inflammatory dermatosis, eczema, granuloma annulare, cheilitis, lichen planus, discoid lupus erythematosus, localized neurodermatitis, anogenital pruritus, xerosis, psoriasis, and insect bites. It is also used in cases of canker sores, and in general, oral inflammatory or ulcerative lesions, in preparations with oral adhesive excipient. Hydrocortisone acetate is applied ophthalmicly in the form of eye drops and ointments in cases of inflammatory and allergic conditions of the anterior segment of the eye, such as spring and allergic conjunctivitis, episcleritis, iridocyclitis, uveitis, non-herpetic keratitis, corneal lesions, allergic keratoconjunctivitis and keratitis. viral herpes zoster After intramuscular injection, absorption of sodium phosphate esters is rapid. Hydrocortisone can be administered intravenously, by slow injection or infusion, in the form of a water-soluble derivative such as sodium hydrocortisone phosphate.

Dosage
Topical route, at 0.1 - 5%.
Ophthalmic route, 0.5 - 2.5%.

Side effects
Its administration for short periods of time is almost completely free of adverse reactions. Orally, with therapeutic dosages in prolonged treatments may appear an increased susceptibility to infections, psychic disorders, osteoporosis, gastric ulcer, electrolyte balance disturbances, hyperglycemia, dermal striae, collagen loss, and with high doses, Cushing. Topically, for long periods of time, it can produce atrophic alterations of the skin, loss of collagen, skin striate, hypertrichosis, telangiectasia and pigmentary disorders. In the case of hydrocortisone acetate, when used ophthalmicly, there may be a slight increase in intraocular pressure, burning or itching, lacrimation, drooping eyelids and dilated pupils. Very rarely subcapsular posterior cataract can be formed, as well as suppressing the immune response in ocular tissues, thereby increasing the possibility of secondary infections and delayed healing.

Contraindications
Hypersensitivity Viral, bacterial, or fungal infections, as the only treatment.

Precautions
They are contraindicated topically in infections of viral origin (chicken pox, herpes simplex and herpes zoster), tuberculosis and lytic processes in the treatment area. Do not apply in occlusive bandage over large areas and eroded skin, as there is the possibility of systemic side effects. In pregnancy, should not be used in large doses, large areas or prolonged time. In children, avoid the administration of high dosages and in large areas of the skin, given the risk of adrenal suppression and growth retardation after systemic absorption. Gradual suspension in prolonged therapies is recommended. A sudden suspension could cause a regrowth of the injuries. In long and oral therapies, hydrocortisone base should be used with

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869

HIDROCORTISONA ACETATO (EUR. PH.)		
DESCRIPTION DCI: HYDROCORTISONE ACETATE	DESCRIPTION DOE: HIDROCORTISONA ACETATO	
CAS Nº: 50-03-3	EC Nº: 200-004-4	AEMPS CODE: 54AC
MOL. WEIGHT: 404,50	MOL. FORMULA: C23H32O6	ARTICLE CODE: 1083

caution in congestive heart failure, myasthenia gravis, peptic ulcer, gastritis, esophagitis, personality disorders, osteoporosis, ocular herpes simplex, tuberculosis, systemic fungal infections. Use under medical supervision in cases of liver or kidney failure, hypertension, hyperlipidemia, glaucoma, serious infections or with vaccines. Do not use the hydrocortisone base in eye treatments or areas near the eyes. By ophthalmic route, do not use hydrocortisone acetate in fungal eye infections, viral infections of the cornea and conjunctiva, herpetic keratitis, varicella, ocular tuberculosis and vaccination. Given the risk of increases in intraocular pressure, it should be controlled routinely.

Interactions
They occur after oral administration. It can decrease the action of oral hypoglycemic agents. Used together with potassium-sparing diuretics can potentiate hypokalemia, and with cardiac glycosides increase the incidence of arrhythmias or digitalis toxicity associated with hypokalemia. Rifampicin decreases the action of corticosteroids.

Other observations
Is photosensitive.

Compounding examples

HIDROCORTISONE ACETATE and urea cream
HYDROCORTISONE ACETATE - **1 %**
Urea - **5 %**
Emulsion O / W c.s.p. - **50 g**

Modus operandi: The emulsion can be prepared with Neo PCL O / W. In the aqueous phase the urea is dissolved hot. Moisten the HYDROCORTISONE ACETATE in mortar with a little propylene glycol. Add the cream little by little, homogenizing well with the pistil.

HIDROCORTISONE ACETATO cream
HYDROCORTISONE ACETATE - **1 g**
Lanolin anhydrous **- 9 g**
Filament Vaseline - 90 g

Modus operandi: Make the mixture of vaseline and lanolin by melting them and letting them cool. Moisten the HYDROCORTISONE ACETATE in mortar with a little liquid petrolatum. Add little by little the ointment, working well with the pistil to achieve homogenization.

HIDROCORTISONA ACETATE oral suspension 10 mg/5 mL
HYDROCORTISONE ACETATE - **0.224 g**
Saccharin sodium - **0.05 g**
Rubber xantan - **0.25 g**
Raspberry aroma - **0.5 mL**
Propylene glycol - **5 mL**
Simple syrup - **50 mL**
Oral mint essence - **2 drops**
Purified water c.s.p. - **100 mL**

Modus operandi: Heat 30 ml of purified water at 70 - 75 ºC and dissolve the sodium saccharin and disperse the xanthan

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869

TECHNICAL DATA SHEET

1083-TDS-ENG-2025

HIDROCORTISONA ACETATO (EUR. PH.)		
DESCRIPTION DCI: HYDROCORTISONE ACETATE	DESCRIPTION DOE: HIDROCORTISONA ACETATO	
CAS Nº: 50-03-3	EC Nº: 200-004-4	AEMPS CODE: 54AC
MOL. WEIGHT: 404,50	MOL. FORMULA: C23H32O6	ARTICLE CODE: 1083

gum by mixing well. Moisten HYDROCORTISONE ACETATE with Propylene Glycol in mortar. Add the previous solution little by little and mixing well. Add the oral mint essence and the raspberry aroma. Transfer to a test tube and make up to 100 ml with simple Syrup. The pH of greatest stability is 4.5. Conservation: 14 days refrigerated.

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869