SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CORTENE 2 mg, dispersible tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Betamethasone..... 2.00 mg
For a dispersible tablet.
Excipients with known effects: aspartame
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dispersible tablet .

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Conditions or diseases

Collagenoses-connectives

Exacerbations of systemic diseases, including: systemic lupus erythematosus, vasculitis, polymyositis, visceral sarcoidosis.

Dermatological

a-Severe autoimmune bullous dermatoses -, in particular pemphigus and bullous pemphigoid.
b-Severe forms of infantile hemangiomas.
c-Certain forms of flat lichen.
d-Certain acute urticarias.
e-Severe forms of neutrophilic dermatoses.

Digestives

a-Flames of ulcerative colitis and Crohn's disease.
b-Chronic active autoimmune hepatitis (with or without cirrhosis).
c-Severe acute alcoholic hepatitis, histologically proven.

Endocrine

a-Severe subacute De Quervain's thyroiditis.
b-Certain hypercalcemias.

Hematological

a-Severe immune thrombocytopenic purpuras.
b-Autoimmune hemolytic anemias.
c-In association with various chemotherapies in the treatment of malignant lymphoid hematological disorders.
d-Acquired or congenital chronic erythroblastopenias.

Infectious

a-Tuberculous pericarditis and severe forms of tuberculosis that are life-threatening.
b- *Pneumocystis carinii pneumonia* with severe hypoxia.

Neoplastics

a- -Antiemetic treatment during antineoplastic chemotherapy.
b-Edematous and inflammatory flare-up associated with antineoplastic treatments (radio and chemotherapy).

Nephrological

a-Nephrotic syndrome with minimal glomerular lesions.
b-Nephrotic syndrome of primary focal segmental hyalinoses.
c-Stage III and IV of lupus nephropathy.
d-Intrarenal granulomatous sarcoidosis.
e-Vasculitis with renal involvement.
f-Primary extracapillary glomerulonephritis.

Neurological

a-Myasthenia.
b-Cerebral edema of tumoral origin.
c-Chronic, idiopathic, inflammatory polyradiculoneuritis.
d-Infantile spasm (West syndrome)/Lennox-Gastaut syndrome.
e-Multiple sclerosis in relapse, following intravenous corticosteroid therapy.

Ophthalmologists

a-Severe anterior and posterior uveitis.
b-Edematous exophthalmos.
c-Certain optic neuropathies, following intravenous corticosteroid therapy (in this indication, the oral route as a first line of treatment is not recommended).

ENT

a-Certain serous otitis media.
b-Nasosinus polyposis.
c-Certain acute or chronic sinusitis.
d-Seasonal allergic rhinitis in short course of treatment.
e-Acute stridulous laryngitis (subglottic laryngitis) in children.

Respiratory

a-Persistent asthma, preferably in short courses of treatment in case of failure of treatment by inhaled route at high doses.
b-Exacerbations of asthma, in particular severe acute asthma.
c-Chronic obstructive bronchopneumopathy in evaluation of the reversibility of the obstructive syndrome.
d-Progressive sarcoidosis.
e-Diffuse interstitial pulmonary fibrosis.

Rheumatological

a-Rheumatoid arthritis and certain other polyarthritides.
b-Pseudo polyarthritis rhizomelic and Horton's disease.
c-Acute rheumatic fever.
d-Severe and refractory cervicobrachial neuralgia.

Organ transplantation and allogeneic hematopoietic stem cell transplantation

a-Prophylaxis or treatment of graft rejection.
b-Prophylaxis or treatment of graft-versus-host disease.

4.2. Posology and method of administration

Posology

For adults only

CORTENE is particularly suitable for initial treatment or short-term treatment requiring medium or high doses in adults.

For maintenance treatment, there are more appropriate dosages.
For children, there are more suitable dosages and pharmaceutical forms.
The dosage varies depending on the diagnosis, the severity of the condition, the prognosis, the patient's response, and tolerance to treatment.
Initial treatment: 0.05 mg to 0.2 mg/kg/day (equivalent to 0.35 mg to 1.2 mg/kg/day prednisone). As a guide: 1.5 to 6 tablets for a 60 kg adult.
In severe inflammatory diseases, the dosage varies from 0.1 to 0.2 mg/kg/day of betamethasone (0.75 mg/kg/day to 1.2 mg/kg/day prednisone equivalent). As a guide: 3 to 6 tablets per day for a 60 kg adult.
Highly exceptional situations may require higher doses.

In general

The initial treatment dose should be continued until the disease is under sustained control. The dose should be tapered slowly. The goal is to achieve complete withdrawal. Maintaining a maintenance dose (minimum effective dose) is sometimes a necessary compromise.
For prolonged treatment and high doses, the initial doses may be divided into two daily administrations. Subsequently, the daily dose may be administered as a single dose, preferably in the morning with food.

Stopping treatment

The rate of withdrawal depends mainly on the duration of treatment, the starting dose and the disease.
The treatment leads to suppression of ACTH and cortisol secretion, sometimes resulting in prolonged adrenal insufficiency. During withdrawal, discontinuation must be gradual, in stages, due to the risk of relapse: a reduction of 10% every 8 to 15 days on average.
For short courses of less than 10 days, stopping treatment does not require tapering.
During dose reduction (prolonged treatment): at a dosage of 5 to 7 mg of prednisone equivalent, when the underlying disease no longer requires corticosteroid therapy, it is advisable to replace the synthetic corticosteroid with 20 mg/day of hydrocortisone until the corticotropic function is restored.
If corticosteroid therapy must be maintained at a dose below 5 mg of prednisone equivalent per day, a small dose of hydrocortisone can be added to reach a hydrocortisone equivalent of 20 to 30 mg per day. When the patient is only taking hydrocortisone, the hypothalamic-pituitary-adrenal (HPA) axis can be tested using endocrine tests. These tests alone do not rule out the possibility of adrenal insufficiency occurring during a period of stress.
While taking hydrocortisone, or even some time after stopping it, the patient should be warned of the need to increase the usual dosage or to resume replacement therapy (for example, 100 mg of hydrocortisone intramuscularly every 6 to 8 hours) in case of stress: surgery, trauma, infection.

Method of administration

Oral route.
Anti-inflammatory equivalence (equipotency) for 5 mg of prednisone: 0.75 mg of betamethasone.
The tablets can be swallowed whole with a little water or dissolved in a little water, preferably with meals.

4.3. Contraindications

This medication is generally contraindicated in the following situations (however, there is no absolute contraindication for corticosteroid therapy when vital):

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1;
- any infectious condition excluding the specified indications (see section 4.1);
- certain evolving viral infections (including hepatitis, herpes, chickenpox, shingles);
- psychotic states not yet controlled by treatment;
- live vaccines;
- Due to the presence of aspartame, this medication is contraindicated in cases of phenylketonuria.

This medicine is generally not recommended in combination with non-antiarrhythmic drugs, which can cause torsades de pointes (see section 4.5).

4.4. Special warnings and precautions for use

Special warnings

- In the case of gastroduodenal ulcer -, corticosteroid therapy is not contraindicated if an anti-ulcer treatment is associated.
- In cases of a history of ulcers, corticosteroid therapy may be prescribed, with clinical monitoring and, if necessary, after fibroscopy.

- Corticosteroid therapy can promote the development of various infectious complications, particularly those caused by bacteria, yeasts, and parasites. The development of severe strongyloidiasis is a significant risk.

All subjects coming from an endemic area (tropical, subtropical regions, southern Europe) must have a parasitological examination of stools and systematic eradication treatment before corticosteroid therapy.
The evolving signs of an infection can be masked by corticosteroid therapy. Before starting treatment, it is important to rule out any possibility of a visceral focus, particularly tuberculosis, and to monitor for the development of infectious diseases during treatment.
In cases of past tuberculosis, prophylactic anti-tuberculosis treatment -is necessary if there are significant radiological sequelae and if it cannot be ensured that a well-conducted 6-month course of rifampicin treatment has been given.

- The use of corticosteroids requires particularly appropriate monitoring, especially in elderly subjects and in cases of ulcerative colitis (risk of perforation), recent intestinal anastomoses, renal failure, hepatic failure, osteoporosis, myasthenia gravis.

- This medicine contains lactose. Its use is not recommended in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases).

- A potentially fatal pheochromocytoma crisis has been reported following the administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or confirmed pheochromocytoma after a careful benefit-risk assessment.

Precautions for use

- In the case of long-term corticosteroid treatment:

o a diet low in rapidly absorbed sugars and high in protein must be associated, due to the hyperglycemic effect and protein catabolism with negative nitrogen balance;

o Sodium and water retention is common, partly responsible for a possible increase in blood pressure. Sodium intake will be reduced for daily doses above 15 or 20 mg of prednisone equivalent and moderated in long-term treatments at low doses;

o Potassium supplementation is only justified for high-dose treatments, prescribed for a long period of time, or in cases of risk of rhythm disorders or combinations with hypokalemic treatment;

o the patient must systematically receive a supply of calcium and vitamin D;

o When corticosteroid therapy is essential, diabetes and high blood pressure are not contraindicated, but the treatment may lead to their destabilization. Their management should be reassessed.

o Patients should avoid contact with individuals suffering from chickenpox or measles.

Visual disturbances may occur during systemic or local corticosteroid therapy (including nasal, inhaled, and intraocular routes). If blurred vision or any other visual symptoms develop during corticosteroid therapy, an ophthalmological examination is required to investigate for visual disturbances, including cataracts, glaucoma, or rarer conditions such as central serous chorioretinopathy, which have been reported with systemic and local corticosteroid administration.

4.5. Interactions with other medicinal products and other forms of interaction

Associations not recommended

+ Drugs that can cause torsades de pointes (astemizole, bepridil, IV erythromycin, halofantrine, pentamidine, sparfloxacin, sultopride, terfenadine, vincamine)

Use substances that do not have the disadvantage of causing torsades de pointes in cases of hypokalemia.
+ CYP3A inhibitors
It is expected that concomitant administration of CYP3A inhibitors, including products containing cobicistat, will increase the risk of systemic side effects. This combination should be avoided unless the benefits outweigh the increased risk of systemic corticosteroid side effects; in such cases, patients should be monitored for potential systemic corticosteroid side effects.

Associations requiring precautions for use

+ Acetylsalicylic acid administered systemically and, by extrapolation, other salicylates
Decreased salicylemia during corticosteroid treatment and risk of salicylate overdose after its discontinuation, due to increased elimination of salicylates by corticosteroids.
Adjust the doses of salicylates during the combination and after stopping treatment with corticosteroids.
+ Antiarrhythmics that can cause torsades de pointes (amiodarone, bretylium, disopyramide, quinidine, sotalol)
Hypokalemia is a contributing factor, as are bradycardia and a pre-existing long QT interval.
Prevent hypokalemia, correct it if necessary; monitor the QT interval. In case of torsades de pointes, do not administer antiarrhythmics (use electrical pacing).
+ Oral anticoagulants
Potential impact of corticosteroid therapy on the metabolism of the oral anticoagulant and on that of coagulation factors.
Risk of bleeding specific to corticosteroid therapy (digestive mucosa, vascular fragility) at high doses or in prolonged treatment exceeding 10 days.
When the combination is justified, strengthen monitoring: biological control on the 8th day, then every 15 days during corticosteroid therapy and after its cessation.
+ Other hypokalemic agents (hypokalemic diuretics alone or in combination, stimulant laxatives, amphotericin B (IV route))
Increased risk of hypokalemia due to additive effect.
Monitor potassium levels, correct them if necessary, especially in cases of digitalis therapy.
+ Digitalis
Hypokalemia promotes the toxic effects of digitalis.
Monitor potassium levels, correct if necessary, and possibly perform an ECG.
+ Heparins administered parenterally
Aggravation by heparin of the hemorrhagic risk specific to corticosteroid therapy (digestive mucosa, vascular fragility) at high doses or in prolonged treatment exceeding 10 days.
The association must be justified, and monitoring must be strengthened.
+ Enzyme inducers: carbamazepine, phenobarbital, phenytoin, primidone, rifabutin, rifampicin
Decreased plasma levels and reduced efficacy of corticosteroids due to increased hepatic metabolism. The consequences are particularly significant in patients with Addison's disease and in transplant recipients.
Clinical and biological monitoring, adjustment of corticosteroid dosage during combination therapy and after discontinuation of the enzyme inducer.
+ Insulin, metformin, sulfonylureas
Elevated blood glucose levels, sometimes with ketosis (decreased carbohydrate tolerance due to corticosteroids).
Inform the patient and reinforce self-monitoring of blood and urine, especially at the start of treatment. Adjust the dosage of the antidiabetic medication if necessary, during corticosteroid treatment and after its discontinuation.
+ Isoniazid (described for prednisolone)
Decreased plasma levels of isoniazid. Proposed mechanism: increased hepatic metabolism of isoniazid and decreased metabolism of glucocorticoids.
Clinical and biological monitoring.
+ Gastrointestinal topicals -: magnesium, aluminum and calcium salts, oxides and hydroxides (described for prednisolone, dexamethasone)
Decreased gastrointestinal absorption of glucocorticoids.
Take gastrointestinal topicals -separately from glucocorticoids (more than 2 hours apart if possible).

Associations to consider

+ Antihypertensives
Decreased antihypertensive effect (sodium and water retention caused by corticosteroids).
+ Alpha interferon
Risk of inhibition of the action of interferon.
+ Live attenuated vaccines
Risk of potentially fatal systemic disease. This risk is increased in individuals already immunocompromised by the underlying disease.
Use an inactivated vaccine when available (poliomyelitis).

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

In animals, experimentation highlights a teratogenic effect that varies depending on the species.
In humans, there is placental transfer. However, epidemiological studies have not detected any malformation risk associated with taking corticosteroids during the first trimester.
In cases of chronic diseases requiring treatment throughout pregnancy, a slight delay in intrauterine growth -is possible. Neonatal adrenal insufficiency has been observed in rare cases following high-dose corticosteroid therapy.
It is justified to observe a period of clinical (weight, diuresis) and biological monitoring of the newborn.
Consequently, corticosteroids may be prescribed during pregnancy if needed.

Breastfeeding

In the case of treatment with high doses and on a chronic basis, breastfeeding is not recommended.

4.7. Effects on the ability to drive vehicles and use machinery

Not applicable.

4.8. Undesirable effects

They are most concerning at high doses or during prolonged treatment over several months:

- hydro-electrolytic disorders: hypokalemia, metabolic alkalosis, sodium and water retention, arterial hypertension, congestive heart failure;

- endocrine and metabolic disorders: iatrogenic Cushing's syndrome, inertia of ACTH secretion, sometimes permanent adrenocortical atrophy, decreased glucose tolerance, revelation of latent diabetes, growth arrest in children, menstrual irregularities;

- musculoskeletal disorders -: muscle atrophy preceded by muscle weakness (increased protein catabolism), osteoporosis, pathological fractures in particular vertebral compression fractures, aseptic osteonecrosis of the femoral heads;

- Digestive disorders: hiccups, gastroduodenal ulcers, small bowel ulceration, perforations and digestive bleeding, acute pancreatitis have been reported, especially in children;

- skin disorders: acne, purpura, ecchymosis, hypertrichosis, delayed wound healing and angioedema -;

- neuropsychiatric disorders:

  - frequently: euphoria, insomnia, excitement;

  - rarely: manic episodes, confusional or -dreamlike states, convulsions (general or intrathecal route);

  - Depressive state upon cessation of treatment.

- Eye disorders: certain forms of glaucoma and cataracts; blurred vision (see also section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any adverse effects suspected unwanted substance via the FRILAB declaration form available under the tab pharmacovigilance information from the website : www.frilab.ch

4.9. Overdose

Treatment of acute overdose includes gastric lavage and induction of vomiting, followed by symptomatic treatment, if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: glucocorticoid – systemic use (H. Non-sex hormones), ATC code: H02AB01.
Physiological glucocorticoids (cortisone and hydrocortisone) are essential metabolic hormones. Synthetic corticosteroids, including this product, are used primarily for their anti-inflammatory effect. At high doses, they suppress the immune response.
Their metabolic and sodium retention effect is less than that of hydrocortisone.

5.2. Pharmacokinetic properties

Betamethasone is absorbed in the digestive tract. Protein binding is approximately 60%.
Betamethasone is metabolized in the liver and eliminated by the kidneys. The -plasma half-life of betamethasone is approximately 5 hours. The biological half-life is 36 to 54 hours.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

MicroceLac 100, crospovidone XL, aspartame, magnesium stearate

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Store at a temperature not exceeding 30°C, in a dry place and away from light.

6.5. Nature and contents of container

Blister pack of 14 dispersible tablets.

6.6. Special precautions for disposal and handling

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER AND OPERATOR

FRILAB SA
17 RUE DES PIERRES DU NITON
1207 GENEVA - SWITZERLAND

8. MANUFACTURER

MJ BIOPHARM PVT.LTD.
PLOT NO.L7,MIDC INDUSTRIAL AREA, TALOJA
RAIGAD 410208 MAHARASHTRA STATE, INDIA

9. DATE OF REVISION OF THE TEXT

January 2026.

10. DOSIMETRY

Not applicable.

11. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List I.